Regulating lifestyle risks in EU law: Promoting health in a diverse market

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Foreword

I have always been fascinated by the enduring allure of risk in human existence and the dispositions taken by society towards it. Why is it that some people drink, smoke or consume other drugs, while others stay away from such habits their entire lives ? Is restricting these behaviours a legitimate role for the State ? If yes, how should such regulation be designed ? This dissertation addresses these questions from the specific angle of European Union law. Regulating risk and promoting health in a federal, market driven and diverse polity such as the European Union offers unique opportunities and raises specific challenges. Lifestyle risks question the very soul of the European Union and its (legal) integration project. I hope that this thesis not only demonstrates this, but that it also offers convincing answers to the questions raised and stimulates further research and action in this field.

This doctoral project originates from an early research work conducted at the College of Europe, in Bruges, as part of the Master of European Law. What started with a thirty-page long master thesis ended up occupying a substantial part of the last five years of my life. Five years of intellectual challenge, of doubts, but of happiness above all. As any grand life endeavour, conducting this research would not have been possible without the support of many individuals and organisations, in Brussels, Paris, Bruges (College of Europe), Louvain-la-Neuve (Centre Charles de Visscher pour le droit international et européen) and Leiden (Europa Instituut). May they all be warmly thanked.

I would like to start by expressing my sincere recognition to my supervisor, Anne-Lise Sibony, for her guidance and support throughout the course of the doctorate. Always respectful of my choices, she made sure that these would withstand academic scrutiny. Her expertise and her experience have been instrumental in shaping the direction of this research. I would also like to thank the members of my doctoral committee and jury – Alberto Alemanno, Loïc Azoulai, Henri Culot, Olivier De Schutter and Amandine Garde – who have all generously devoted some of their precious time to my project. The pages that follow have greatly benefited from their knowledge and insights.

I am immensely indebted to the College of Europe and the truly inspiring people that I had the chance to meet there. My passion for EU law is born of my studies in Bruges. Through my work as an academic assistant, this institution gave me the financial and intellectual support needed to pursue my doctoral journey. My heartfelt gratitude goes to Sacha Garben. As a professor, master thesis supervisor, colleague and, I dare to say, mentor, she has shaped my understanding of EU law, unveiling to me its most thorny and exciting questions. I wish to also thank Inge Govaere for having put her trust in me, allowing me to grow professionally and personally within the European Legal Studies Department of the College of Europe. My thoughts go to all the friends, colleagues and professors that I met in Bruges. A special *merci* to Pierre and Celia for having been such wonderful colleagues and remaining such wonderful friends.

Last, but certainly not least, I would like to extent my profound gratitude to my loved ones: friends and family, old and new relationships, lawyers or non-lawyers. Consciously or

unconsciously, their unwavering belief in my abilities has been a constant source of motivation and comfort. A special thank you to Benjamin, Celia and Morgane for helping proofread some of the pages that follow.

To my parents, for their unconditional love and support.

To Stefan, for having been present all those years, in good and bad times.

Paris, 14 May 2023

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General introduction

The regulation of lifestyle risks: a dynamic yet understudied field of EU law

1. Contextual aspects of the research

Unhealthy lifestyles and the contested nature of risk

Popularised by the work of the German sociologist Ulrich Beck,[1] the concept of 'risk society' describes a future-oriented society where a 'growing expectation [exists] that governments intervene to protect people and to prevent risks to health, safety, and to the environment from materializing'.[2] While this expression is most often used in connection to wide-ranging systemic risks born of scientific progress and technological developments, such as climate change or nuclear energy, citizens' concern and governmental regulation have expanded to an ever-growing array of hazards. Risks arising from people's lifestyles, ubiquitous in our societies, are increasingly debated and controlled by public authorities.[3] The risks posed by diets, alcohol and other substances and activities may have been known for millennia,[4] but the idea that the State has a role to play in fostering healthier lifestyles has only recently emerged. Public management of health risks and lifestyles is considered an essential feature of late modernity, industrialisation, urbanisation, and cultural change.[5]

What we eat, drink or smoke is an essential determinant of our health. This is especially true in high-income countries, where sanitation policies and the development of public healthcare systems have led to a steady decrease in the burden of infectious diseases and other causes of ill-health. Infectious diseases caused by pathogens, while remaining a public health challenge, have ceased to be the main cause of mortality and morbidity and have been progressively replaced by chronic non-communicable diseases (NCDs), for which unhealthy lifestyles are a key behavioural risk factor. The prevalence of NCDs such as cancers, cardio-vascular diseases or diabetes, is rising globally, fuelled by a growing standardisation of lifestyles and a buoyant world market for unhealthy commodities. In 2011, the United Nations General Assembly

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[1] Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE Publications Ltd 1992).

[2] Maria Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology* (Oxford University Press 2019) 2. See also Christian Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level - Stories on Baby Dummies, Mad Cows and Hormones in Beef' (2001) 7 Columbia Journal of European Law 1, 2; Julia Black, 'The Role of Risk in Regulatory Processes' in Robert Baldwin, Martin Cave and Martin Lodge (eds), *The Oxford Handbook of Regulation* (Oxford University Press 2010) 301–303.

[3] Deborah Lupton, 'Risk as Moral Danger: The Social and Political Functions of Risk Discourse in Public Health' (1993) 23 International Journal of Health Services 425.

[4] See e.g. Daniel Droixhe, *Alimentation et Maladie : Consultations à Padoue : À l'aube Des Temps Modernes* (Académie royale des sciences, des lettres et des beaux-arts de Belgique 2021).

[5] Anthony Giddens, *Modernity and Self–Identity: Self and Society in the Late Modern Age* (Polity Press 1991); Beck, (n 1); William C Cockerham, Thomas Abel and Günther Lüschen, 'Max Weber, Formal Rationality, and Health Lifestyles' (1993) 34 The Sociological Quarterly 413; William C Cockerham, Alfred Rütten and Thomas Abel, 'Conceptualizing Contemporary Health Lifestyles: Moving beyond Weber' (1997) 38 The Sociological Quarterly 321.

adopted a Political Declaration on the Prevention and Control of Non-communicable Diseases (the 'UN Political Declaration on NCDs'), according to which:

> [T]he global burden and threat of non-communicable diseases constitutes *one of the major challenges for development in the twenty-first century*, which undermines social and economic development throughout the world, and threatens the achievement of internationally agreed development goals.[6]

The General Assembly recognised 'the urgent need for greater measures at global, regional and national levels to prevent and control non-communicable diseases in order to contribute to the full realization of the right of everyone to the highest attainable standard of physical and mental health'.[7] To help governments tackle this challenge, the World Health Assembly of the World Health Organisation (WHO) adopted the Global Action Plan for the Prevention and Control of NCDs,[8] spanning the 2013-2020 period, followed by the Global NCD Compact 2020-2030,[9] adopted in 2020. At the core of these various public health strategies is a reduction in the consumption of tobacco products, alcoholic beverages and unhealthy foodstuffs, through a mix of fiscal incentives, awareness-raising measures, and stronger forms of product regulation.

Harmful lifestyles have implications that go well beyond health. The large socio-economic impact of NCDs threaten development across countries and within countries, with the most socially disadvantaged bearing a disproportionate burden. Social position has a powerful influence on health outcomes in societies. Not only is exposure to most risk factors inversely related to social position, but a similar exposure may have different effects on different socio-economic groups, depending on their environment.[10] In the field of food, efforts to promote a healthier dietary habits cannot be dissociated from broader issues of sustainability and the necessity to diminish the environmental impact of that sector.[11]

Risk is a complex and contested concept, situated at the juncture of scientific uncertainties and political controversies. Risk may be analysed as the physical, measurable attribute of a certain hazardous object, as it is the case, for instance, when describing the causes and prevalence of various NCDs. It may also be considered a socially constructed attribute which does not exists completely independently of the humans who assess and experience its effects.[12] The

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[6] United Nations General Assembly, 'Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases' (2011) 1, emphasis added, <https://digitallibrary.un.org/record/710899?ln=fr> accessed 11/05/2023.

[7] ibid 2.

[8] WHO, 'Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020' (2013), <http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf?ua=1> accessed 11/05/2023.

[9] WHO, 'Global Noncommunicable Diseases (NCD) Compact 2020-2030', <https://cdn.who.int/media/docs/default-source/ncds/final_ncd-compact-(1).pdf?sfvrsn=d8895106_1> accessed 11/05/2023.

[10] Erik Blas and Anand Sivasankara Kurup (eds), 'Equity, social determinants and public health programmes' (2010) World Health Organization.

[11] Lucia Reisch, Ulrike Eberle and Sylvia Lorek, 'Sustainable Food Consumption: An Overview of Contemporary Issues and Policies' (2013) 9 Sustainability: Science, Practice and Policy 7.

[12] Judith A Bradbury, 'The Policy Implications of Differing Concepts of Risk' (1989) 14 Science, Technology, & Human Values 380.

perception of a risk in the population can differ widely from its objective characteristics.[13] Some would probably even question the possibility of an 'objective' assessment of risk. This aspect is particularly pronounced in the case of lifestyles, which involve long-term risks, arising from habits that are present in our lives from an early age and featuring a large degree of social acceptance. These behaviour fulfil a role, for the individual and for society, which goes beyond the satisfaction of mere physiological needs. They constitute defining habits for various social groups, shaping individual and collective identities. Alcohol is a good example.[14] A toxic substance that does not meet any physiological needs in humans, and is hence best avoided, alcohol is often not experienced as such by people. Alcohol consumption is seen as a pleasurable activity and alcoholic beverages as quality products, epitomising cultural traditions and know-how. All of this explains why public intervention in the field of lifestyles is experienced by many individuals as undue interference with their freedom, and outright paternalism.

Caught between these contradictory dimensions of lifestyle risks, devastating habits which remain, by and large, positively valued, governments often muddle through. They tend to follow what Bogart describes as a 'permit but discourage' approach,[15] adopting taxes, labels, and warnings to discourage consumption, but staying short of banning unhealthy practices altogether. Illicit drugs are the only exception to this approach. Worse, from a public health perspective, public authorities continue supporting some segments of the industry responsible for marketing unhealthy products, and keep promoting their use. While timidly trying to curb the consumption of alcohol in its population, the European Union (EU) continues for instance to provide massive financial support to the wine sector, in the framework of the Common Agricultural Policy (CAP). In particular, the EU supports promotion and communication activities carried out in third countries, 'aimed at improving the competitiveness of the wine sector, and the opening, diversification or consolidation of the markets'.[16] The Regulation on a common organisation of the markets in agricultural products (CMO Regulation), a key legal instrument of the CAP, was very explicit in this regard. In a previous version, it considered that, 'the perspectives of progressive growth of demand at world market level provide an incentive to *increase supply capacity*, and therefore to *plant new vines*, over the next decade'.[17] At a more trivial level, it is also telling that the WHO, a body that cannot be suspected to ignore the devastating consequences of alcohol consumption, still serves alcoholic beverages in its

[13] For an introduction to risk perception, see Glynis M Breakwell, *The Psychology of Risk* (2nd edition, CUP 2014).
[14] Jürgen Rehm, Dirk W Lachenmeier and Robin Room, 'Why Does Society Accept a Higher Risk for Alcohol than for Other Voluntary or Involuntary Risks?' (2014) 12 BMC Medicine 189, 190.
[15] William A Bogart, *Permit But Discourage* (Oxford University Press 2010).
[16] See Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 [2021] OJ L435/1, art 58(1)(k).
[17] Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products (CMO Regulation) [2013] OJ L347/671, recital 55, emphasis added.

functions and lunchrooms. In 2020, a resolution for the WHO Executive Board proposing to remove alcohol from the organisation's premises was rejected.[18] Yet, no one imagines tobacco products freely on display and accessible for purchase in the buildings of the institution in charge of protecting global health.

These examples highlight the difference in perception existing between various products which exhibit comparable danger to health, and the often-contradictory approaches adopted by public authorities when regulating these products. They also illustrate the powerful economic interests at play. Trade in unhealthy commodities generates a considerable amount of revenues worldwide, captured in the hands of a few powerful global market players, colloquially referred to as 'Big Tobacco', 'Big Alcohol' and 'Big Food', in whose interests it is not to see a decline in unhealthy consumptions. Their interference with policy-making has greatly contributed to the slow pace of adoption of strong lifestyle interventions and continue to be an obstacle to progress today.

The urgency of the 'NCDs epidemic', the complex and contested nature of risk, the plurality of interests involved: all of this makes of lifestyle risks a fascinating topic of enquiry, with many political and legal ramifications.

Lifestyle risks and the European Union

Lifestyle-induced diseases are an acute problem in the European Union. Tobacco consumption is the largest avoidable behavioural risk factor to health and the most significant cause of premature death in the EU.[19] Europeans remain the world's heaviest smokers and alcohol drinkers.[20] Obesity prevalence has increased in the last twenty years, from 11% of the population in 2000 to 17% in 2018.[21] It is estimated that in 2017 over 950,000 deaths were attributable to unhealthy diets and the resulting NCDs in the EU.[22]

The EU is well aware of this pressing public health issue and is increasingly active in this field. Over the last four decades, it has used its powers to promote healthier lifestyles in the European population, adopting a wide range of measures aimed at curbing the consumption of tobacco products, alcoholic beverages, and unhealthy foodstuffs. The effort is particularly visible as regards tobacco, subject to an almost complete advertising ban and to stringent packaging and labelling obligations. Regulating lifestyle-related health risks, perhaps overshadowed by the recent policy and legal developments that followed the outbreak of COVID-19, remains one of

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[18] Robin Room, 'Global Intergovernmental Initiatives to Minimise Alcohol Problems: Some Good Intentions, but Little Action' (2021) 12 European Journal of Risk Regulation 419, 432.

[19] OECD and European Commission, 'Health at a Glance: Europe 2020' (2020) 140, <https://ec.europa.eu/health/state/glance_fr> accessed 11/05/2023.

[20] WHO, 'European Health Report 2018: More than numbers – evidence for all' (2018) WHO Regional Office for Europe, <https://apps.who.int/iris/bitstream/handle/10665/279904/9789289053433-eng.pdf> accessed 11/05/2023.

[21] OECD and European Commission (n 19) 152.

[22] European Commission, 'EU burden from non-communicable diseases and key risk factors' *Health Promotion and Disease Prevention Knowledge Gateway*, <https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/eu-burden-non-communicable-diseases-key-risk-factors_en> accessed 11/05/2023.

the EU's main public health priorities. The 'Europe's Beating Cancer Plan', released by the European Commission in 2021, puts further action on tobacco, alcohol, and diets at its core.[23]

European Union law scholars tend to be somewhat familiar with EU tobacco control, for this field of law has yielded some of the discipline's landmark rulings by the European Court of Justice:[24] *Germany v European Parliament and Council*,[25] better known as the *Tobacco Advertising* judgement, followed a couple of years later by *Tobacco Advertising II*,[26] *British American Tobacco*[27] or, more recently, *Philip Morris*.[28] These judgements touched upon some of the EU's most sensitive constitutional questions, regarding the respect for the principles of conferral, subsidiarity and proportionality and the complex interplay between EU internal market law and health policy. These questions are at the core of the present research. This work aims to understand how the fundamental features of the Union legal order have shaped the EU's approach towards lifestyle risks and, in turn, how EU the regulation of lifestyle risks has shaped the way in which some of the EU's fundamental constitutional principles and key legal concepts have been understood and applied.

As in many – most? – other fields of EU law and policy, the objective of establishing and ensuring the functioning of an internal market where goods, persons, services and capital circulate freely has been central to the inception and development of EU regulation of lifestyle risks. A wide range of national measures are liable to constitute obstacles to free movement, whether these are taxes, product requirements or rules on advertising. Creating and maintaining an internal market where hazardous commodities and services can freely circulate across borders requires to exercise an oversight on national measures, to ensure that these do not unduly restrict the free flow of goods, services or persons. It also leads the EU to directly regulate these activities and to adopt common health standards at the EU level. In legal terms, EU regulation of lifestyle risks remains thus primarily internal market driven. This has offered considerable potential for the development of such regulation, but has also lead a number of constitutional tensions, which the present work seeks to unveil.

That the boundaries of Union competence have been shaped by judgements rendered in the field of tobacco is no coincidence. As rightly put by Bartlett, '[s]eeking to alter the lifestyles and behaviours of citizens is a controversial use of law-making power for any institution, especially one such as the EU that functions on the basis of conferred powers'.[29] On may also add to this: especially one such as the EU that encompasses such great political and cultural

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[23] European Commission, Communication from the Commission to the European Parliament and the Council, 'Europe's Beating Cancer Plan', COM (2021) 44 final.

[24] As rightly put by Advocate General Kokott, '[h]ardly any EU legislation has led to such fierce legal disputes over the years as the various directives on the manufacture, presentation and sale of tobacco and related products in the European internal market': Case C-477/14 *Pillbox 38* [2016] EU:C:2016:324, Opinion of Advocate General Kokott, para 1.

[25] Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising)* [2000] EU:C:2000:544.

[26] Case C-380/03 *Germany v European Parliament and Council (Tobacco Advertising II)* [2006] EU:C:2006:772.

[27] Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] EU:C:2002:741.

[28] Case C-547/14 *Philip Morris Brands e.a.* [2016] EU:C:2016:325.

[29] Oliver Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (2016) 5 Cambridge International Law Journal 50, 53.

diversity. How to effectively control lifestyle-related health risks in a supranational and diverse polity such as the EU, through the use of regulatory powers primarily geared towards economic integration ?

Opposition to governmental interference with lifestyle choices is reconfigured, and potentially amplified, when control measures are adopted at the EU level. Supranational involvement in lifestyles carries the risk of a standardisation of practices and a threat to cultural diversity. Originating from a foreign and distant body, EU intervention in people's daily lives may bring an even greater feeling of alienation. From a purely health perspective, it is also unclear why the EU would want to act in the field of unhealthy lifestyles, the damaging consequences of which are highly localised. This makes a difference with contagious diseases such as Covid-19.

The contested aspect of EU involvement with lifestyle risks is perhaps best illustrated by the current controversy surrounding the 'Nutri-Score', a colour-coded nutrition label whose possible roll-out on all food packages in the EU is fiercely opposed by major market players and Member States. Despite being widely supported by the scientific community, this seemingly rather innocuous label, which ranks products according to their nutritional quality, is facing determined resistance. What is in dispute here is not only, or mostly, the scientific underpinning of the system, but the very legitimacy of the EU to adopt a label that would tell people which products are 'good' or 'bad'. This, some say, endangers local traditional productions and unduly interferes with people's dietary choices, leading to a uniformisation of culinary practices.[30] By offering a way for consumers to navigate their food choices more easily, the EU gets embroiled in political controversies that go well beyond health.

2. Research question, scope and methodology

These fundamental questions – the justification for an EU involvement in lifestyle risks regulation, the political and ethical implications of that intervention, the possibility, or not, to reconcile health and market objectives in that field – have only partially been addressed to date. Some pioneer works, to which the present thesis is greatly indebted, have laid down the foundations of a study of 'lifestyle risks' as a specific field of EU law and policy.[31] Some other

[30] See Morgane Fialon, Lydiane Nabec and Chantal Julia, 'Legitimacy of Front-of-Pack Nutrition Labels: Controversy Over the Deployment of the Nutri-Score in Italy' (2022) 11 International Journal of Health Policy and Management 2574.

[31] See Alberto Alemanno and Amandine Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (2013) 50 Common Market Law Review 1745; Alberto Alemanno and Amandine Garde, *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (Cambridge University Press, 2015); Alberto Alemanno and Amandine Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' in Hans-Wolfgang Micklitz and Takis Tridimas (eds), *Risk and EU law* (Edward Elgar Publishing 2015). More generally, see the works published in the 'Lifestyle risks' section of the European Journal of Risk Regulation, <https://www.cambridge.org/core/journals/european-journal-of-risk-regulation> accessed 11/05/2023.

works are dedicated to a single 'lifestyle' issue: food and nutrition,[32] tobacco,[33] alcohol,[34] gambling[35] or NCDs more generally.[36] Mostly, lifestyles have been approached as a part of the broader EU health policy.[37] EU legal scholarship lacks a comprehensive study of lifestyle risks regulation. Such work is needed first to get a clearer idea of the breadth and impact of EU law in the field. EU lifestyle risks regulation, like EU health law and policy in general, is fragmented, for historical and conceptual reasons. Understanding EU involvement requires to look both at how EU law intervenes in people's lifestyles and how it constrains Member States in their own policy choices. There is also a need to gain a better understanding of the nature and fundamental characteristics of lifestyle risks and what this implies for (EU) regulation.[38] Finally, an analysis of the adequacy of the Union constitutional framework with healthy lifestyles promotion efforts, understood as the framework under which both the EU and Member States deploy their policies, is missing. This is the main purpose of our enquiry.

Against this background, this work's central research questions can be laid down as follows.

How does the EU meet its two constitutional objectives of (i) removing obstacles to free movement and (ii) promoting health and preventing disease, in the specific area of lifestyle risks ? How does this dual character of EU lifestyle risks regulation affect the integration into

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[32] See Caoimhín MacMaoláin, *EU Food Law: Protecting Consumers and Health in a Common Market* (Hart Publishing 2007); Amandine Garde, *EU Law and Obesity Prevention* (Kluwer Law International 2010); Caoimhín MacMaoláin, *Food Law: European, Domestic and International Frameworks* (Hart Publishing 2015).

[33] Scott Crosby, 'The New Tobacco Control Directive : An Illiberal and Illegal Disdain for the Law' (2002) 27 European Law Review 177; Alberto Alemanno, 'Out of Sight Out of Mind: Towards a New EU Tobacco Products Directive' (2012) 18 Columbia Journal of European Law 197.

[34] Ben Baumberg and Peter Anderson, 'Health, Alcohol and EU Law: Understanding the Impact of European Single Market Law on Alcohol Policies' (2008) 18 The European Journal of Public Health 392; Oliver Bartlett and Amandine Garde, 'Time to Seize the (Red) Bull by the Horns : The EU's Failure to Protect Children from Alcohol and Unhealthy Food Marketing' (2013) 38 European Law Review 498; Oliver Bartlett and Angus Macculloch, 'Evidence and Proportionality in Free Movement Cases: The Impact of the Scotch Whisky Case' (2020) 11 European Journal of Risk Regulation 109.

[35] Julia Hörnle, 'Online Gambling in the European Union: A Tug of War without a Winner?' (2011) 30 Yearbook of European Law 255; Stefaan Van den Bogaert and Armin Cuyvers, '"Money for Nothing": The Case-law of the EU Court of Justice on the Regulation of Gambling' (2011) 48 Common Market Law Review 1175; Simon Planzer, *Empirical Views on European Gambling Law and Addiction* (Springer 2014).

[36] Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29); Oliver Bartlett, 'Power, Policy Ideas and Paternalism in Non-Communicable Disease Prevention' (2018) 24 European Law Journal 474; Nikhil Gokani, 'Regulation for Health Inequalities and Non-Communicable Diseases: In Want of (Effective) Behavioural Insights' (2018) 24 European Law Journal 490.

[37] See in particular the relevant chapters in Elias Mossialos and others (eds), *Health Systems Governance in Europe : The Role of European Union Law and Policy* (Cambridge University Press 2010); Tamara K Hervey and Jean V McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015); Scott L Greer and Paulette Kurzer (eds), *European Union Public Health Policy: Regional and Global Trends* (Routledge 2016); Tamara K Hervey, Calum Alasdair Young and Louise E Bishop, *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017).

[38] For some early work, see Alberto Alemanno and Simon Planzer, 'Lifestyle Risks: Conceptualising an Emerging Category of Research' (2010) 1 European Journal of Risk Regulation 335; Liana Giorgi, 'Lifestyle Risk: The Challenging Marriage of Two Thorny Concepts (2012) 1 European Journal of Risk Regulation 97. See also Fernando D Simões, 'Paternalism and Health Law: Legal Promotion of a Healthy Lifestyle' (2013) 4 European Journal of Risk Regulation 347.

law and policy of competing interests, that of Member States, economic operators and consumers in particular, through the operation of the EU's fundamental constitutional principle ?

As will be shown through the thesis, the EU pursues two main objectives when regulating lifestyle risks, whether directly when adopting its own measures or indirectly when controlling those adopted by the Member States: protecting and promoting human health and ensuring the functioning of the internal market, i.e. preserving the free movement of goods, services and persons. The main problem is that these two objectives can only be partially reconciled. To put it simply, more trade in unhealthy commodities is difficult to square with lower consumption of the same commodities. Current legislative and judiciary practice, however, fails to fully acknowledge this tension, which affects the protection given to the principles of conferral, subsidiary, proportionality and respect for fundamental rights. This results in a law impoverished on substance and lacking in legitimacy.

The analysis deployed in the thesis leads to findings made at three distinct levels. The first level is that of lifestyle risks themselves. The tensions and trade-offs analysed in this thesis – market v health, State v individual, uniformity v diversity – are present in other fields of (EU) law but take here a specific form, because lifestyles are quite unique in the way they relate to our individual and collective selves.[39] Lifestyle risks are different from other health or environmental risks regulated at the EU level, like food safety[40] or agricultural biotechnology,[41] in relation to which questions of individual autonomy, for instance, may not be as acute. In the following excerpt from Tamara Hervey and Jean McHale, these trade-offs are admirably laid down. They have however never been studied in depth.

> We are also interested in the ways in which EU health law *balances risks to consumers with freedom to make lifestyle choices, to run a business, or the free pursuit of profit maximizing by capital investors*. Here we immediately see how EU public health law could be constructed not as concerned with questions of protection of consumers from harm but as unjustified paternalism or restriction of individual autonomy, or even human dignity in the sense of choice over one's own affairs, including bodily integrity. To what extent does EU tobacco, food or alcohol law explicitly present itself as considering these sorts of ethical questions? What are the consequences?
>
> Of equal interest is the extent to which EU law constrains *national* autonomy. Can the intention to protect (national) population health justify different approaches to regulation of tobacco, food or alcohol, in the different Member States? After all, population health differs quite considerably across the EU, not only between Member States, but also within them. The logic of the internal market, and its mandating of free trade in goods throughout the EU, pulls against finely grained laws that seek to tackle specific public health problems, which may be

[39] Regarding individual autonomy, Brooks and De Ruijter observe that 'health law and policy is not a neutral site of regulation. Its regulatory function requires it to continuously balance collective rights and benefits against individual freedoms and preferences': Eleanor Brooks and Anniek de Ruijter, 'Towards More Comprehensive Health Law and Policy Research' (2021) 16 Health Economics, Policy and Law 104, 106.

[40] Alberto Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (Cameron May 2007).

[41] Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology* (n 2).

> geographically or culturally limited to certain parts of the EU. Does EU health law support population health in those circumstances?[42]

The second level of reflection is that of risk as a general field of study. This work addresses questions that are typical of risk studies, where scientific expertise plays a key role. To name a few: the integration of scientific knowledge in the law and the role of evidence, in judicial reasoning especially, the opposition between expert assessment and lay perception of risk, the choice of the most appropriate regulatory tools to drive behaviour change. As already mentioned, these questions are of particular relevance for the EU, because the State/individual opposition is reconfigured along a national/European line, further complicating regulatory endeavours.[43] The Nutri-Score debate is a prime example of that. As such, our work is closely related to that of Maria Weimer on agricultural biotechnology:

> As a supranational and functionally driven risk regulator, how does the EU meet the above-mentioned challenges of regulating risk including the need to stabilize risk decision-making and to secure its legitimacy?[44]
>
> EU regulators have to secure the acceptability of risk regulation in the face of the legal-institutional, socio-economic, and cultural diversity in the Member States, while acting on the basis of a narrow and functionally delineated mandate.[45]

Finally, on a third level, traditional EU law questions will be addressed in this thesis, the 'lifestyle risks' lens hopefully offering fresh ideas and new insights. 'EU [lifestyle risks] intervention is constrained not only by the existence of sufficient political will but also by the key constitutional principles of [conferral], subsidiarity, proportionality and respect for fundamental rights.'[46] These four key constitutional principles, constitute the bedrock of this work. As rightly put by Anniek de Ruijter regarding EU health law and policy:

> This is not to put forward a view that health care and public health law and policy are different from other sensitive EU policy areas. However, the case of human health clearly puts into view some of the constitutional conundrums for the EU.[47]

Lifestyle risks function as a case study for some of the main EU constitutional conundrums, allowing to reassess fundamental questions as to the boundaries of Union action and the role played by the principles of conferral, subsidiarity, proportionality and respect for fundamental rights in this regard.

Hence, while it is hoped that this thesis proves to be understandable and interesting to a wide audience, it has been written with three specific categories of readers in mind. Those interested in health policy, the prevention of NCDs in particular, that wish to understand what the EU is doing and what are the specific challenges of conducting a lifestyle health promotion policy

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[42] Hervey and McHale (n 37) 390.
[43] In the area of food safety and agricultural biotechnology, see Damian Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (2003) 66 Modern Law Review 532; Damian Chalmers, 'Risk, anxiety and the European mediation of the politics of life' (2005) 30 European Law Review 649; Weimer, *Risk Regulation in the Internal Market* (n 2).
[44] Weimer, *Risk Regulation in the Internal Market* (n 2) 48.
[45] ibid 49.
[46] Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation' (n 31) 151–152.
[47] Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019) 178.

under the purview of EU law. Risk scholars, who will find here developments on horizontal questions regarding the interplay of science, politics, and the law. EU lawyers, finally, who will feel familiar with the main materials used in this work, internal market case-law and EU measures of harmonisation, but may come to look at it in a different way.

As regards the scope of the study, detailed explanations will be given in Chapter 1. Some remarks should nonetheless be made at this stage. First, as already said, EU regulation of lifestyle risks is here understood in a broad sense, as encompassing not only the tools adopted by the EU to promote healthier lifestyles but also the effect of EU law, free movement provisions in particular, on national policies. Second, the analysis is limited to a number of 'lifestyles', i.e. activities detrimental to health: tobacco, alcohol, diets and, to a lesser extent, illicit drugs and gambling. While this choice flows from practical reasons – the study could not possibly cover all unhealthy lifestyles – the selection of these five lifestyles is also justified by their characteristics and their relative importance in EU law. Third, the thesis focuses on internal EU action, that affecting the health of Europeans, citizens or residents of the EU. EU external action, which is also relevant to health and lifestyles, through trade policy for instance,[48] falls outside the scope of the present study.

To answer the main research question, and the many sub-questions that arise in its wake, this thesis adopts a 'law in context' approach, understood as a way to 'treat[…] legal subjects broadly, using materials from other humanities and social sciences, and from any other discipline that helps to explain the operation in practice of the particular legal field or legal phenomena under investigation'.[49] The study combines a classical doctrinal analysis of legal and policy materials with the use of a body of knowledge belonging to other disciplines, public health and behavioural sciences in particular. It would be difficult, if not impossible, to treat such a subject without a basic understanding of the risks to health entailed by lifestyle consumptions and of the behavioural implications of the various strategies and interventions chosen. While behavioural sciences are relevant to the study of the law in general, and increasingly popular among lawyers,[50] their use is particularly pertinent in a field where behaviour *change* is the avowed goal.

These non-legal materials will prove useful to answer a series of questions, both from an internal and an external perspective to the law. We understand internal legal questions as 'questions about how legal norms relate to other legal norms: questions about validity, consistency, interpretation and scope of rules' and external ones as 'pertain[ing] to how rules relates to the world: questions about effectiveness and efficiency'.[51] The typical internal legal

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[48] On the role and place of health in EU external action, see Elisabet Ruiz Cairo, *The Promotion of Public Health in EU External Relations* (Schulthess LGDJ 2021).

[49] Cambridge Core, 'Law in Context', <https://www.cambridge.org/core/series/law-in-context/387EA14AA111E65AB0120DA893AFAFCB> accessed 11/05/2023.

[50] Avishalom Tor, 'The Methodology of the Behavioral Analysis of Law' (2008) 4 Haifa Law Review 237.

[51] Anne-Lise Sibony, 'Data and Arguments: Empirical Research in Consumer law' in Hans-W Micklitz, Anne-Lise Sibony and Fabrizio Esposito (eds), *Research Methods in Consumer Law: A Handbook* (Edward Elgar Publishing 2018) 172.

questions for which scientific data are important in the context of this work are those concerned with the validity, proportionality and coherence of rules.[52] As regards external legal questions, these data will be particularly helpful to uncover and assess the underlying assumptions behind the adoption of certain rules and their interpretation. A prime example is the vast body of knowledge existing on the way consumers handle information and its relevance to the study of EU labelling rules.

As defended by Sibony and Alemanno, this work subscribes to a 'law and behavioural sciences' vision, or 'law and sciences' more generally, where the function of (behavioural) sciences 'may be to shed light on facts (rather than law), leaving it to legal analysis to decide whether and how this knowledge about facts could and should be incorporated'.[53] While the non-alignment between legal prescriptions and empirical facts may be regretted, there may be good reasons for the law to be resistant to the incorporation of these findings.[54]

This brings us to a last important point as regards interdisciplinarity. The use of non-legal materials by a non-expert, in fields as complex as those involved with the regulation of health lifestyles, presents a risk of erroneous interpretation.[55] In full awareness of this, several steps have been taken to minimise this problem, acknowledging that it may nonetheless not be fully eliminated. First, all the analyses made are based as much as possible on systematic reviews and meta-analyses of previous studies and refrain from relying on single isolated studies, especially where these conflict with predominant views. Second, uncertainty, where it exists, is systematically acknowledged. Results are presented with the necessary words of caution. Finally, as already said, this work does not aim at arbitrating empirical questions regarding the existence of a risk or the effectiveness of different interventions to tackle it. It remains first and foremost a legal work answering legal questions.

3. Structure of the thesis

Reflecting its scope and objectives, the thesis is structured is as follows.

Part I lays down the foundations of a study of lifestyle risks regulation in EU law. Chapter 1 defines the concept of lifestyle risks and presents its main features : health, consumption, individual choice and collective identity. Through the lens of risk regulation, the chapter further investigates these various dimensions. The aim is to better understand what the consequences of unhealthy behaviours are, in terms of mortality and morbidity, and how public policy may be an adequate tool to alter lifestyle behaviours and seek better health outcomes. Chapter 2

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[52] ibid 173-182.

[53] Anne-Lise Sibony and Alberto Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' in Alberto Alemanno and Anne-Lise Sibony (eds), *Nudge and The Law* (Hart Publishing 2015) 9. See also Anne-Lise Sibony, Geneviève Helleringer and Alberto Alemanno, 'L'Analyse Comportementale du Droit: Manifeste pour un Nouveau Champ de Recherche en Europe' (2016) 2016 Revue Internationale de Droit Economique 315.

[54] Sibony, 'Data and Arguments: Empirical Research in Consumer law' (n 51) 178. On the relationship between science and law, see more generally Robin Feldman, *The Role of Science in Law* (Oxford University Press 2009).

[55] Nicky Priaulx and Martin Weinel, 'Behaviour on a Beer Mat: Law, Interdisciplinarity and Expertise' (2014) 2014 Journal of Law Technology and Policy 361.

analyses the EU constitutional framework, the Treaty of the Functioning of the European Union (TFEU) in particular, to determine the extent to which the regulation of lifestyle risks is part of the EU's objectives and what its powers are in this regard. When regulating lifestyles, the EU pursues two main objectives: protecting health and facilitating the free movement of goods, services and persons in the internal market. Because EU competence in public health, as regards lifestyles, is limited, harmonisation measures in this area must necessarily be tied to the internal market. This has profound consequences for the EU's regulatory regime.

Part II looks at the first dimension of EU lifestyle risks regulation, the application of the TFEU free movement provisions to national measures on lifestyle risks, the area where health and the market are most frontally pitted against one another. As EU law on lifestyles remains primarily internal market law, free movement provisions are the necessary starting point of our inquiry, both historically and conceptually. Considering the functional link existing between restrictions to free movement, justifications and harmonisation, such analysis is necessary to understand the kind of policy options available to the EU legislator. Chapter 3 methodically examines the various measures adopted by Member States to determine whether these constitute restrictions to the free movement of goods, services or the freedom of establishment. This is the case for most interventions, meaning that these are in principle prohibited unless they are justified by a legitimate public interest, health, mostly, and proportionate. Chapter 4 analyses Member State defences of lifestyle risks measures and shows how the principle of proportionality shapes the risk regulatory process at the national level. This affects the level of public health protection decided upon by Member States and their ability to conduct a lifestyle risks policy that integrates other non-risk concerns, linked to specific cultural or moral conceptions.

Part III, finally, addresses the second dimension of EU lifestyle risks regulation, the development of a health promotion policy on lifestyles at the EU level. Chapter 5 and 6 provide the reader with a complete overview of EU law and policy on lifestyle risks, analysing the various measures adopted by the EU legislator to reduce smoking, harmful drinking, the consumption of unhealthy foodstuffs and illicit drug use. Chapter 5 presents the objectives of EU lifestyle risks policy before analysing the measures adopted that are most restrictive of individual choice: bans and taxation measures. Chapter 6 focuses on measures targeting commercial communications and regulating product information. Chapter 7, finally, analyses these measures through the fundamental principles governing the competence of the EU: conferral, subsidiarity, proportionality and respect for fundamental rights. It shows that the EU legislator is constrained in its choices due to the internal market nature of its legislative competence, and how this limited competence undermines the ability to conduct a policy which properly balances the different objectives, values and interests at stake.

Part I

Foundations of EU lifestyle risks regulation

Chapter 1

Conceptualising and regulating lifestyle risks

1. Introduction

As a response to the growing demands of the 'risk society', governments are increasingly active in the management of health risks and the regulation of lifestyles. Two factors may account for this evolution. First, health has generally gained in importance as a value. Health may have been a preoccupation in most societies, yet 'the extent and intensity of health-related concerns evident in many contemporary Western societies are remarkable'.[56] The concept of 'healthism' was coined to describe the growingly health-conscious society and the idea that individuals have a role to play in maintaining their health.[57]

> Whereas people may have more or less taken their health for granted in previous historical eras, this is presently not the case. Health in late modernity has become viewed as an achievement – something people are supposed to work at to enhance their quality of life or risk chronic illness and premature death if they do not.[58]

Second, the nature of the health risks to which individuals are exposed has changed. Fuelled by the 'epidemiologic transition' described in the introduction,[59] a 'new' public health is coming of age.[60] Contrary to the 'old' public health of the 19th century, preoccupied mostly with hygiene, filth and contagion, the new public health focuses on the root causes of non-communicable diseases, where life habits play a key role.[61] Lifestyle change appears as a 'tantalising', 'cheap, effective, non-toxic, low-risk solution' to the chronic ill health that plagues our societies.[62]

Public intervention in lifestyles aims primarily at reducing, or eliminating, a range of harmful consumptions, that of tobacco, alcohol and nutritionally poor food in particular. At the same time, lifestyles, as the very term suggests, go well beyond health. They constitute defining habits and routines for individuals and societies. They are based on the consumption of commodities whose manufacture and trade have become central in today's economies,

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[56] Alan Petersen and Deborah Lupton, *The New Public Health: Health and Self in the Age of Risk* (SAGE Publications Ltd 2000) 1.
[57] Nike Ayo, 'Understanding Health Promotion in a Neoliberal Climate and the Making of Health Conscious Citizens' (2012) 22 Critical Public Health 99, 100; Friedrich Schorb, 'Fat Politics in Europe: Theorizing on the Premises and Outcomes of European Anti-"Obesity-Epidemic" Policies' (2013) 2 Fat Studies 3, 6–7; Alexander Somek, *Individualism: An Essay on the Authority of the European Union* (Oxford University Press 2008) 52–53.
[58] William C Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (2005) 46 Journal of Health and Social Behavior 51, 51. See also Brian P Hinote, 'William C Cockerham: The Contemporary Sociology of Health Lifestyles' in Fran Collyer (ed), *The Palgrave Handbook of Social Theory in Health, Illness and Medicine* (Palgrave Macmillan UK 2015) 473–475.
[59] Abdel R Omran, 'The Epidemiologic Transition: A Theory of the Epidemiology of Population Change' (2005) 83 The Milbank Quarterly 731; Robert E McKeown, 'The Epidemiologic Transition: Changing Patterns of Mortality and Population Dynamics' (2009) 3 American Journal of Lifestyle Medicine 19S.
[60] Petersen and Lupton (n 56) 2–4.
[61] ibid.
[62] Dominic Upton and Kathryn Thirlaway, *Promoting Healthy Behaviour: A Practical Guide* (2nd edition, Routledge, Taylor & Francis Group 2014) 2.

generating an importance source of revenue for private operators and governments. Regulating lifestyle risks is therefore no easy task. It requires to select the appropriate tools leading to behaviour change while paying due consideration to other non-health interests. This is true for public policy in general and for risk regulation in particular, as risk is in itself a contested concept.

This first chapter constitutes a general introduction to the regulation of lifestyle risks. As a prerequisite to a proper understanding of what this area of regulation entails, the chapter defines and conceptualises lifestyle risks and outlines the main characteristics of this category. The reader is then introduced with the basic concepts of risk regulation, the methods used to elaborate regulatory responses and the tools used to meet the objectives of lifestyle risks regulation.

2. What are health lifestyles?

A person's health status is determined by a number of factors. These 'determinants of health' are plural and can be 'behaviour-related, biological, socio-economic and environmental'.[63] The WHO, the European Union and other public health authorities consider individual lifestyles to be an essential determinant of health and a key area for health promotion.[64] Although there is no fixed list nor consensus as to which activities constitute 'health lifestyles',[65] four main behaviours are usually considered under this umbrella term: tobacco and alcohol consumption, diets and physical (in)activity.[66] These all constitute risk factors for a range of NCDs and other health hazards.[67]

Apart from the connection made to a host of damaging health consequences, health lifestyles are rarely, if ever, defined in public policy. According to the WHO a healthy lifestyle is 'a way of living that lowers the risk of being seriously ill or dying early',[68] implying that, on the

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[63] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027 [2021] OJ L107/1, art 2(11); see also WHO, 'Determinants of health' (2017), <https://www.who.int/news-room/questions-and-answers/item/determinants-of-health> accessed 11/05/2023.

[64] WHO, 'Healthy living: what is a healthy lifestyle? (1999) WHO Regional Office for Europe, <https://apps.who.int/iris/handle/10665/108180> accessed 11/05/2023; United Nations General Assembly (n 6); WHO, 'Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020' (n 8). See, for the EU, Regulation (EU) 282/2014 of the European Parliament and of the Council on the establishment of a third Programme for the Union's action in the field of health (2014-2020) [2014] OJ L86/1, art 3(1); Regulation 2021/522, art 3(a); Council of the European Union, Council Conclusions of 2 December 2003 on healthy lifestyles: education, information and communication [2004] OJ C22/1; Council of the European Union, Council Conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours [2011] OJ C359/5.

[65] Kathryn Thirlaway and Dominic Upton, *The Psychology of Lifestyle: Promoting Healthy Behaviour* (Routledge, Taylor & Francis Group 2009) 6–7.

[66] See ibid; Alemanno and Garde, 'The emergence of an EU lifestyle policy: The case of alcohol, tobacco and unhealthy diets' (n 31); Alemanno and Garde, *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (n 31); Upton and Thirlaway (n 62).

[67] United Nations General Assembly (n 6), para 20.

[68] WHO, Healthy living: what is a healthy lifestyle?' (n 64) 1.

contrary, an unhealthy lifestyle is a way of living that increases those risks. As such, most ways of living, most habits and behaviours have an influence on health and could thus qualify as health lifestyles, 'from brushing one's teeth and using automobile seat belts to relaxing at health spas',[69] or, conversely, from not wearing proper clothing during wintertime to cycling without a helmet. There is therefore a need for a definition that is both *narrower in scope*, which allows to consider only a number of specific health lifestyles, and *wider in substance*, which reveals, beyond health, a number of key characteristics which are common to these various health lifestyles.

William Cockerham, one of the leading contemporary theorists of health lifestyles, offers such a definition. Drawing on elements from the sociology of Max Weber, Pierre Bourdieu and Anthony Giddens,[70] Cockerham and his co-authors define health lifestyles as:

> [C]ollective patterns of health-related behavior based on choices from options available to people according to their life chances.[71]

This definition underlines three central aspects of health lifestyles.[72] First, lifestyles are associated with status groups. They are not primarily an individual but a collective phenomenon. Second, and this is central to Max Weber's understanding of lifestyles in modern times, these status groups are defined by consumption rather than production, consumption being regarded 'as a set of social and cultural practices that establish differences between social groups'.[73] Third, these lifestyles arise from the interplay between a person's 'life choices' – to smoke or not to smoke, to drink or not to drink – and 'life chances', one's position in society which orients and limits the range of possible choices.[74] Life chances are affected by various variables, including social class, age, gender, race and ethnicity.[75] Health lifestyles are therefore influenced by a mixture of individual and collective factors.

Under this definition, what health lifestyles have in common is to be (i) consumption behaviours (ii) chosen by individuals within the constraints of their social position, (iii) expressing belonging to certain social groups. The focus of this thesis is on (iv) the health *risks* associated with these lifestyles, 'risk' being defined as the 'intuitive, qualitative meaning of something undesirable, which may or may not happen, but gives reason for concern'.[76] These risks are mostly but not only related to NCDs, as will be further explored in Section 4.

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[69] Cockerham, Abel and Lüschen (n 5) 419.
[70] See Cockerham, Rütten and Abel (n 5) and Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58).
[71] Cockerham, Rütten and Abel (n 5) 338; Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 55; William C Cockerham, 'Health Lifestyle Theory' in *The Wiley-Blackwell Encyclopedia of Social Theory* (John Wiley & Sons 2017) 1; emphasis added.
[72] Cockerham, Rütten and Abel (n 5) 325, 338; Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 55. See also Cockerham, Abel and Lüschen (n 5) 416-418.
[73] Cockerham, Rütten and Abel (n 5) 324.
[74] Cockerham, Rütten and Abel (n 5) 325; Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 55.
[75] Cockerham, Rütten and Abel (n 5) 338; Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58).
[76] Bernardo Delogu, *Risk Analysis and Governance in EU Policy Making and Regulation* (Springer International Publishing 2016) 9.

Conceptualised in this way, health lifestyles come close to the description given by Thirlaway and Upton of 'lifestyle behaviours', whose main characteristics will be further unpacked in the chapter:

> [I]t is possible to put together a cohesive argument that *lifestyle behaviours share more than their ability to influence a range of chronic diseases*. First, lifestyle behaviours have multiple functions; *they are not simply or even primarily health focused*. Lifestyle behaviours can be mood enhancing; they can be used as a coping strategy; they are often *pleasurable*; and they play an important function in the development and maintenance of *social relationships*. Second, lifestyle behaviours are all *under some degree of volitional control*, although the amount of control individuals have over their lifestyle choices is *contentious and likely to vary widely from context to context*. Third, lifestyle behaviours are all *chronic rather than acute behaviours*. Usually individuals will practise regular patterns of these behaviours and their future behaviour will be best predicted by the choices they have made in the past. Finally, *lifestyle behaviours have the majority of their positive consequences in the present and the majority of their negative outcomes in the future*. Any lifestyle behavioural change intervention consequently requires individuals to be future orientated. Consequently, *it is possible to argue that lifestyle behaviours, although each unique, share a set of common factors that unify them* and indicates that common theoretical principles may underpin the aetiology and progression of these behaviours.[77]

With the Cockerham definition in hand, the purpose is not to draw up a fixed list of health lifestyles but to be able to isolate a number of key behaviours on the basis of their common characteristics, rather than solely because they have been given particular importance in public policy. Tobacco consumption, alcohol consumption and unhealthy diets undoubtedly fit that definition. These health-damaging individual behaviours present a strong collective aspect, in terms of social groups and cultures, and are embedded in a consumer relationship. The same can be said of the consumption of illicit drugs, although their illicit character gives rise to a number of specific challenges as regards public policy. Gambling, finally, is rarely mentioned when referring to health lifestyles but share similar features. It is an economic activity which exposes players to various health risks and whose place in society has long been determined by cultural and moral considerations.[78]

This definition also allows to exclude certain other behavioural risk factors from our inquiry, which, while being part of people's lifestyles, understood broadly, are nonetheless fundamentally different from the health lifestyles presented above.[79] Two of them should be particularly distinguished: sexual activity[80] and the consumption of unsafe food.

Sexuality is undoubtedly part of someone's lifestyle and presents individual and collective dimensions. It is also hazardous, as it exposes people to sexually transmitted diseases. Yet, a

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[77] Thirlaway and Upton (n 65) 9-10, emphasis added.

[78] See chapters 5 to 7 in Bogart (n 15). In this book, Bogart makes a connection between these five 'lifestyles': '[t]he capacity of some individuals to drink immoderately, smoke, eat non nutritiously and be sedentary, take drugs, and gamble too much is a phenomenon that persists — despite all manner of threats and inducements, legal and otherwise': ibid 4. Alemanno and Planzer also include gambling in their discussion of 'lifestyle risks': Alemanno and Planzer (n 38).

[79] Such as extreme sports: see Giorgi (n 38) 99. See also Alemanno and Planzer (n 38) 335.

[80] Upton and Thirlaway include sex in their discussion of healthy behaviours: Upton and Thirlaway (n 62); Thirlaway and Upton (n 65).

crucial difference between sex and, say, tobacco or alcohol consumption, is the absence, in most cases, of an underlying economic or consumer relationship. Choice is also an important distinction. Sex-induced risks are not truly voluntary risks in the sense that few people would willingly engage in an unprotected sexual intercourse with someone that they know for sure is infectious. Sex can be risk-free, smoking and drinking are never risk-free.

The case of food safety is more complex. As they arise from food consumption, food safety risks are inevitably closely linked to the nutritional risks referred to under the term 'unhealthy diets'. Yet, it seems to be commonly accepted that a difference exists between food *safety* and food *quality*,[81] the latter being the focus of nutrition policy. Intuitively, most would agree that food safety and nutrition are not the same thing. Food safety usually refers to issues of contamination by an agent which leads to injurious consequences to health or to food that is unfit for consumption. Similarly to sex-related health risks, the choice aspect seems to be lacking for food safety risks in the sense that, arguably, no one willingly consumes food infected with, say, salmonella or the E. coli bacteria. Nutritional risks are voluntary, to a certain degree, while food safety risks are not.[82]

From a legal perspective, food safety and food quality issues may also be distinguished.[83] Under EU law, a food is deemed unsafe within the meaning of Regulation 178/2002 (the 'General Food Law Regulation' or 'GFL Regulation')[84] 'if it is considered to be *injurious to health* [or] *unfit for human consumption*'.[85] Unfit for human consumption refers to instances where something is 'wrong'[86] with a foodstuff, 'for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay'.[87] A foodstuff of poor nutritional quality is not, for this reason alone, unfit for human consumption. It could,

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[81] MacMaoláin, *EU Food Law: Protecting Consumers and Health in a Common Market* (n 32) 224; Garde, *EU Law and Obesity Prevention* (n 32) 23; Wieke Willemijn Huizing Edinger, 'Food Health Law: A Legal Perspective on EU Competence to Regulate the "Healthiness" of Food' (2014) 9 European Food and Feed Law Review 11, 11–12; Iris Goldner Lang, 'Public Health in European Union Food Law' in Hervey, Alasdair Young and Bishop (n 37) 405.

[82] See Rehm, Lachenmeier and Room (n 14) 190.

[83] A similar question arises regarding product safety more generally. Would cigarette qualify as a 'safe product' within the meaning of the EU General Product Safety Directive? See Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [2001] OJ L11/4, art 2(b). This question remains theoretical as the directive does not apply to tobacco and related products, since these are already subject to specific safety requirements under specific legislative instruments: see ibid art 1(2).

[84] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1 (General Food Law Regulation).

[85] ibid, art 14(2), emphasis added. The alternative rather than cumulative character of these two conditions was confirmed in Case C-636/11 *Berger* [2013] EU:C:2013:227, paras 36–37. See also Commission Standing Committee on the Food Chain and Animal Health, 'Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) 178/2002 on General Food Law' (2010) 8, <https://ec.europa.eu/food/system/files/2016-12/gfl_req_implementation-guidance_en.pdf> accessed 11/05/2023 ; Wieke Willemijn Huizing Edinger, 'Food, Safety and the Behavioural Factor of Risk' (2014) 5 European Journal of Risk Regulation 491, 497.

[86] Edinger, 'Food, Safety and the Behavioural Factor of Risk' (n 85) 498.

[87] General Food Law Regulation, art 14(5). See also Garde, *EU Law and Obesity Prevention* (n 32) 24.

however, be considered as injurious to health within the meaning of that Regulation and hence be deemed unsafe.[88] Yet, the health risks that are considered under the GFL Regulation are those arising from exposure to a hazard, defined as 'a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect',[89] leaving aside the nutritional composition of food.[90] Hence, foodstuffs that are unhealthy due to their nutritional composition do not qualify as 'unsafe' under EU law. This finding is corroborated by the fact that, under the GLF Regulation, unsafe food must not be placed on the market, or must be withdrawn from the market if it is found to be unsafe,[91] a requirement which has obviously not been applied to fatty and salty food or alcoholic beverages. Similarly, under WTO law, a distinction seems to be drawn between measures coming under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 'measures regarding the spread of pests and diseases, food safety and "additives, contaminants [and] toxins" that are in some way unnatural or out of place (such as food colouring)', and 'measures relating to the provision of information about normal food nutrients that are not typically considered additives, contaminants or toxins, even if over-consumption may be detrimental for one's health'.[92]

The difference between food safety and food quality is yet not always clear-cut.[93] Could the 'hidden' sugars or the trans-fats added in processed food, insofar as they are not naturally present in our foods and are often consumed unbeknownst to consumers, be considered as hazardous agents within the meaning of the GLF Regulation? It is true, after all, that 'few gain enjoyment from consuming trans-fats in and of themselves; they just happen to be placed in some of the foods we eat'.[94] A similar interrogation arises with fortified foods, products reinforced with certain vitamins and minerals that are otherwise naturally present in food and also involve health risks. Furthermore, the safety and the quality of food can go hand in hand, as illustrated by the growing role played by the European Food Safety Authority in EU nutrition policy.[95] Hence, although food safety remains conceptually different from food quality and is therefore excluded from the ambit of this work, the EU food safety legal framework will nonetheless be used where pertinent.

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[88] See General Food Law Regulation, art 14(3).
[89] ibid, art 3(14), see also art. 3(9).
[90] Edinger, 'Food, Safety and the Behavioural Factor of Risk' (n 85) 500; Goldner Lang (n 81) 405.
[91] General Food Law Regulation, arts 14(1) and 19.
[92] Jessica C Lai and Shmuel I Becher, 'Front-of-Pack Labelling and International Trade Law: Revisiting the Health Star Rating System' (2020) 21 Melbourne Journal of International Law 24.
[93] Garde, *EU Law and Obesity Prevention* (n 32) 24-25; Edinger, 'Food, Safety and the Behavioural Factor of Risk' (n 85).
[94] Adam Oliver, 'Nudging, Shoving, and Budging: Behavioural Economic-Informed Policy' (2015) 93 Public Administration 700, 710; see also Edinger, 'Food, Safety and the Behavioural Factor of Risk' (n 85) 492.
[95] Marine Friant-Perrot and Amandine Garde, 'From BSE to Obesity: EFSA's Growing Role in the EU's Nutrition Policy' in Alberto Alemanno and Simone Gabbi (eds), *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority* (Ashgate 2013).

3. Regulating lifestyle risks

Lifestyle-related health risks are publicly regulated so as to reduce the level of harm affecting the population. Regulation as a concept is notoriously difficult to define.[96] In a broad sense, it designates 'the intentional intervention in the activities of a target population, where the intervention is typically direct – involving binding standard-setting, monitoring and sanctioning – and exercised by public-sector actors on the economic activities of private-sector actors'.[97] This intervention takes place with 'the intention of producing a broadly identified outcome or outcomes'.[98] When applied to risks, regulation seeks to determine 'which risks to accept and what measures need to be taken to minimise those risks'.[99] It is typically exercised by public-sector actors and interferes 'with market and social processes to control or at least minimize possible adverse consequences to publicly protected interests, such as health and the environment'.[100] Risk represents both the object of risk regulation and the justification for such government intervention.[101]

To gain a proper understanding of the risk regulatory process, it is important to better define the concept of risk, including in its relation to uncertainty, and to distinguish it from the closely related concept of 'hazard'. Regulating risks typically involve two interrelated exercises: risk assessment and risk management.

3.1. Risk, hazard and uncertainty

In simple terms, a risk is the possibility of a negative consequence. From a technical perspective, risk is defined and calculated 'as the function of the probability of an event and the severity and size of its adverse consequences'.[102] In the present case, the risks arising from

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[96] See Julia Black, 'Critical Reflections on Regulation' (2002) 27 Austrian Journal of Legal Philosophy 1; Robert Baldwin, Martin Cave and Martin Lodge, 'Introduction: Regulation—the Field and the Developing Agenda' in Robert Baldwin, Martin Cave and Martin Lodge (eds), *The Oxford Handbook of Regulation* (Oxford University Press 2010); Christel Koop and Martin Lodge, 'What Is Regulation? An Interdisciplinary Concept Analysis' (2017) 11 Regulation & Governance 95.

[97] Koop and Lodge (n 96) 105; see also the neighbouring definition given by Black, 'Critical Reflections on Regulation' (n 96) 26.

[98] Black, 'Critical Reflections on Regulation' (n 96) 26.

[99] Alberto Alemanno, 'Risk and Regulation' in Adam Burgess, Alberto Alemanno and Jens O Zinn (eds.), *Routledge Handbook of Risk Studies* (Routledge 2016) 197. See also Weimer, *Risk Regulation in the Internal Market* (n 2) 23.

[100] Weimer, *Risk Regulation in the Internal Market* (n 2) 23. See also Christopher Hood, Henry Rothstein and Robert Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press 2001) 3.

[101] Black, 'The Role of Risk in Regulatory Processes' (n 2) 303. See also Alemanno, 'Risk and Regulation' (n 99) 197.

[102] Delogu (n 76) 12. See also Weimer, *Risk Regulation in the Internal Market* (n 2) 28. Under the GFL Regulation, art 3(9), 'risk' means 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'.

smoking or drinking alcohol vary in their probability, their severity and size. The probability of developing a lung cancer after decades of smoking may not be the same as that of developing a cardiovascular disease, as also differ the consequences of both diseases in terms of morbidity and mortality. Risk is influenced by exposure and vulnerability:[103] it depends on how exposed a person is, how many drinks or cigarettes per day are for instance consumed, and how vulnerable a person is, how their body will react to it.

The concept of 'risk' must not be confused with that of 'hazard'. A hazard is 'something than can cause harm'.[104] It is 'any source of potential damage, harm or adverse effects on someone or something' and is a function of 'the inherent properties of the agent/event in question'.[105] Cancer hazard depends on the carcinogenic nature of the compounds present in cigarettes or alcoholic beverages. 'While hazard represents a danger, risk expresses the combination of the level of hazard and the likelihood of its occurrence', based on exposure and vulnerability.[106] Hence, a hazard may be great – lung cancer is for instance a particularly deadly form of cancer – but the risk of developing it may be low, if one is for instance an occasional smoker. A plane crash is a hazard with devastating consequences, although the risk of a plane crash is extremely low. The same can be said of a nuclear catastrophe.

Distinguishing between hazard and risk is important for regulatory purposes. Focusing on the existence of a hazard, regardless of the level of risk involved, tends to lead to more heavy-handed regulation:[107]

> A risk-based approach in legislation aims at controlling or limiting exposure to a hazard; it is managing the risk while accepting the existence of a hazard. A hazard-based approach in legislation aims at eliminating the hazard without an in-depth assessment of the risk […] i.e. the likelihood of being exposed to that harm.[108]

As regards lifestyle risks regulation, tobacco control usually follows a risk-based approach, as there is no real question, yet, to ban the consumption of tobacco products altogether. For drugs that are made illicit, in the opposite, public authorities favour a hazard-based approach, seeking to eliminate the danger without always having a clear idea of its consequences.

Uncertainty is inherent to risk, as risk entails the probability of an event. Harm could occur, or not. This can be referred to as 'uncertainty *in* risk'.[109] The severity and size of a possible negative event are known, and the probability of its occurrence may be calculated. It is a

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[103] European Commission, 'Better Regulation Toolbox' (2021) 100, < https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox-0_en> accessed 11/05/2023.
[104] ibid.
[105] ibid. Under the GFL Regulation, art 3(14): '"hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect'.
[106] European Commission, 'Better Regulation Toolbox' (n 103) 100.
[107] Ragnar E Lofstedt, 'Risk versus Hazard – How to Regulate in the 21st Century' (2011) 2 European Journal of Risk Regulation 149. See also Alberto Alemanno, 'Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt' (2011) 2 European Journal of Risk Regulation 169.
[108] European Commission, 'Better Regulation Toolbox' (n 103) 101, emphasis added.
[109] Delogu (n 76) 26, emphasis added.

'measurable uncertainty'[110] without which the concept of risk would be meaningless. This first type of uncertainty must be distinguished from 'uncertainty *on* risk',[111] which refers to the 'uncertainties of different nature and level, which play an important part in most cases, which are often related to one or more of the various components of the risk considered'.[112] A risk is uncertain if it is for instance impossible to predict the severity of the possible outcomes or their probability.

This uncertainty on risk can take several forms. First, the possible outcomes resulting from exposure to a hazard as well as their characteristics may be known, but not their probability. This uncertainty is present for many risks, as calculating accurately the likeliness of a harmful event in real life is a difficult task. Second, in a situation of 'ignorance',[113] the hazardous nature of an event or activity is known or suspected, but some or all of the possible outcomes are not identified. This is for instance the case of the cultivation of GMOs.[114] A third situation of 'radical ignorance' covers 'unknown unknowns', when 'we are not even aware that things or activities may produce adverse impacts at all'.[115] The potentially hazardous activity or event is not even identified by regulators.

Regarding lifestyle-related health risks, regulators are for the most part not in a position of ignorance, much less of radical ignorance. The range of possible negative outcomes is overall well-established – some of them may still be unknown, as regards e-cigarettes for instance or certain dietary risks – even if their probability may not be precisely calculated in all situations. Lifestyle risks are 'certain risks'. The harmful nature of tobacco and alcohol is not anymore contested, although the measures to be taken to tackle that harm remain divisive. Regulation is usually less controversial when the risk is certain than when it is not. 'The struggle between science and politics is particularly pronounced in situations of scientific uncertainty – which by their nature are prone to societal contestation'.[116]

3.2. Risk assessment and risk management

Risks regulation as a process is usually understood as requiring to perform two separate and consecutive analyses: risk assessment and risk management.[117] While the first concept refers to the 'technical assessment of risk', the second consists in 'the identification and evaluation

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[110] Eyal Zamir and Doron Teichman, *Behavioral Law and Economics* (Oxford University Press 2018) 39.
[111] Delogu (n 76) 26, emphasis added.
[112] ibid.
[113] Weimer, *Risk Regulation in the Internal Market* (n 2) 30.
[114] See ibid 17
[115] Black, 'The Role of Risk in Regulatory Processes' (n 2) 310.
[116] Weimer, *Risk Regulation in the Internal Market* (n 2) 66.
[117] Along with 'risk communication', risk assessment and risk management are often considered to be three basic components of the broader concept of 'risk analysis': see Delogu (n 76) 38; GFL Regulation, art 3(10). The thesis uses the concept of risk regulation rather than the one of risk analysis, to put a greater emphasis on the actual adoption and implementation of control measures.

of options leading to the establishment and implementation of policy and regulatory measures'.[118]

Risk assessment can be defined as 'the process or method to identify hazard that has the potential to cause harm and to analyse risk associated with that hazard (assessing what is the likelihood of exposure to hazard and what are the likely impacts of exposure if hazard happens)'.[119] It comprises three main steps:[120] (i) identifying and characterising the hazard,[121] (ii) assessing the likelihood of its occurrence, and (iii) characterising the risk.[122] It typically involves experts and scientists rather than bureaucrats or politicians.

Managing a risk is to decide what should be done about it, it is:

> [T]he the process, distinct from risk assessment, of *weighing policy alternatives* in consultation with interested parties, considering risk assessment and *other legitimate factors*, and, if need be, selecting appropriate prevention and control options.[123]

Risk managers decide, on the basis of the risk assessment available, whether to act and how. Risk assessors provide a necessary scientific evaluation – risk regulation should not be built on thin air – which is not sufficient to determine which course of action should follow. Other considerations than the nature and level of a risk must be included to decide on which policies to adopt, if any, to tackle that risk. This division between risk assessment and management reflects the dual nature of risk, a technical but also a political concept.[124] Risk regulation is a complicated endeavour, which requires to balance competing objectives, integrate complex scientific facts and to answer normative questions,[125] for instance what is undesirable and who should do something about it.[126] 'In fact, not all risks are or could or should be "regulated"':[127]

> The borderline between public and individual responsibility for risks is variable in time, across jurisdictions and sectors, and is not necessarily consistent even within the same jurisdiction. *It depends on many factors, like for example habits, preferences, history*.[128]

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[118] Delogu (n 76) 38.
[119] European Commission, 'Better Regulation Toolbox' (n 103) 101.
[120] ibid 102. Under the GFL Regulation, art 3(11), '"risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation'.
[121] 'i.e. identify and characterise the inherent properties of the agent or phenomenon in terms of potential negative effects (on population, environment etc.), establish the causal relationship between the hazard and its effect, describe the negative effect and determine its severity (e.g. occurrence of mutations, changes in the cell structure, etc.) and dose-effect relationships': European Commission, 'Better Regulation Toolbox' (n 103) 102.
[122] 'i.e. based on the results from the previous steps, determine quantitatively (e.g. death, injury, production loss, increase of poverty and inequality) and if not possible, qualitatively, the level of risk under given assumptions and uncertainties': ibid.
[123] GFL Regulation, art 3(12), emphasis added.
[124] Weimer, *Risk Regulation in the Internal Market* (n 2) 69.
[125] ibid 3-4.
[126] Black, 'The Role of Risk in Regulatory Processes' (n 2) 310-311.
[127] Delogu (n 76) 35.
[128] ibid 36, emphasis added.

As regards lifestyle risks, risk assessment would for instance allow to determine what are the harmful consequences associated with alcohol and how likely a given individual is to suffer these consequences under a certain pattern of consumption. To manage alcohol risks and decide on the kind of policies to adopt, the regulator needs to factor in other considerations than that related to human health: the cultural relevance of a given product, the importance of a specific sector for the economy or the extent to which individuals should be granted control over their own lifestyles or not. On the basis of a similar risk assessment, risk managers in different contexts may decide to adopt different control measures, depending on the relative weight given to these considerations.

To conduct this exercise of weighing policy alternatives, risk managers may have recourse to a regulatory impact assessment, or simply impact assessment (IA): 'a systematic and mandatory appraisal of how proposed […] legislation will affect certain categories of stakeholders, economic sectors, and the environment',[129] usually formalised in a document. IAs serve to compare, usually ex-ante, various regulatory options, on the basis of their contribution to the stated objectives of a legislation and of their impacts, positive or negative, on a range of stakeholders and/or protected interests. They provide regulators with the necessary evidence-base for decision-making and allow the public and affected parties to understand why a certain course of action has been selected over another. Impact assessments will prove particularly useful for the analysis of the EU lifestyle risks regulatory apparatus contained in Chapter 7.

A last important concept to mention as regards risk regulation is the precautionary principle. This concept is notoriously difficult to define and has generated considerable debates, both as to its meaning and as to its application in EU law.[130] Following the approach taken by De Sadeleer, we 'will not reopen discussion on the meaning of this principle, other than to recall its function as the expression of a philosophy of anticipated action, not requiring that the entire corpus of scientific proof be collated in order for a public authority to be able to adopt a preventive measure'.[131] Linked to the situations of uncertainty described above, the precautionary principle requires, in its most basic understanding, that, 'where there is uncertainty as to the existence or extent of risks, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent'.[132] Maria Weimer distinguishes two main applications of that principle. Under a 'weak' approach, the precautionary principle may be relied on where there is 'a threat of serious or irreversible

[129] Claudio M Radaelli and Fabrizio de Francesco, 'Regulatory Impact Assessment' in Robert Baldwin, Martin Cave and Martin Lodge (eds), Claudio M Radaelli and Fabrizio de Francesco, *The Oxford Handbook of Regulation* (Oxford University Press 2010) 278.
[130] See Paul Craig, *EU Administrative Law* (Oxford University Press 2006) 694–721; Nicolas de Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12 European Law Journal 139; Alessandra Donati, *Le Principe de Précaution en Droit de l'Union Européenne* (Bruylant 2021).
[131] De Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (n 130) 139.
[132] Case C-452/20 *Agenzia delle dogane e dei monopoli and Ministero dell'Economia e delle Finanze* [2022] EU:C:2022:111, para 34.

damage, the occurrence of which is likely or probable', and where the measures taken are cost-effective.[133] Under a 'strong approach', regulators may take preventive action in 'presence of any threats to the environment or health', regardless of its costs.[134]

The precautionary principle has gained in importance in EU risk regulation over the last decades and has established itself as a general principle of EU law. As already mentioned, and as will be developed in the coming section, most lifestyle-related health risks are well-known risks. The range of possible outcomes arising from exposure to lifestyle risks factors and the nature of these outcomes is well established. This means that precaution does not play a central role in the regulation of lifestyle risks,[135] save for certain areas where uncertainty persists, as regards for instance e-cigarettes.

4. Risk assessment: what are the risks associated with health lifestyles?

This section provides an overview of the risks to human health associated with the five 'lifestyles' considered in this thesis, and the resulting health burden in terms of mortality and morbidity. As most EU legislative measures in the field of lifestyle risks concern tobacco products, it is necessary to present and discuss in greater detail the health risks associated with tobacco consumption.

This section relies extensively on the data collected by the Global Burden of Disease (GBD) study and the analyses based thereon. Led by the Institute for Health Metrics and Evaluation at the University of Washington, Seattle, and published in the medical journal *The Lancet*, the GBD study is 'the most comprehensive worldwide observational epidemiological study to date'.[136] It examines worldwide trends in diseases, injuries and impairments, and their risk factors. The health burden for each disease is expressed via two main metrics: the number of deaths caused by a disease or a risk factor and the loss of disability-adjusted life years (DALYs) resulting therefrom. DALYs are a time-based measure that combines years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health, or disability.[137] DALYs combine mortality and morbidity in a single metric, allowing for comparison between diseases and risk factors across countries and continent.

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[133] Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology* (n 2) 36.
[134] ibid.
[135] A good illustration thereof may be found in *Agenzia delle dogane* (n 132), para 34: 'As regards […] the applicability of the precautionary principle in the present case, […] it is sufficient to note, first, that *none of the parties to the proceedings denies the risks linked to the consumption of tobacco products for smoking* and, second, that it is apparent from the preamble to the FCTC that *scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability*, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases. Therefore, as the Advocate General observed in point 65 of his Opinion, *that principle does not apply to the situation at issue in the main proceedings*.' Emphasis added.
[136] The Lancet, 'About the Global Burden of Disease', <https://www.thelancet.com/gbd/about> accessed 11/05/2023.
[137] WHO, 'Disability-adjusted life years (DALYs)' The Global Health Observatory, <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/158> accessed 11/05/2023.

While the present thesis focuses on risks and harm to health, it is not the only protected interest that may be adversely affected by human activities related to health lifestyles. It is also the case, in particular, of the environment. The manufacture and consumption of tobacco products, for instance, has dire consequences for the environment,[138] the most visible form of which are the cigarette butts and toxic filters that litter streets and beaches. These are considered 'the most ubiquitous form of litter worldwide' and constitute the most common form of waste collected during coastal clean-ups each year.[139] As regards diets, environmental and health impacts can go hand in hand, insofar as some foods whose intake should be limited may also be those whose production has the most negative consequences on the environment, in terms of climate change, biodiversity loss or freshwater use.[140] That is why research and public policy increasingly adopt a 'food systems' approach combining both elements.[141]

Health is a notoriously ambiguous concept that is prone to disagreements.[142] Under its most commonly accepted definition, provided by the WHO, health is 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'.[143] This definition, in particular the reference to a 'complete' well-being, has been criticised for being too broad and not medical enough.[144] Some prefer to use a narrower definition, where scientific biomedical judgement is used to determine whether a condition 'is a deviation from the normal functioning of the (human) species',[145] in which case it is considered as affecting health. Regardless of one's position regarding what constitutes 'health', there is no disagreement that lifestyles pose a risk to human health, whether understood as leading to disease or infirmity or more broadly as affecting the well-being of individuals. This harm takes various forms. Tobacco, alcohol and diets are leading risk factors for a wide range of diseases, injuries, and impairments.[146] The resulting harm is mostly self-inflicted but may also be inflicted to others, as in the case of second-hand smoking and interpersonal violence resulting from alcohol consumption.

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[138] WHO, 'Tobacco and its environmental impact: an overview' (2017) <https://apps.who.int/iris/bitstream/handle/10665/255574/9789241512497-eng.pdf> accessed 11/05/2023.
[139] Thomas E Novotny and Elli Slaughter, 'Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption' (2014) 1 Current Environmental Health Reports 208, 208.
[140] See Walter Willett and others, 'Food in the Anthropocene: The EAT–Lancet Commission on Healthy Diets from Sustainable Food Systems' (2019) 393 The Lancet 447.
[141] ibid.
[142] Machteld Huber and others, 'How Should We Define Health?' (2011) 343 BMJ d4163; Thomas Abel and David V McQueen, 'Current and Future Theoretical Foundations for NCDs and Health Promotion' in David V McQueen (ed), *Global Handbook on Noncommunicable Diseases and Health Promotion* (Springer 2013); G McCartney and others, 'Defining Health and Health Inequalities' (2019) 172 Public Health 22; de Ruijter (n 47) 52–58.
[143] Preamble to the Constitution of the World Health Organisation: WHO, Constitution, Basic Documents (49th edition, 2020).
[144] See Huber and others (n 142); Angus Dawson and Kalle Grill, 'Health Promotion: Conceptual and Ethical Issues' (2012) 5 Public Health Ethics 101, 101; de Ruijter (n 47) 53.
[145] de Ruijter (n 47) 53.
[146] See Christopher JL Murray and others, 'Global Burden of 87 Risk Factors in 204 Countries and Territories, 1990–2019: A Systematic Analysis for the Global Burden of Disease Study 2019' (2020) 396 The Lancet 1223.

The main risk arising from unhealthy lifestyles, a common denominator to these various risk factors, is that of developing a non-communicable disease, a term that refers to 'any condition which is not transmissible between people'.[147] Countless NCDs exist, but four conditions exert a particularly high mortality and morbidity burden on the population globally: cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes.[148] It is estimated that these four NCDs claim at least 25% of health spendings in the EU.[149] Other NCDs include, inter alia, mental and neurological disorders and renal diseases. These NCDs are usually chronic rather than acute diseases, i.e. diseases that build-up over time in response to different risk factors and whose effects are prolonged in time.[150] NCDs are currently the leading cause of death and disability worldwide. This is especially true in high-income countries, where infectious diseases have been largely tamed. The 2017 GBD study estimates that over 91% of deaths and almost 87% of DALYs incurred in the EU result from NCDs, with the largest burden in terms of deaths and DALYs arising from cardiovascular diseases and cancer.[151] Smoking, alcohol, diets, and physical inactivity constitute 'key behavioural risk factors' for these NCDs.[152]

4.1. Tobacco

The harm resulting from smoking is well-established. The smoke from combustible cigarettes contains over 4000 chemicals and at least 70 known carcinogens.[153] In 2011, it was estimated that, at current consumptions patterns, one billion people would die from smoking in the 21st century.[154] The GBD study estimates that, in the European Union, in 2017, over 810,000 deaths and 19.8 million DALYs were attributable to smoking and almost 67,000 deaths and 1.6 million DALYs to second-hand smoke.[155] These are mainly attributable to three types of NCDs: cancers, cardiovascular diseases and chronic respiratory diseases.[156] It should be stressed,

[147] Mike Rayner and others (eds), *An Introduction to Population-Level Prevention of Non-Communicable Diseases* (Oxford University Press 2017) 13.
[148] ibid; see also United Nations General Assembly (n 6).
[149] Désirée Vandenberghe and Johan Albrecht, 'The Financial Burden of Non-Communicable Diseases in the European Union: A Systematic Review' (2020) 30 European Journal of Public Health 833.
[150] Upton and Thirlaway (n 62) 4.
[151] European Commission, 'EU burden from non-communicable diseases and key risk factors' (n 22).
[152] Mike Rayner and others, 'NCDs: Risk factors and determinants' in Rayner and others (n 147) 32; see also the most recent GBD study: Murray and others (n 146).
[153] Shannon Gravely and others, 'European Adult Smokers' Perceptions of the Harmfulness of E-cigarettes Relative to Combustible Cigarettes: Cohort Findings from the 2016 and 2018 EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health iii38, iii38.
[154] Prabhat Jha, 'Avoidable Deaths from Smoking: A Global Perspective' (2011) 33 Public Health Reviews 569, 570.
[155] European Commission, 'EU burden from non-communicable diseases and key risk factors' (n 22).
[156] ibid.

regarding smoking, that *no safe level* of exposure exists. 'Light' or 'intermittent' smoking, regardless of how these terms are defined,[157] poses significant health risks.[158]

Tobacco for smoking, usually in the form of cigarettes, is by far the most commonly used form of tobacco product in the European Union. According to 2021 Eurobarometer data, almost one quarter (23%) of the EU and UK populations are daily users of tobacco and related products, ranging from more than one third of the Greek (42%) or Bulgarian (38%) populations to 10% in the Netherlands.[159] A similar proportion (23%) of the European population declares smoking, meaning that the consumption of other tobacco and related products, such as smokeless tobacco products or e-cigarettes, is either way marginal or confined to dual use.[160]

A study assessing the relative harm of twelve nicotine-containing products, encompassing harm to self and harm to others and society, concluded that the harm resulting from tobacco products for smoking, cigarettes especially, far outweighed the harm resulting from other products.[161] This is explained by the fact that, despite its strong addictiveness, and contrary to a widespread misperception,[162] it is not nicotine in itself which is responsible for most of the harm resulting from smoking – the health risks posed by nicotine are debated –[163] but the tobacco *smoke* emitted during the combustion of cigarettes, cigarillos or cigars.[164]

Smokeless tobacco products (STPs) are tobacco products that do not involve any inhalation. They vary in form – chewing tobacco, nasal tobacco, tobacco for oral use –[165] and content of

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[157] See Corinne G Husten, 'How Should We Define Light or Intermittent Smoking? Does It Matter?' (2009) 11 Nicotine & Tobacco Research 111; Rebecca E Schane, Pamela M Ling and Stanton A Glantz, 'Health Effects of Light and Intermittent Smoking: A Review' (2010) 121 Circulation 1518, 1518–1519. Husten finds that 'light smoking' can be defined very differently, from not having smoked within the past 30 days to smoking 10 to 20 cigarettes a day: Husten (n 157) 111.

[158] Kjell Bjartveit and Aage Tverdal, 'Health Consequences of Smoking 1–4 Cigarettes per Day' (2005) 14 Tobacco Control 315; Husten (n 157); Shane, Ling and Glantz (n 157).

[159] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (2021) Special Eurobarometer 506, 54, <https://europa.eu/eurobarometer/surveys/detail/2240> accessed 11/05/2023.

[160] ibid 13.

[161] David J Nutt and others, 'Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach' (2014) 20 European Addiction Research 218.

[162] Ann McNeill and others, 'Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England' (2018) Public Health England 190-191, <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review> accessed 11/05/2023.

[163] See ibid 13; Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), 'Opinion on electronic cigarettes' (2021) 7, <https://ec.europa.eu/health/document/download/50b3adac-5451-47c1-8427-ea67e874c970_en> accessed 11/05/2023; European Commission, 'Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms' (2016) 18, <https://ec.europa.eu/health/publications/study-identification-potential-risks-public-health-associated-use-refillable-electronic-cigarettes_en> accessed 11/05/2023.

[164] Sharon Cox and Lynne Dawkins, 'Global and Local Perspectives on Tobacco Harm Reduction: What Are the Issues and Where Do We Go from Here?' (2018) 15 Harm Reduction Journal 32; Renée O'Leary and Riccardo Polosa, 'Tobacco Harm Reduction in the 21st Century' (2020) 20 Drugs and Alcohol Today 219, 226.

[165] See below Chapter 5, Section 3.2.1.

toxicants.[166] STPs involve health risks, such as that of developing cancer or cardiovascular diseases,[167] but remain far less harmful than tobacco products for smoking. Their use is negligible in the EU: 93% of the EU and UK populations have never tried STPs and less than 1% use it monthly, weekly or daily.[168] A notable exception is Sweden, where 16% of the population declare using *snus* daily, a specific form of tobacco for oral use.[169] Snus is a 'moist oral tobacco product which is placed behind the upper lip, either loose or in portioned sachets, which resemble miniature tea bags'.[170] While the sale of any form of tobacco for oral use is prohibited in the EU since 1992, such sales remain legal in Sweden (see Chapter 1, Section 3.2.1), which explains why it is the only country where it is consumed on such scale. Consuming snus is substantially less hazardous than smoking[171] and brings health benefits if used as a substitute for smoking.[172] The wide consumption of snus in Sweden, as a substitute for cigarettes, explains why tobacco-related mortality is much lower in that country than in the rest of the EU.[173]

Electronic cigarettes or e-cigarettes, sometimes designated under the wider umbrella term of electronic nicotine delivery systems (ENDS), are a relatively new category of 'tobacco products'. E-cigarettes are electronic devices used to inhale an aerosol, or vapour – hence the use of the term 'vaping' – created from heating up a liquid that usually contains nicotine and different flavours. Although they resemble conventional cigarettes, e-cigarettes do not contain tobacco and do not involve any combustion process, which makes them very different from tobacco products for smoking. Their use is more common than that of STPs but remains nonetheless limited. In the EU and the UK, more than eight in ten (85%) respondents of the 2021 Eurobarometer had never used e-cigarettes and only a small proportion (2%) declared to currently use them.[174]

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[166] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 'Health Effects of Smokeless Tobacco Products' (2008) 119, <https://ec.europa.eu/health/other-pages/health-sc-basic-page/scientific-committee-emerging-and-newly-identified-health-risks-0_en> accessed 11/05/2023.
[167] ibid 119-120.
[168] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 47.
[169] ibid 48.
[170] Elizabeth Clarke and others, 'Snus: A Compelling Harm Reduction Alternative to Cigarettes' (2019) 16 Harm Reduction Journal 62, 1.
[171] Clarke and others (n 170); Konstantinos Farsalinos, 'Snus: Swedish Snus Is Different' (2019) 226 British Dental Journal 85; Lars M Ramström, 'Much Safer with Snus' (2019) 226 British Dental Journal 85.
[172] Ellen Meier and others, 'A Randomized Clinical Trial of Snus Examining the Effect of Complete Versus Partial Cigarette Substitution on Smoking-Related Behaviors, and Biomarkers of Exposure' (2020) 22 Nicotine & Tobacco Research 473.
[173] Karl Fagerström and Elsy-Britt Schildt, 'Should the European Union Lift the Ban on Snus? Evidence from the Swedish Experience' (2003) 98 Addiction 1191; Lars Ramström and Tom Wikmans, 'Mortality Attributable to Tobacco among Men in Sweden and Other European Countries: An Analysis of Data in a WHO Report' (2014) 12 Tobacco Induced Diseases 14; Lars Ramström, Ron Borland and Tom Wikmans, 'Patterns of Smoking and Snus Use in Sweden: Implications for Public Health' (2016) 13 International Journal of Environmental Research and Public Health 1110.
[174] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 63.

Although the debate is rife within the scientific community – the WHO still refuses to clearly acknowledge that e-cigarettes pose a smaller risk to health than conventional cigarettes –[175] ample evidence seems to demonstrate that users of e-cigarettes are only exposed to a small fraction of the risks posed by conventional cigarettes.[176] This is not surprising since e-cigarettes do not involve any combustion, from where most of the harm of cigarettes originates.

A great degree of uncertainty nonetheless remains as to the specific harm arising from the use of e-cigarettes. In its 2021 opinion on the matter, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), a European Commission body, concluded that the quality of the evidence regarding the health risks posed by e-cigarettes remained weak to moderate.[177] Apart from the presence of nicotine, an addictive substance with unclear direct effects on health,[178] the risks that are best established are those resulting from ingestion or contact with the e-liquid, through spillage or leakage, or burns and explosions from the device.[179] These risks are low however, both in terms of probability and magnitude.[180] Most health effects come from chemicals present in the aerosol, with acute and local effects on the respiratory systems, here as well with a low incidence.[181] The long-term risks are still uncertain. A risk exists concerning lung cancer and cardiovascular diseases.[182] The question of passive vaping is debated, with weak to moderate evidence establishing the existence of a risk for bystanders,[183] although that risk is significantly lower than that resulting from exposure to second-hand tobacco smoke.

Uncertainty remains as to the role played by e-cigarettes in smoking initiation or cessation, whether these products help smokers to quit and hence reduce their exposure to risk, or whether, on the contrary, e-cigarettes act as a gateway towards smoking, especially for young people.[184] In its opinion, the SCHEER found moderate evidence that electronic cigarettes act

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[175] WHO, 'Tobacco: E-cigarettes' (2020), <https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes> accessed 11/05/2023.

[176] Gravely and others, 'European Adult Smokers' Perceptions of the Harmfulness of e-Cigarettes Relative to Combustible Cigarettes: Cohort Findings from the 2016 and 2018 EUREST-PLUS ITC Europe Surveys' (n 153) iii39; McNeill and others (n 162) 20.

[177] SCHEER, 'Opinion on electronic cigarettes' (n 163). The SCHEER 'provides Opinions on questions concerning health, environmental and emerging risks', in particular 'on questions concerning emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies': <https://health.ec.europa.eu/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer_en> accessed 11/05/2023.

[178] ibid 6-7, 18; McNeill and others (n 162) 12.

[179] McNeill and others (n 162) 17; European Commission, 'Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms' (n 163) 18-19; SCHEER, 'Opinion on electronic cigarettes' (n 163) 16.

[180] McNeill and others (n 162) 17; European Commission (n 163) 18-19; SCHEER, 'Opinion on electronic cigarettes' (n 163) 16.

[181] European Commission (n 163) 18; SCHEER, 'Opinion on electronic cigarettes' (n 163) 7.

[182] McNeill and others (n 162) 19; SCHEER, 'Opinion on electronic cigarettes' (n 163)7.

[183] McNeill and others (n 162) 19.

[184] Regarding the gateway hypothesis, see Simon Chapman, David Bareham and Wasim Maziak, 'The Gateway Effect of E-Cigarettes: Reflections on Main Criticisms' (2018) 21 Nicotine & Tobacco Research 695; Peter N

as a smoking gateway for young people but strong evidence that the nicotine present in e-liquids is addictive and that flavours contribute to the attractiveness of electronic cigarettes and their initiation.[185] The last 2021 Eurobarometer data illustrates the risk of initiation, for young people especially. Although a majority of e-cigarettes users (57%) still declare having started vaping to stop or reduce their tobacco consumption, a growing percentage say that they have done so because e-cigarettes became popular around them or because they have been attracted by flavours.[186] The youngest respondents are the least likely to say that they started using e-cigarettes for cessation purposes but the most likely to mention that they liked the flavours.[187] As to their use for cessation purposes, e-cigarettes do offer an interesting potential since they release nicotine and involve a gesture very similar to that of smoking.[188] Although they are increasingly popular as a cessation tool among smokers in the EU,[189] their effectiveness remains unclear in this regard. They may help to reduce smoking but not to quit altogether, leading to dual use.[190] A majority of current or former smokers in the EU who have used e-cigarettes have managed to quite or reduce their consumption of cigarettes, a sizeable increase since 2017.[191]

Finally, a last class of tobacco products that should be mentioned are heated tobacco products (HTPs). Heated tobacco products are a form of tobacco that is heated in a device at a high enough temperature to release an aerosol, without however burning it or producing smoke. As HTPs have been used for less than a decade, evidence remains scant as to the health risks associated with their consumption and the relationship between HTPs consumption and that of cigarettes. It seems yet that such products expose users and bystanders to fewer risks than conventional cigarettes and to probably more risks than e-cigarettes.[192] They are currently a

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Lee, Katharine J Coombs and Esther F Afolalu, 'Considerations Related to Vaping as a Possible Gateway into Cigarette Smoking: An Analytical Review' (2019) 7 F1000Research 1915; Thomas Martinelli and others, 'Exploring the Gateway Hypothesis of E-Cigarettes and Tobacco: A Prospective Replication Study among Adolescents in the Netherlands and Flanders' [2021] 32 Tobacco Control 170; Emma Beard, Jamie Brown and Lion Shahab, 'Association of Quarterly Prevalence of E-Cigarette Use with Ever Regular Smoking among Young Adults in England: A Time–Series Analysis between 2007 and 2018' (2022) 117 Addiction 2283.

[185] SCHEER, 'Opinion on electronic cigarettes' (n 163) 8; see however McNeill and others (n 162) 13: '[d]espite some experimentation with these devices among never smokers, e-cigarettes are attracting very few young people who have never smoked into regular use'.

[186] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 122.

[187] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 123.

[188] Caitlin Notley and others, 'The Unique Contribution of E-Cigarettes for Tobacco Harm Reduction in Supporting Smoking Relapse Prevention' (2018) 15 Harm Reduction Journal 31.

[189] Filippos T Filippidis and others, 'Changes in Smoking Cessation Assistance in the European Union between 2012 and 2017: Pharmacotherapy versus Counselling versus e-Cigarettes' (2019) 28 Tobacco Control 95.

[190] Sara Kalkhoran and Stanton A Glantz, 'E-Cigarettes and Smoking Cessation in Real-World and Clinical Settings: A Systematic Review and Meta-Analysis' (2016) 4 The Lancet. Respiratory Medicine 116; McNeill and others (n 162) 16; Peter Hajek and others, 'A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy' (2019) 380 New England Journal of Medicine 629; SCHEER, 'Opinion on electronic cigarettes' (n 163) 19.

[191] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 128.

[192] Małgorzata Znyk, Joanna Jurewicz and Dorota Kaleta, 'Exposure to Heated Tobacco Products and Adverse Health Effects, a Systematic Review' (2021) 18 International Journal of Environmental Research and Public Health 6651. See also European Commission, 'Support study to the report on the application of Directive

niche market in the EU, with more than nine in ten respondents (93%) from the 2021 Eurobarometer declaring that they have never used these products and only 1% declaring to currently use them.[193]

As will be further explored in Chapters 5 to 7, these alternative to conventional cigarettes find themselves at the centre of an important and complex debate within the public health community, as regards their contribution to the overall fight against tobacco harm and their use in a tobacco control strategy.

Those championing 'harm reduction', a term that refers 'to strategies designed to reduce the health risks associated with tobacco smoking but which may involve the continued use of nicotine',[194] point at the difficulty that smokers have to quit – 'successful quit rates are abysmally low, relapse rates are high and in addition, a number of people wish to smoke' –[195] to favour an approach based on the transition from cigarettes to other lower-risk products, such as e-cigarettes, tobacco for oral use or HTPs. Hence, from this perspective, these products should be regulated in a more nuanced way if compared to cigarettes, so that they remain as little attractive as possible to non-users of tobacco while constituting a suitable alternative to smokers.

Other actors in the scientific community, while acknowledging that these alternatives may be adapted to some individuals wishing to reduce their risks, refuse to recommend their use at a broader population level and defend a regulatory model that treats tobacco for oral use, e-cigarettes or HTPs similarly to tobacco products for smoking.[196] They consider that no clear evidence has been adduced as to their effective role as cessation tools and point to the risk of gateway effect and renormalisation.[197] The concept of renormalisation refers to 'a change of social norms to the effect that smoking would become more visible and would be seen as more desirable than it is now'.[198] Moreover, because smoking is so harmful, a reduced consumption

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2014/40/EU' (2021) 392-394, <https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1> accessed 11/05/2023.

[193] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 64.

[194] Cox and Dawkins (n 164).

[195] O'Leary and Polosa (n 164) 219. See also Shannon Gravely and others, 'Changes in Smoking and Vaping over 18 Months among Smokers and Recent Ex-Smokers: Longitudinal Findings from the 2016 and 2018 ITC Four Country Smoking and Vaping Surveys' (2020) 17 International Journal of Environmental Research and Public Health 7084; Sophia Papadakis and others, 'Quitting Behaviours and Cessation Methods Used in Eight European Countries in 2018: Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health iii26. The 2021 Eurobarometer shows that half of current smokers (49%) have never tried to quit smoking, and that only 15% of them have attempted to give up smoking in the last 12 months of the poll: European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 104. Nonetheless, the Eurobarometer also shows that there has been a nine-percentage point decline between 2006 and 2020 in the proportion of those who smoke (from 32% to 23%) in the EU and the UK: ibid 21.

[196] See Charlotta Pisinger and others, 'ERS and Tobacco Harm Reduction' (2019) 54 European Respiratory Journal.

[197] ibid.

[198] Kristin Voigt, 'Smoking Norms and the Regulation of E-Cigarettes' (2015) 105 American Journal of Public Health 1967, 1968. No clear evidence of such an effect exists: see Máirtín S McDermott and others, 'Social Norms for E-Cigarettes and Smoking: Associations with Initiation of e-Cigarette Use, Intentions to Quit Smoking and

of cigarettes combined to the consumption of one of these alternatives may not actually lead to a reduction of the overall level of risk for an individual but rather to an increase of it.[199]

4.2. Alcohol

Ethanol is the main psychoactive ingredient present in alcoholic drinks. Produced by fermentation, it is responsible for most of the harm to human health arising from the consumption of these beverages.[200] Although ethanol and alcohol are not synonymous terms – ethanol is only one type of alcohol – alcohol is the term used in common language to refer to ethanol and to drinks that contain it.

The harmful impact of alcohol consumption on health is a well-established but complex phenomenon. It is a leading mortality and morbidity risk factor globally. It is linked to 60 acute and chronic diseases,[201] NCDs in particular, such as cancer, diabetes, neuropsychiatric diseases (including alcohol use disorders), cardiovascular diseases, and liver and pancreas diseases.[202] Alcohol consumption affects health in various ways: 'through cumulative consumption leading to adverse effects on organs and tissues; by acute intoxication leading to injuries or poisoning; and by dependent drinking leading to impairments and potentially self-harm or violence'.[203] Apart from harm to the person consuming it, alcohol is also responsible for a wide range of other negative health consequences to third parties, such as harm to the foetus caused by prenatal exposure to alcohol or intentional and unintentional injuries and homicides.[204] The type of adverse health outcomes incurred depends on one's volume of consumption and frequency of drinking. A moderate but frequent consumption of alcohol may result in the development of NCDs, while heavy episodic drinking, defined as the consumption of 60 or more grams of pure alcohol on at least one single occasion at least once a month,[205] might also result in poisoning, injuries, and violence. The GBD 2017 study estimated that over 300,000 deaths and 10 million DALYs were attributable to alcohol use annually in the EU.[206]

As for tobacco, and contrary to a widely held opinion, no level of alcohol consumption can be considered risk-free. The prevailing view in the scientific community is that the safest level of

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Quit Attempts: Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health 46, 47.

[199] O'Leary and Polosa (n 164) 224.

[200] European Commission 'Alcoholic Beverages' in *Health Promotion and Disease Prevention Knowledge Gateway*, <https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/alcoholic-beverages_en> accessed 11/05/2023.

[201] Max G Griswold and others, 'Alcohol Use and Burden for 195 Countries and Territories, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016' (2018) 392 The Lancet 1015, 1015.

[202] Jürgen Rehm, 'The Risks Associated with Alcohol Use and Alcoholism' (2011) 34 Alcohol Research & Health 135.

[203] Griswold and others (n 201) 1015.

[204] European Commission 'Alcoholic Beverages' (n 200).

[205] WHO, 'Global Status Report on Alcohol and Health 2018' (2018) 47, <https://www.who.int/publications/i/item/9789241565639> accessed 11/05/2023.

[206] European Commission, 'EU burden from non-communicable diseases and key risk factors' (n 22).

drinking is none.[207] Since complete abstinence is unattractive to most people, public health authorities have devised 'low-risk' drinking guidelines. These guidelines appear however for the most part to be set at an excessive level. While it is estimated that the threshold for the lowest risk of all-cause mortality is situated at about 100 g of alcohol per week[208] – equivalent to ten regular glasses (25 cl) of light beer (5 % vol) – many guidelines advise to limit consumption for men to a level that is twice as high (200g).[209]

After some studies had shown that a moderate consumption of alcohol, wine especially, could have a protective effect on some cardiovascular diseases, the so-called 'French paradox',[210] a persisting belief exists in the general population that health benefits could arise from moderate alcohol use.[211] The most recent evidence has fully discredited this idea, not only because the protective effect of wine has been found to be non-existent or non-significative, but because any such effect is would in any case be offset by the overall risk of harm associated with alcohol.[212] Scientific experts consider that '[a]t the policy level, the hypothesis of health benefits from moderate drinking should no longer play a role in decision making'.[213]

Alcoholic beverages are of a hybrid nature if compared to food products on the one hand and tobacco products on the other, something to keep in mind when discussing alcohol control by public authorities. Alcoholic drinks are made from raw materials that are similar to those used in the manufacture of other foods and contain calories and similar nutrients. Both types of products are consumed in the same way, ingested, often together. At the same time, from a risk perspective, alcoholic beverages bear much closer resemblance to tobacco products. All things considered, alcoholic beverages make no positive contribution to the health of humans and should, from that perspective alone, be entirely avoided. As we shall see, the picture is quite different for food. Food is generally indispensable to human life and a wide range of food products do actually bring benefits to human health, unlike alcohol.

4.3. Diets and physical inactivity

Unhealthy diets have been singled out as the largest cause of health loss globally, posing a greater risk of morbidity and mortality than unsafe sex, alcohol, drug, and tobacco use

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[207] Griswold and others (n 201).
[208] Angela M Wood and others, 'Risk Thresholds for Alcohol Consumption: Combined Analysis of Individual-Participant Data for 599 912 Current Drinkers in 83 Prospective Studies' (2018) 391 The Lancet 1513.
[209] Agnieszka Kalinowski and Keith Humphreys, 'Governmental Standard Drink Definitions and Low-Risk Alcohol Consumption Guidelines in 37 Countries' (2016) 111 Addiction 1293.
[210] Jules Constant, 'Alcohol, Ischemic Heart Disease, and the French Paradox' (1997) 20 Clinical Cardiology 420; Serge Renaud and René Gueguen, 'The French Paradox and Wine Drinking' (1998) 216 Novartis Foundation Symposia 208.
[211] Tanya Chikritzhs and others, 'Has the Leaning Tower of Presumed Health Benefits from "moderate" Alcohol Use Finally Collapsed?' (2015) 110 Addiction 726.
[212] ibid; Griswold and others (n 201); World Heart Federation, 'The Impact of Alcohol Consumption on Cardiovascular Health: Myths and Measures' (2022), <https://world-heart-federation.org/wp-content/uploads/WHF-Policy-Brief-Alcohol.pdf> accessed 11/05/2023.
[213] Chikritzhs (n 211) 727.

combined.[214] The GBD study estimates that, in the European Union in 2017, over 950,000 deaths and over 16 million DALYs were attributable to dietary risks due to unhealthy diets, resulting mainly from NCDs such as cardiovascular diseases, cancer, diabetes and kidney diseases.[215]

Defining what constitutes an (un)healthy diet is difficult. The link between nutrition and health is not only extremely complex – myriads of nutrients and compounds, whose effects are not all yet well-known, are involved – but people have different dietary needs according to their age, sex, physical activity or health status.[216] Eating is a prerequisite to human life. Unlike for alcohol and tobacco products, where abstinence is the healthiest choice, some nutrients associated with health risks when consumed in excess, such as fats, are actually necessary to healthy bodily functions. While the consumption of certain nutrients leads to an increase of the risk of developing certain NCDs, and should therefore be limited, the consumption of other nutrients may conversely contribute to decreasing that risk, in which case their intake should be recommended. A given food may contain both positive and negative nutrients, which makes the classification of foods as healthy or unhealthy challenging. Medical or governmental intervention in diets is hence a question of balance, adding an additional layer of complexity.

The consumption of foods high in fat, salt and sugar (HFSS foods) and the disbalance in energy/calorie intake are among the best-established dietary risk factors[217] and have been to date one a central focus of health authorities.[218] These are however only a fraction of the risk factors associated with unhealthy diets. The Global Burden of Disease distinguishes fifteen different dietary risks, linked to the over- or underconsumption of some categories of foods or nutrients. Such risks are associated with the under consumption of fruits, vegetables, legumes, whole grains, nuts and seeds, milk, fibre, calcium, seafood omega-3 fatty acids and

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[214] Willett and others (n 140) 447; Boyd A Swinburn and others, 'The Global Syndemic of Obesity, Undernutrition, and Climate Change: The Lancet Commission Report' (2019) 393 The Lancet 791,795; Ashkan Afshin and others, 'Health Effects of Dietary Risks in 195 Countries, 1990–2017: A Systematic Analysis for the Global Burden of Disease Study 2017' (2019) 393 The Lancet 1958, 1967.

[215] European Commission, 'EU burden from non-communicable diseases and key risk factors' (n 22).

[216] Willet and others (n 140) 453.

[217] According to the WHO, the following dietary habits are constitutive of a 'healthy diet': 'Energy intake (calories) should be in balance with energy expenditure. To avoid unhealthy weight gain, total fat should not exceed 30% of total energy intake. Intake of saturated fats should be less than 10% of total energy intake, and intake of trans-fats less than 1% of total energy intake, with a shift in fat consumption away from saturated fats and trans-fats to unsaturated fats, and towards the goal of eliminating industrially-produced trans-fats. Limiting intake of free sugars to less than 10% of total energy intake is part of a healthy diet. A further reduction to less than 5% of total energy intake is suggested for additional health benefits. Keeping salt intake to less than 5 g per day (equivalent to sodium intake of less than 2 g per day) helps to prevent hypertension, and reduces the risk of heart disease and stroke in the adult population.' See WHO, 'Healthy Diet' (2020), <https://www.who.int/news-room/fact-sheets/detail/healthy-diet> accessed 11/05/2023.

[218] Regarding the EU, see European Commission, White Paper: 'A Strategy for Europe on Nutrition, Overweight and Obesity related health issues' (EU Nutrition Strategy) COM (2007) 279 final. See also Council of the European Union, Council conclusions on obesity, nutrition and physical activity [2005] 9803/5; Council of the European Union, Council conclusions on nutrition and physical activity [2014] OJ C213/1; Council of the European Union, Council conclusions - Healthy Nutrition for Children: The Healthy Future of Europe [2018] OJ C23/1.

polyunsaturated fatty acids; and overconsumption of red meat, processed meat, sugar-sweetened beverages, trans fatty acids and sodium.[219]

In 2017, globally, the consumption of nearly all healthy foods and nutrients was suboptimal and the daily intake of all unhealthy foods and nutrients exceeded the optimal level.[220] In Europe, the consumption of red and processed meat, sugar-sweetened beverages and sodium largely exceeds the optimal intake.[221] That year, dietary risks were responsible for 11 million deaths and 255 million DALYs globally.[222] Cardiovascular disease are, by far, the leading cause of diet related deaths and DALYs, followed by cancers deaths and type 2 diabetes.[223] High intake of sodium, low intake of whole grains and low intake of fruits are leading dietary risk factors, causing more than half of diet-related deaths and two-thirds of diet-related DALYs.[224] Importantly, diet-related diseases and mortality find their origin more in the lack of consumption of certain foods and nutrients than in the over consumption of sugar and fat. Hence, 'promoting the intake of components of diet for which current intake is less than the optimal level might have a greater effect than policies only targeting sugar and fat'.[225]

In a 2019 article published in *The Lancet*, a multi-disciplinary and international panel of experts on the transformation of the global food system concluded that dietary patterns with the following characteristics promoted a low risk of major chronic disease and overall wellbeing:

> (1) protein sources primarily from plants, including soy foods, other legumes, and nuts, fish or alternative sources of omega-3 fatty acids several times per week with optional modest consumption of poultry and eggs, and low intakes of red meat, if any, especially processed meat; (2) fat mostly from unsaturated plant sources, with low intakes of saturated fats, and no partly hydrogenated oils; (3) carbohydrates primarily from whole grains with low intake of refined grains and less than 5% of energy from sugar; (4) at least five servings of fruits and vegetables per day, not including potatoes; and (5) moderate dairy consumption as an option.[226]

Over-consumption of sugar and fat is closely associated with excessive calorie intake and weight gain. The global rise in overweight and obesity, the so-called 'obesity epidemic',[227] is one of today's main public health challenges. As previously mentioned, the prevalence of obesity in the EU has starkly increased over the last twenty years, from 11% in 2000 to 17% of the population in 2018.[228] Obesity – its definition, causes and consequences – is the subject

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[219] The Lancet, 'GBD cause and risk summaries', <https://www.thelancet.com/gbd/summaries> accessed 11/05/2023.
[220] Afshin and others (n 214) 1961.
[221] ibid 1962.
[222] ibid 1962.
[223] ibid 1962.
[224] ibid 1963.
[225] ibid 1967.
[226] Willett and others (n 140) 459. For a similar conclusion, see Lars T Fadnes and others, 'Estimating Impact of Food Choices on Life Expectancy: A Modeling Study' (2022) 19 PLOS Medicine e1003889.
[227] WHO, 'Controlling the global obesity epidemic', <https://www.who.int/activities/controlling-the-global-obesity-epidemic> accessed 11/05/2023. See also Schorb (n 57) 6.
[228] OECD and European Commission (n 19) 152.

of many contemporary scientific and societal debates, as will be further discussed throughout the thesis.

Simply put, obesity can be defined as an excess of body fat.[229] Qualifying an individual as obese is usually done by relying on a specific metric, the Body Mass Index (BMI), which is calculated by dividing a person's weight in kilograms by the square of that person's height in metres (kg/m^2).[230] A BMI situated between 18.5 and 24.9 is considered to reflect a normal weight and one between 25 and 29.9 to signal overweight. Above 30, one is considered obese. The BMI is however a contested tool. Many consider that it is a poor proxy for body fat mass and criticize the fact that it does not account for how fat is distributed in the body, which greatly matters as far as health risks are concerned.[231]

Whether obesity should be considered as a disease in itself or simply a risk factor for other diseases is under debate.[232] Obesity and overweight are major risk factors for NCDs such as cardiovascular diseases – heart disease and stroke – diabetes and cancer,[233] and were among the leading risk factors for deaths and DALYS worldwide in 2019.[234] Some consider however that evidence for the health risks associated with being overweight, with a BMI below 30, is unclear and that it is not proven that 'pre-obesity' on its own leads to higher morbidity and mortality.[235]

The causes of obesity are complex.[236] At the individual level, obesity and overweight are primarily caused by an energy imbalance, thus directly linked to poor dietary habits and physical inactivity, but are also largely influenced by genetic factors.[237] As will be further discussed in Section 5.1.2 in this chapter, the global rise in obesity can only be explained by structural population-level factors, which pertain to changes in, among other things, food supply, eating, life habits and working environments.

Due to its link with weight management and obesity, physical activity, or the lack thereof, is often considered together with nutrition in scientific and policy discussions.[238] Physical activity

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[229] Frank Q Nuttall, 'Body Mass Index' (2015) 50 Nutrition Today 117, 118.
[230] WHO, 'A healthy lifestyle - WHO recommendations' (2010), <https://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-lifestyle/body-mass-index-bmi> accessed 11/05/2023.
[231] Julie Guthman, 'Fatuous Measures: The Artifactual Construction of the Obesity Epidemic' (2013) 23 Critical Public Health 263; Lee F Monaghan, Rachel Colls and Bethan Evans, 'Obesity Discourse and Fat Politics: Research, Critique and Interventions' (2013) 23 Critical Public Health 249; Nuttall (n 229) 120–121.
[232] See Howard Rosen, 'Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right?' (2014) 111 Missouri Medicine 104; John PH Wilding, Vicki Mooney and Richard Pile, 'Should Obesity Be Recognised as a Disease?' (2019) 366 BMJ l4258.
[233] WHO, 'Obesity and overweight' (2021) <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight> .
[234] Murray and others (n 146).
[235] Katherine M Flegal and others, 'Association of All-Cause Mortality With Overweight and Obesity Using Standard Body Mass Index Categories: A Systematic Review and Meta-Analysis' (2013) 309 Journal of the American Medical Association 71; Guthman (n 231) 268; Nuttall (n 229) 123-124.
[236] See Murray and others (n 146) 1242.
[237] ibid.
[238] Regarding EU policy, see Chapter 5, Section 2.3.

has yet a far broader influence on health. It contributes to a wide range of health outcomes, physical and mental.[239] It is associated with greater self-control capacities which may also influence other behaviours.[240] The GBD study estimates that almost 53,000 deaths and over 2.1 million DALYs were attributable to low physical activity in 2017 in the EU.[241]

Physical inactivity differs from the other risk-factors addressed in this thesis in at least two fundamental ways. First, the health risks or benefits involved with physical activity are not necessarily embedded in a consumer relationship, as is almost always the case for other lifestyle risks. Second, the goal of public authorities as regards physical activity is not to prevent a certain behaviour from happening but is entirely aimed at promoting a healthy one. Hence, most of the regulatory tools mentioned in Section 6 in relation to other risk-factors find little or no application here: information disclosure, tax measures, bans, etc.

4.4. Illicit drugs

'Drug' is an ambiguous term which may be applied to a wide range of legal and illegal products and substances, including pharmaceutical drugs. Taking as a basis the international classifications ICD-10 and DSM-5,[242] a recent review identified ten main groups of drugs: alcohol, caffeine, tobacco/nicotine, anxiolytics/hypnotics, opioids, cannabinoids, cocaine, amphetamine stimulants, hallucinogens, and volatile substances.[243] Licit and illicit drugs share a number of characteristics: psychoactive effect, addictive potential and risk of harm, among other things. What matters from a legal point of view are not these attributes but the licit or illicit status of these various substances, which is in turn of fundamental importance for public policy and risk regulation.

The use and trade in illicit drugs are a global phenomenon, subject to an international drug control regime placed under the auspices of the United Nations. This regime is composed of

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[239] I-Min Lee and others, 'Impact of Physical Inactivity on the World's Major Non-Communicable Diseases' (2012) 380 Lancet 219; Kathleen Mikkelsen and others, 'Exercise and Mental Health' (2017) 106 Maturitas 48; Elizabeth Anderson and J Larry Durstine, 'Physical Activity, Exercise, and Chronic Diseases: A Brief Review' (2019) 1 Sports Medicine and Health Science 3.

[240] Emely de Vet and Kirsten T Verkooijen, 'Self-Control and Physical Activity: Disentangling the Pathways to Health' in Denise de Ridder, Marieke Adriaanse and Kentaro Fujita (eds), *The Routledge International Handbook of Self-Control in Health and Well-Being: Concepts, Theories, and Central Issues* (Routledge 2018) 277-281.

[241] European Commission, 'EU burden from non-communicable diseases and key risk factors' (n 22). Low physical activity is defined as 'less than 8,000 metabolic equivalent (MET) minutes per week, with one MET being the energy spent while sitting quietly'.

[242] International Statistical Classification of Diseases and Related Health Problems (ICD), authored by the WHO, and Diagnostic and Statistical Manual of Mental Disorders (DSM), authored by the American Psychiatric Association (APA). These two publications are recognised internationally as the main authorities on the classification of diseases and mental disorders. Their current versions are, respectively, the 11th and 5th editions: see WHO, 'ICD-11 for Mortality and Morbidity Statistics' (2021), <https://icd.who.int/browse11/l-m/en> accessed 11/05/2023; American Psychiatric Association, 'Diagnostic and Statistical Manual of Mental Disorders (DSM–5)' (2013), <https://www.psychiatry.org/psychiatrists/practice/dsm> accessed 11/05/2023.

[243] Peter Janik and others, 'Categorization of Psychoactive Substances into "Hard Drugs" and "Soft Drugs": A Critical Review of Terminology Used in Current Scientific Literature' (2017) 43 The American Journal of Drug and Alcohol Abuse 636.

three United Nations conventions that regulate the production, export, import, distribution, trade, use and possession of drugs: the UN Single Convention on Narcotic Drugs of 1961 (the 'Single Convention'), the UN Convention on Psychotropic Substances of 1971 and the UN Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (the 'Convention against Illicit Traffic'). All Member States are party to these three conventions, the EU being only a party to the Convention against Illicit Traffic.[244] The international drug control framework, taken in its entirety, requires parties to adopt measures to prohibit the production, use and trade of drugs.

Under the Single Convention, a 'drug' is any of the substances listed in its Schedules I and II, whether natural or synthetic.[245] The Convention on Psychotropic Substances contains a similar definition of psychotropic substances : 'any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV'.[246] Beyond drugs stricto sensu, the Single Convention also contains provisions applicable to the 'substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances', which are contained in Table I and Table II annexed to the Convention.[247] These substances, also called 'drug precursors', are chemicals that are used primarily for the manufacture of various legal products, such as medicines, plastics or cosmetics, but whose usage can also be diverted in the production of illicit drugs. Acetic anhydride, for instance, is used in many industrial processes, like the production of pharmaceuticals or textiles, but is also an important reaction agent for the production of heroin. These schedules and tables are regularly updated by the United Nations Commission on Narcotic Drugs.

Although the international legal framework refers to narcotic drugs and psychotropic substances, for the sake of clarity, the various prohibited substances and products will be referred to as 'illicit drugs' in this thesis. A 'narcotic' is a 'chemical agent that induces stupor, coma, or insensibility to pain' and the term 'narcotic drugs' is 'often used imprecisely to mean illicit drugs, irrespective of their pharmacology'.[248] Some licit products, like alcohol, have narcotic properties. The same can be said of psychotropic substances.[249] It is thus better to differentiate between substances on the basis of their licit or illicit character, for it is this aspect

[244] Council Decision of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances [1990] OJ L326/56.
[245] Single Convention on Narcotic Drugs, art 1(j).
[246] ibid, art 1(e).
[247] ibid, art 12(1).
[248] See <https://www.who.int/substance_abuse/terminology/who_lexicon/en/> accessed 11/05/2023.
[249] A psychotropic substance may be defined as '[a] drug or other substance that affects how the brain works and causes changes in mood, awareness, thoughts, feelings, or behavior': National Cancer Institute, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/psychotropic-substance>accessed 11/05/2023. 'Examples of psychotropic substances include alcohol, caffeine, nicotine, marijuana, and certain pain medicines': ibid.

which is most pertinent for law and policy. The most commonly used illicit drugs in the EU are cannabis, cocaine, heroin and other opioids, MDMA and amphetamines.[250]

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) publishes a yearly European Drug Report.[251] According to the 2021 edition, all indicators 'suggest that at the beginning of 2020 the European drug market was characterised by the widespread availability of a diverse range of drugs of increasingly high purity or potency'.[252] A diversification can be seen, 'both in the products available and the people who use them', and drugs have become over the last 25 years, 'a much more pervasive problem, one that impacts in some way across all major policy areas'.[253]

In 2021, it was estimated that around 83 million or 28.9% of adults (aged 15-64) in the EU had used illicit drugs at least once in their lifetime, which should be regarded as a minimum estimate due to reporting biases.[254] The most consumed of these drugs is by far cannabis, with an estimate of lifetime use of 78,5 million adults (27,2% of the population), followed by cocaine with 13,8 million (4,8%) and MDMA with 10,4 million (3,6%).[255] As regards cannabis, levels of lifetime use differ considerably between countries, ranging from around 4% of adults in Malta to 45% in France.[256]

Cannabis comes from the plant *cannabis sativa* and is usually sold in herbal form, the dried flowering tops and leaves of the plant, or resin, a compressed solid made from the resinous parts of the plant.[257] The main psychoactive constituent of cannabis is tetrahydrocannabinol (THC). Cannabidiol or 'CBD' is a molecule extracted from cannabis used for medicinal or recreative purposes, which, unlike THC, does not have any psychotropic effects. CBD is extracted from hemp, a variety of the cannabis plant with lower concentration of THC, used for industrial purposes and whose commerce is legal in the EU (see Chapter 5, Section 3.1.1).

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[250] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 'European Drug Report: Trends and Developments' (2021) Publications Office of the European Union, <https://www.emcdda.europa.eu/publications/edr/trends-developments/2021_en> accessed 11/05/2023.

[251] The EMCDDA was established by Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction [1993] OJ L36/1, now recast in Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction [2006] OJ L376/1. Its main role is to provide 'factual, objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences': Regulation 1920/2006, art 1(2). Its priority areas of activity are (i) to monitor the state of the drugs problem in the EU, as well as (ii) the solutions applied so as to share information on best practices in the Member States, (iii) to assess the risks of new psychoactive substances and maintain a rapid information system with regard to their use, and (iv) to develop tools and instruments to help Member States and the Commission to monitor and evaluate their policies: Regulation 1920/2006, art 3 and annex I.

[252] EMCDDA (n 250) 8.

[253] ibid 9.

[254] ibid 12.

[255] ibid 13.

[256] ibid 12.

[257] EMCDDA, 'Cannabis drug profile', <https://www.emcdda.europa.eu/publications/drug-profiles/cannabis_en> accessed 11/05/2023.

The potency of the cannabis resin sold in Europe has largely increased over the last years, with a THC content ranging from 20 % to 28 % on average, almost twice that of herbal cannabis.[258]

Illicit drugs expose their users to a wide range of hazards: use disorders, NCDs, such as cancer and cardiovascular diseases, and acute harm in the form of overdoses or interpersonal violence.[259] Harm is linked to the substance but also the mode of use. Smoking cannabis has comparable consequences to smoking tobacco, resulting from the toxic elements produced during the combustion process. For some illicit drugs, the use of a syringe for injection carries a risk of infection by communicable diseases such as HIV or viral hepatitis, or a risk of other injection-related diseases.

The terms 'soft' and 'hard' drugs are sometimes used in the public debate, so as to differentiate between substances on the basis of their addictive potential and the degree of harm involved. Tobacco, alcohol, and cannabis are usually considered to be 'soft' drugs, while 'hard' is used to refer to illicit drugs, especially cocaine, heroin and MDMA.[260] These terms, however, are ambiguous and not standardised, and the distinction between the two categories of drugs lacks a proper scientific basis.[261]

Due to their sheer variety, comparing drugs with one another and classifying them according to their harmfulness is a difficult exercise. What is clear is that the hard/soft dichotomy, as it is commonly used, does not withstand scrutiny. In a seminal British study published in 2010, various specialists were asked to score 20 drugs according to the level of harm involved, to users and to others. It was found that alcohol was the most harmful drug overall, far outweighing other legal drugs such as tobacco and causing significantly more harm than illicit substances such as cocaine or heroin.[262] This method was applied in other countries, yielding similar results.[263] Although the methodology used and the very idea of a drug ranking have been criticised,[264] a number of experts consider that these studies provide a first, albeit

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[258] EMCDDA (n 250) 16.

[259] Louisa Degenhardt and others, 'The Global Burden of Disease Attributable to Alcohol and Drug Use in 195 Countries and Territories, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016' (2018) 5 The Lancet Psychiatry 987.

[260] Janik and others (n 243).

[261] ibid. In their review, the authors identify some of the aspects that make a drug being classified as 'hard': (i) addictive potential, (ii) physical addiction with physical withdrawal state; (iii) assumed harm to user; (iv) poor prognosis of addiction remission; and (v) assumed harm to public health and society': see ibid 651.

[262] David J Nutt, Leslie A King and Lawrence D Phillips, 'Drug Harms in the UK: A Multicriteria Decision Analysis' (2010) 376 The Lancet 1558. The ranking is based on 16 criteria, nine related to self-harm produces and seven related to harms to others. For harm to others the criteria used were the following: injury to others, crime, environmental damage, family adversities, international damage, economic costs (include healthcare) and damage to communities.

[263] Jan van Amsterdam and others, 'European Rating of Drug Harms' (2015) 29 Journal of Psychopharmacology 655; Yvonne Bonomo and others, 'The Australian Drug Harms Ranking Study' (2019) 33 Journal of Psychopharmacology 759.

[264] Jonathan P Caulkins, Peter Reuter and Carolyn Coulson, 'Basing Drug Scheduling Decisions on Scientific Ranking of Harmfulness: False Promise from False Premises' (2011) 106 Addiction 1886; Lee C Claridge, 'Drugs and Harm to Society' (2011) 377 The Lancet 552.

imperfect, basis to start reflecting about the relative hazardousness of drugs.[265] This matters for drug policy, as public authorities subject different substances to widely diverging legal regimes which do not necessarily reflect the nature of the health problem at stake.

The finding that alcohol represents a particularly pressing public health issue, as far as drugs are concerned, is corroborated by other studies and figures. Data from the GBD study show that the number of deaths and DALYS attributable to alcohol use worldwide is much higher than that attributable to illicit drugs, with alcohol causing three times more DALYS and more than five times more deaths.[266] In another study making a comparative risk assessment of ten substances, using a method based on toxicology and estimated human intake, four substances, alcohol, nicotine, cocaine and heroin, were found to fall into the 'high risk' category for individual exposure, while, on a population scale, only alcohol fell into the 'high risk' category, followed by cigarettes.[267]

4.5. Gambling

Gambling can be defined as any activity 'which involves wagering a stake with monetary value in games of chance, including those with an element of skill, such as lotteries, casino games, poker games and betting transactions'.[268] Unlike its lifestyle counterparts, gambling does not involve the incorporation of a hazardous substance into the human body. For most individuals, it is an 'enjoyable and harmless' activity, but it exposes its users to the risk of developing an addictive behaviour, resulting in damaging life impairments.[269] Gambling is widely viewed as a socially acceptable form of recreation – '[a]lmost all national surveys have concluded that most individuals have gambled at some point during their lives, and there are more gamblers than non-gamblers'[270] – but has also been identified as an emergent public health issue.[271]

Also known as 'pathological gambling' or 'problem gambling', addiction to gambling and related problems are most commonly referred to as 'gambling disorder', the term now in use in both the ICD-11 and the DSM-5. The most recent research findings show that 'gambling

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[265] Benedikt Fischer and Perry Kendall, 'Nutt et al.'s Harm Scales for Drugs—Room for Improvement but Better Policy Based on Science with Limitations than No Science at All' (2011) 106 Addiction 1891; Isidore S Obot, 'Improved Ranking of Drugs on Harmfulness Can Bring Sense and Order to a Failed System' (2011) 106 Addiction 1894; David Nutt, 'Let Not the Best Be the Enemy of the Good' (2011) 106 Addiction 1892.
[266] Degenhardt (n 259).
[267] Dirk W Lachenmeier and Jürgen Rehm, 'Comparative Risk Assessment of Alcohol, Tobacco, Cannabis and Other Illicit Drugs Using the Margin of Exposure Approach' (2015) 5 Scientific Reports 8126. The margin of exposure (MOE) approach was used in this study, defined as the ratio between toxicological threshold and estimated human intake.
[268] Commission Recommendation 2014/478/EU of 14 July 2014 on principles for the protection of consumers and players of online gambling services and for the prevention of minors from gambling online (Gambling Recommendation) [2014] OJ L214/38, para 3(a).
[269] Filipa Calado and Mark D Griffiths, 'Problem Gambling Worldwide: An Update and Systematic Review of Empirical Research (2000–2015)' (2016) 5 Journal of Behavioral Addictions 592.
[270] ibid 608.
[271] Calado and Griffiths (n 269); Heather Wardle and others, 'Gambling and Public Health: We Need Policy Action to Prevent Harm' (2019) 365 BMJ l1807.

disorder is similar to substance-related disorders in clinical expression, brain origin, comorbidity, physiology, and treatment'.[272] It is characterised 'by a pattern of persistent or recurrent gambling behaviour, which may be online (i.e., over the internet) or offline, manifested by': (i) 'impaired control over gambling (e.g., onset, frequency, intensity, duration, termination, context)', (ii) 'increasing priority given to gambling to the extent that gambling takes precedence over other life interests and daily activities', and (iii) 'continuation or escalation of gambling despite the occurrence of negative consequences'.[273] A diagnosis is usually assigned where the gambling behaviour occur over a period of at least 12 months.[274] Gambling disorder 'results in significant distress or in significant impairment in personal, family, social, educational, occupational or other important areas of functioning'.[275]

A 2016 systematic review estimated that lifetime prevalence of problem gambling across the world ranged from 0.7% to 6.5% and that past-year problem gambling prevalence varied between 0.12% and 5.8%,[276] between 1 and 3 percent for Europe specifically.[277]

4.6. Addiction

Addiction is a common trait to the five main lifestyle risk factors surveyed in this section. Addiction is difficult to define and is a hotly debated concept, belonging to the field of medicine and psychology but also social sciences, including philosophy.[278] In simple terms, 'a person is [addicted] upon something to the extent that s/he wants to give it up, tries to give it up, but tends to fail to do so'.[279]

On the question of addictive disorders, the DSM-5 and the ICD-10 are the main authorities recognised internationally. The DSM-5 category 'substance-related and addictive disorders' and the ICD-11 category 'disorders due to substance use or addictive behaviours' cover both substance use disorders, including alcohol, tobacco/nicotine, cannabis, cocaine and other drugs, and behavioural addictions, like gambling disorder.[280] Both classifications lay down a

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[272] American Psychiatric Association, 'DSM–5 Fact Sheets: Substance-Related and Addictive Disorders', <https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-Substance-Use-Disorder.pdf> accessed 11/05/2023. See also Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 135–138.

[273] WHO, 'Gambling disorder' in 'ICD-11 for Mortality and Morbidity Statistics' (n 242). For further developments on the nature and mechanism of gambling addiction, see Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 123–157.

[274] WHO, 'Gambling disorder' (n 273).

[275] ibid.

[276] Calado and Griffiths (n 269) 608.

[277] ibid. See also Simon Marmet and others, 'Problem Gambling' in Simon Marmet, Gerhard Gmel and Jürgen Rehm (eds), *Addiction and Lifestyles in Contemporary Europe: Reframing Addictions Project (ALICE RAP): Prevalence of substance use, dependence and problematic gambling in Europe* (2014), <http://www.alicerap.eu/resources/documents/doc_download/158-deliverable-05-1-prevalence-of-substance-use-dependence-and-problematic-gambling-in-europe.html> accessed 11/05/2023.

[278] For contemporary debates, see Hanna Pickard and Serge H Ahmed (eds), *The Routledge Handbook of Philosophy and Science of Addiction* (1st edition, Routledge 2018).

[279] Graham Oddie, 'Addiction and the Value of Freedom' (1993) 7 Bioethics 373, 378.

[280] WHO, 'ICD-11' (n 242); APA, 'DSM-5' (n 242).

number of criteria for diagnosis, 11 in total for the DSM-5, which are broadly similar and correspond to different degrees of severity.[281] These classifications and the criteria used to determine what constitutes an addictive behaviour are contested,[282] and so is the very idea that there is a disvalue intrinsic to addiction in itself, beyond the various negative consequences that one may suffer due to the behaviour concerned.[283] This begs the question of whether addiction is in itself a disease or if it is simply a risk factor which increases exposure to various health hazards, NCDs or other forms of harm. The GBD study recognises for instance the disorders linked to alcohol and drugs as diseases but consider tobacco consumption simply as a risk factor. [284]

The difficulty is further reinforced by the fact that a number of substances or activities may lead to patterns of engagement that have common traits with addictive behaviours but for which there is currently not enough evidence to describe them as 'disorders' in the sense of the biomedical classifications used above. This is the case for instance of sex, physical activity, or shopping. Food addiction is also a highly debated issue.[285] The rise of obesity may be explained in part by the addictive potential of highly processed foods, which 'may be capable of powerfully activating systems that evolved to encourage survival and instead contribute to compulsive patterns of consumption'.[286]

As we shall see throughout the thesis, addiction as a phenomenon is not specifically dealt with in EU regulation of lifestyle risks, which tends to address the harmful consequences of lifestyles in bulk. There is hence no need for our purpose to decide on whether addiction is in itself a disease, or simply a factor which aggravates the risk of developing a disease or suffering another kind of lifestyle-related harm.

5. Risk management (i): from the individual to the collective level

Managing lifestyle risks is about weighing policy alternatives and selecting appropriate prevention and control options to limit exposure to the various risk-factors described above. Determining whether public authorities should act and which form this action should take is greatly, if not primarily, influenced by the nature of the health problem at stake. Health, however, is not the only interest under consideration, for lifestyles fulfil a variety of roles for the individual, society, and the economy. On the basis of the characteristics described above – lifestyles are (i) consumption behaviours (ii) chosen by individuals within the constraints of their social position, (iii) expressing belonging to a certain social group – this section presents

[281] John B Saunders, 'Substance Use and Addictive Disorders in DSM-5 and ICD 10 and the Draft ICD 11' (2017) 30 Current Opinion in Psychiatry 227.
[282] Simon Planzer, 'DSM-5: What's New?' (2013) 4 European Journal of Risk Regulation 531, 531.
[283] Oddie (n 279).
[284] The Lancet, 'GBD cause and risk summaries' (n 219).
[285] Ashley Gearhardt, Michelle Joyner and Erica Schulte, 'Food addiction' in Pickard and Ahmed (n 278).
[286] ibid 182.

three aspects of health lifestyles which are particularly relevant for risk management purposes: individual choice, cultural aspect and economic value.

5.1. Choice (i): between agency and structure

Lifestyle risks are for the most part voluntary risks, 'activities in which individuals participate by choice, and where they use their own value system and experience to determine if the risk […] is acceptable to them'.[287] This does not mean that one's lifestyle choices are fully desired or proceed from a perfectly reasoned and unfettered deliberation, but that these choices always entail a certain degree of volition on the part of the individual, save for cases of pure coercion or unvoluntary exposure to hazard, like second-hand smoking. This is one of the main features differentiating lifestyle risks from environmental risks, such as air pollution or climate change, where individual choice plays a far more minor role.

From the perspective of risk management, this element of choice matters for two main reasons. Understanding why people act in a certain way is crucial if one is to enact policies which can effectively achieve behavioural change. This requires going beyond the individual level and understanding the social structures that guide choice. Further, the centrality of choice in lifestyles raises specific ethical questions as regards the legitimacy of public intervention, questions that do not arise for involuntary risks. Few people would object to the State taking action to reduce the risk of a nuclear catastrophe. Intervening to protect people from their own choices is likely to raise more opposition. These debates influence law and policy, and the type of regulatory measures that may be enacted in the field.

As defined by Cockerham, health lifestyles are at the convergence of agency and structure,[288] meaning that 'individuals have a range of freedom, yet not complete freedom, in choosing a lifestyle', they 'have the freedom to choose within the social constraints that apply to their situation in life'.[289] It is commonly accepted that NCDs are caused by a complex causal web of underlying socioeconomic, cultural, political and environmental determinants, personal factors like genetics and common modifiable behavioural risk factors.[290] The UN Political Declaration on NCDs recognises in this regard that:

> *[T]he conditions in which people live and their lifestyles* influence their health and quality of life, and that poverty, uneven distribution of wealth, lack of education, rapid urbanization and population ageing, and the economic social, gender, political, behavioural and environmental determinants of health are among the contributing factors to the rising incidence and prevalence of non-communicable diseases.[291]

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[287] Rehm, Lachenmeier and Room (n 14) 189. See also Cockerham, Abel and Lüschen (n 5) 423.
[288] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58).
[289] Cockerham, Rütten and Abel (n 5) 325. See also Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 55.
[290] Rayner and others, 'NCDs: Risk factors and determinants' (n 152).
[291] United Nations General Assembly (n 6), para 21, emphasis added.

5.1.1. Agency: understanding risk-taking

Looking into the role of agency in risk-taking triggers a perhaps ingenuous question: it may appear puzzling, at first sight, that people continue to willingly, and massively, live hazardous lives despite being reasonably informed about the risk entailed. 'Common sense suggests that if a person knows that an action of theirs will bring about negative consequences and they are able to avoid doing it, then they do.'[292] It can be assumed that nowadays people know, to an acceptable extent, that smoking, drinking, and eating unhealthily is bad for them, which does not prevent them from doing it.

In that regard, it is important to keep in mind that '[l]ifestyle behaviours […] are not simply or even primarily health focused'.[293] They are deeply engrained in individual and collective habits, which are often experienced as pleasurable, and involve substances which function as 'pacifier[s] of life', giving 'humans comfort and help[ing] them cope with life's endless stream of misery'.[294] Health risk itself may be seen as attractive for people seeking transgressive behaviours and life-threatening experiences,[295] or for those who simply think that life would be pretty dull without risk.[296] From a postmodern perspective, 'hazards are *themselves* socially constructed: created from the contingent judgements about the adverse or undesirable outcomes of choices made by human beings'.[297] Some believe that health itself should be made relative as people have different agenda for living and dying.[298]

That being said, it is also reasonable to think that good health is a value that is held dear by most people and that many individuals are not satisfied with their current lifestyle and would like to change it. Health is not only 'an outcome, a state of being, which is highly valued and prioritised within society', '[i]t is also a "resource for living", in that it allows people to function and participate in the assortment of activities that characterise any society'.[299] Pleasure and social interactions cannot alone explain unhealthy lifestyles. Leaving aside the question of addiction,[300] briefly addressed above: what is it that makes people unable to adopt behaviours that are better in line with their long-term interests? This question is of paramount importance for regulation, as it determines what kind of measures should be put in place and how these should be designed. Without an understanding of the factors influencing lifestyle behaviours,

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[292] Hanna Pickard, 'The puzzle of addiction' in Pickard and Ahmed (n 278).
[293] Upton and Thirlaway (n 62) 8.
[294] Somek (n 57) 3. See also ibid 42-43
[295] Jens O Zinn, 'Risk taking' in Burgess, Alemanno and Zinn (n 99).
[296] Deborah Lupton and John Tulloch, '"Life Would Be Pretty Dull without Risk": Voluntary Risk-Taking and Its Pleasures' (2002) 4 Health, Risk & Society 113.
[297] Nick J Fox, 'Postmodern Reflections on "Risk", "Hazards" and Life Choices' in Deborah Lupton (ed), *Risk and Sociocultural Theory: New Directions and Perspectives* (Cambridge University Press 1999) 19.
[298] ibid.
[299] McCartney and others (n 142) 22.
[300] Individuals suffering from addiction may no longer have control over their behaviour. See Stephen J Bahr and John P Hoffmann, 'Social Scientific Theories of Drug Use, Abuse, and Addiction' in Henry H Brownstein (ed), *The Handbook of Drugs and Society* (John Wiley & Sons 2015).

policy runs the risk of being ill-defined. Legislatures and courts often make assumptions about human actions, when crafting or interpreting laws, that need to be confronted to behavioural reality.

An important aspect to keep in mind is that lifestyle risks are, for the most part, long term risks. Harmful consequences occur in the future only after a repeated occurrence of the hazardous behaviour. 'Health promotion is asking people to make unpalatable changes to their life now in order to reduce a risk that is a long way in the future',[301] something that most of us are not particularly well equipped to deal with.

We present in the following developments some key findings of behavioural sciences relevant to judgement and decision-making on lifestyle risks,[302] along two main lines: risk perception and risk taking.[303] These behavioural phenomena may first affect our perception of the risk, how severe the harmful event is and how likely it is to occur, and thus lead people to over- or, most frequently, under-estimate its dangerousness. They may also affect one's capacity to make decisions aligned with that perception, to effectively avoid exposure to something identified as hazardous. Someone may wrongly assume that smoking a few cigarettes a day is unlikely to result in harm. That person may also be fully aware of the risk but finding themselves nonetheless unable to resist the temptation to smoke. These two different aspects of people's relationship to risk and decision-making can be loosely assimilated to the concepts of *bounded rationality*, 'the obvious fact that human cognitive abilities are not infinite', [304] and *bounded willpower*, 'the fact that human beings often take actions that they know to be in conflict with their own long-term interests'.[305] This separation between perception and action is a simplification, used for the sake of clarity and presentation. Distinguishing between both is not always easy, as many of the phenomena highlighted thereafter influence each other.

As regards risk perception, experts and laypersons differ in their approach to risk:

> Experts define and quantify risk by focusing on two core elements: the *probability* of a hazardous event and the *severity* of the negative consequences. The perception of risk by laypersons, however, is more complex and is influenced by characteristics beyond probability and severity.[306]

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[301] Upton and Thirlaway (n 62) 79

[302] The term 'behavioural sciences' is used an umbrella term referring to various neighbouring disciplines: psychology, cognitive psychology, behavioural economics, neuroeconomics, etc. The borders between the different branches of psychology and between psychology and other disciplines may be blurry, see Zamir and Teichman, *Behavioral Law and Economics* (n 110) 19-20. Decision-making refers to the fact of choosing between alternatives. It is not always easy to make a difference between a bias affecting judgement or decision-making. It appears that a lot of study labelled under decision-making are actually not really about choice but rather about judgement, see Breakwell (n 13) 121.

[303] '[R]isk perception is used in the literature to refer to various types of attitudes about risks and hazards' and to 'subjective responses to hazard and risk': Breakwell (n 13) 21.

[304] Christine Jolls, Cass R Sunstein and Richard H Thaler, 'A Behavioral Approach to Law and Economics' (1998) 50 Stanford Law Review 1471, 1477.

[305] ibid 1479.

[306] Ralf Schmälzle, Britta Renner and Harald T Schupp, 'Health Risk Perception and Risk Communication' (2017) 4 Policy Insights from the Behavioral and Brain Sciences 163, 164.

Emotions play for instance an important role in risk perception. The concept of 'affect heuristic' describes situations in which people negative or positive responses to risk are driven by their feelings towards it rather than the reality of that risk.[307] There is a 'central role of positive feelings in the determination of risk perception'.[308] The positive image of alcohol appears for instance to be one of the main barriers to behavioural change.[309] Young people's decision to start smoking is also particularly motivated by feelings, the attractive character of a new and transgressive activity that reinforces belonging to the group. [310] It is only afterwards, when thinking of quitting, that a more accurate risk assessment is performed.[311]

One may not only misperceive the reality of a risk in general, as applying to anyone, but may also have a distorted 'personal risk perception',[312] believing to be less at risk than the rest of the population. People tend to overestimate the prospect of good outcomes, or underestimate that of bad ones, a bias referred to as 'overoptimism' which is particularly relevant to health behaviours.[313] Overoptimism 'is one of the most consistent, prevalent, and robust biases documented in psychology'.[314] People may also engage in a motivated form of reasoning, meaning that they are not actually interested in accessing 'true' scientific evidence but rather evidence that suits their opinions and beliefs. They do not only 'look for confirmatory evidence' but 'also tend to ignore disproving evidence, or at least give it less weight, and to interpret the available evidence in ways that confirm their prior attitudes'.[315] People see in the data what they expect to find,[316] a bias sometimes also referred to as the 'confirmation bias'.[317] Due to motivated reasoning, unwarranted optimism may persist despite the presence of

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[307] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 36.
[308] Daniel Romer and Patrick Jameson, 'The Role of Perceived Risk in Starting and Stopping Smoking' in Paul Slovic (ed), *Smoking: Risk, Perception & Policy* (Sage 2001) 68. Regarding smoking, see also Lucy Popova and others, 'Affect, Risk Perception, and the Use of Cigarettes and e-Cigarettes: A Population Study of U.S. Adults' (2018) 18 BMC Public Health 395.
[309] TNS European Behaviour Studies Consortium, 'Study on the Impact of Food Information on Consumers' Decision Making' (2014) 19-22, <https://ec.europa.eu/food/document/download/bab136cd-638d-4b8d-a7e2-d23e44cb07b6_en> accessed 11/05/2023. See also Rehm, Lachenmeier and Room (n 14) 192.
[310] Romer and Jameson (n 308) 69.
[311] ibid 79.
[312] Schmälzle, Renner and Schupp (n 306) 164-165.
[313] Richard Thaler and Cass R Sunstein, *Nudge: Improving Decisions About Health, Wealth and Happiness*, (Penguin Books 2009) 32; Tali Sharot, 'The Optimism Bias' (2011) 21 Current Biology R941 ; Sean H Williams, 'Probability Errors: Overoptimism, Ambiguity Aversion, and the Certainty Effect' in Eyal Zamir and Doron Teichman (eds), *The Oxford Handbook of Behavioral Economics and the Law* (Oxford University Press 2014); Andrew Weymann and Julie Barnett, 'Heuristics and Biases in Decision Making about Risk' in Burgess, Alemanno and Zinn (n 99) 136; Zamir and Teichman, *Behavioral Law and Economics* (n 110) 64.
[314] Sharot (n 313) 941. See also Jon D Hanson and D A Kysar, 'The Joint Failure of Economic Theory and Legal Regulation' in Slovic (n 308) 233. Overoptimism is not only involved in suboptimal choices but also produces good outcomes. Optimists, all things considered, live longer and healthier lives and have higher chances of professional success: see Sharot (n 313) 944.
[315] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 59.
[316] ibid.
[317] See Zamir and Teichman, *Behavioral Law and Economics* (n 110) 58-60.

disconfirming evidence,[318] which makes it particularly difficult to correct,[319] especially when risk information is given based on the average person.[320]

Regarding risk taking, behavioural traits that are more closely related to actual choices, a large body of research shows that when the costs and benefits arising from a course of action materialise at different times, people display 'myopic' tendencies and tend to 'discount future costs and benefits compared with immediate ones'.[321] This phenomenon is referred to as 'hyperbolic discounting' or 'present bias'.[322] It is especially relevant for lifestyle risks, which entail short-term pleasures and long-term negative consequences. 'The gap between what we wish we had done (or what we plan to do) for our health and what we actually do reflects a fundamental driver of decision making: our time preferences.'[323]

This conflict of preferences partly explains failures of self-control, which have particularly large effects on diets, smoking, and drug consumption more generally.[324] Self-control, 'the ability to regulate current thoughts, feelings, and behavio[u]r to secure future benefits', is implicated in most forms of behaviour conducive to a healthy and happy life. Conversely, lack of self-control is at the heart of many societal problems discussed here, including obesity and substance abuse.[325]

Self-control is determined by intertemporal preferences[326] and also influenced by a variety of personal traits and circumstantial elements, such as fatigue, attention, emotions or craving.[327] When not confronted to the actual temptation, people tend to overestimate their capacity to resist to it, a phenomenon referred to as the 'hot-cold empathy gap'.[328] A person that has

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[318] ibid; Sharot (n 313).
[319] Williams (n 313) 339.
[320] Breakwell (n 13) 91.
[321] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 88. See also Oleg Urminsky and Gal Zauberman, 'The Health Consequences of Intertemporal Preferences' in Denise de Ridder, Marieke Adriaanse and Kentaro Fujita (eds), *The Routledge International Handbook of Self-Control in Health and Well-Being: Concepts, Theories, and Central Issues* (Routledge 2018) 89; Jan M Bauer and Lucia A Reisch, 'Behavioural Insights and (Un)Healthy Dietary Choices: A Review of Current Evidence' (2019) 42 Journal of Consumer Policy 3, 26.
[322] Urminksy and Zauberman (n 321) 89.
[323] ibid 88.
[324] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 92. On self-control more generally, see ibid 89, 90; De Ridder, Adriaanse, and Fujita, *The Routledge International Handbook of Self-Control in Health and Well-Being* (n 321).
[325] Denise de Ridder, Marieke Adriaanse, and Kentaro Fujita, 'Self-control in health and well-being : Concepts, theories, and central issues' in De Ridder, Adriaanse, and Fujita, *The Routledge International Handbook of Self-Control in Health and Well-Being* (n 321) 1. See also the specific chapters in this collective book: Arie Dijkstra, 'Self-control in smoking cessation'; Traci Mann and Mary E Panos, 'The self-control of eating behavior'; Jeffrey M. Osgood and Mark Muraven, 'Self-control and alcohol consumption'.
[326] See Urminsky and Zauberman (n 321)
[327] Wilhelm Hofmann, Malte Friese and Reinout W Wiers 'Impulsive versus Reflective Influences on Health Behavior: A Theoretical Framework and Empirical Review' (2008) 2 Health Psychology Review 111; Oleg Urminsky and Gal Zauberman (n 321) 93; Bauer and Reisch (n 321) 19. See also Sendhil Mullainathan and Eldar Shafir, *Scarcity: Why Having Too Little Means So Much* (Times Books 2013) 53.
[328] George Loewenstein, 'Hot-Cold Empathy Gaps and Medical Decision Making' (2005) 24 Health Psychology (2005) 49.

committed not to drink alcohol in a 'cold' state, sitting alone at home for instance, would accept to go to a bar with the firm intention to hold to their word, only to realise once in a the 'hot' state, seeing their friends drinking, that they are unable to refrain from consuming alcohol.

Awareness of these various behavioural phenomena is important if one is to devise appropriate policies on lifestyle risks. Multiplying risk information campaigns is likely to be ineffective if that information is not processed accurately, because people stick to their unwarranted optimism or simply ignore information that conflicts with their beliefs, and if people find themselves unable to put their action in line with that information, due for instance to low self-control. On the contrary, policies that do take into account this behavioural reality have higher chances of leading to behavioural change, as will be explored throughout the thesis and in in Section 6.2 specifically.

5.1.2. Structure: systematic behavioural differences across social groups

People's lifestyle choices are also influenced by a host of structural factors, linked to their life situations and their position in society. '[H]ealth lifestyles are not the uncoordinated behaviors of disconnected individuals, but are personal routines that merge into an aggregate form representative of specific groups and classes.'[329] This is especially true for activities that are performed in the presence of others, such as meals, celebrations and other moments of collective gathering. Recurrent habits and patterns of consumptions can be identified across social groups, along socioeconomic, ethnic, age or gender lines.[330] These differences in lifestyle behaviours result in health inequalities, 'the systematic, avoidable and unfair differences in health outcomes that can be observed between populations, between social groups within the same population or as a gradient across a population ranked by social position'.[331]

Socioeconomic circumstances are the most powerful influence on lifestyles[332] and are strong predictors of the risk of developing NCDs. These are not only more prevalent in people from lower socioeconomic groups but also tend to cause more deaths in these groups.[333] People in low-income groups tend to smoke and drink more, eat less healthy and exercise less than those belonging to high-income groups.[334] Eurobarometer figures from 2021 show for instance that, in the EU and UK, 41% of people declaring having difficulties to pay their bills smoke compared to only 19% of those to which this never or almost never happens.[335]

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[329] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 56.
[330] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58); Upton and Thirlaway (n 62).
[331] McCartney and others (n 142) 28.
[332] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 56.
[333] Gokani, 'Regulation for Health Inequalities and Non-Communicable Diseases: In Want of (Effective) Behavioural Insights' (n 36) 6.
[334] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 57-58; Upton and Thirlaway (n 62) 57.
[335] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 16.

Regarding diets, the higher cost of healthy food, fresh fruits and vegetables for instance, if compared to that of cheap processed food, may partly explain some of the differences in eating habits between social groups. But this is not the only explanatory factor.[336] Another is to be found in diverging preferences and values between social groups. While lower socioeconomic groups associate eating to abundance and satiety, and appreciate heavier and more calory-dense products, higher socioeconomic groups tend to give greater value to health, quality and nutrition.[337] Pierre Bourdieu established for instance that sports preferences and eating habits between the French upper-middle class and the working class differed starkly, with the former preferring food that is tasty, healthy and low in calories, paying more attention to body shape, and the latter favouring food that is both cheap and nutritious, and being more interested in the strength of the male body.[338]

Age, gender and ethnicity/race are also key structural variables.[339] Young people are more prone to taking risks and, conversely, people tend to take better care of their health as they grow older.[340] Gender is a significant variable in that women eat healthier foods, drink and smoke less, and have overall healthier lifestyles than men.[341] Comparisons between the white and black populations in the United States show that while White Americans often drink and smoke more than Black Americans, they also exercise and practice weight control more.[342]

These differences across social groups highlight the power of social norms, the influence of other people's actions on our own behaviour.[343] We might understand norms as 'social attitudes of approval and disapproval, specifying what ought to be done and what ought not to be done'.[344] Young people's choices regarding alcohol consumption and smoking are strongly influenced by that of their peers.[345] If smoking and drinking are considered acceptable, or even desirable behaviours among that age group, that makes young people particularly resistant to messages or policies that try promoting abstinence.

Social norms have an important, and too often overlooked, two-way relationship with laws and regulations.[346] While laws that are buttressed by social norms are more effective, i.e. more

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[336] See Jonathan Peuch, 'Choisir une alimentation nutritionnellement adéquate ? L'incomplète protection des consommateurs en droit de l'Union européenne et ses effets sur les systèmes alimentaires', Thèse de doctorat soumise le 6 juin 2022, 222-233, <https://dial.uclouvain.be/pr/boreal/object/boreal:264767> accessed 11/05/2023.
[337] Fabrice Etilé, *Obésité: santé publique et populisme alimentaire* (Éditions Rue d'Ulm 2013) 52-55.
[338] Pierre Bourdieu, *La Distinction: Critique Sociale du Jugement* (Les Editions de Minuit 1979).
[339] Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 58.
[340] ibid.
[341] ibid.
[342] ibid. Sunstein cites this astounding statistic that in 1993, 22.9% of White American teenagers smoked while only about 4.4% of African-American teenagers did : Cass R Sunstein, 'Social Norms and Social Roles' (1996) 96 Columbia Law Review 903, 905.
[343] Upton and Thirlaway (n 62) 80-81.
[344] Sunstein, 'Social Norms and Social Roles' (n 342) 913.
[345] Upton and Thirlaway (n 62) 81; McDermott and others (n 198) 47.
[346] On the relationship between social norms and the law, see Sunstein, 'Social Norms and Social Roles' (n 342); Bogart (n 15) 91-139.

likely to be respected, a law that goes against an entrenched social norm, something widely held to be an acceptable behaviour, is likely to fail.[347] At the same time, authorities may want to adopt rules that change those norms to accelerate behavioural change, so that people stop engaging in certain activities even where these remain licit, reacting to a perceived change in what constitutes an acceptable behaviour or not. This use of 'legal statements' to change social norms is commonly referred to as the expressive function of law.[348] The prime example of this is the design of smoke-free environments. While being justified by the necessity to protect bystanders from exposure to tobacco smoke, smoke-free environments also serve another purpose, that of 'denormalising' tobacco consumption:[349] 'mak[ing] smoking less visible and seem less acceptable than it currently is [with] the underlying idea […] that because social norms influence behavior, changing the norms surrounding smoking will help, over time, to change smoking behaviors'.[350]

The structural forces at play behind individual lifestyle behaviours matter greatly from a public policy perspective. The existence of health inequalities reinforces the case for addressing lifestyle risks as a collective problem. It is not only a matter of protecting health, as an individually and collectively valued state of being, but also a matter of social justice, ensuring that people's health is not predetermined by conditions that they have not chosen. Looking at structures also results in putting into perspective the individual characteristics and behavioural traits outlined in the previous section. The reliance on behavioural explanations of human agency to explain social phenomena raises a number of epistemological and methodological questions.[351] A recurring criticism directed at health behavioural scholarship is that it favours 'neoliberal' solutions, focusing on individual responsibility rather than addressing the structural causes of ill-health,[352] 'distract[ing] us from the fact that there are deeper socio-

[347] Benjamin van Rooij and Adam Fine, *The Behavioral Code: The Hidden Ways the Law Makes us Better or Worse* (Beacon Press 2021) 122-135. As regards the 'normalisation' of the consumption of illicit drugs, see Amy Eloise Pennay and Fiona Catherine Measham, 'The Normalisation Thesis – 20 Years Later' (2016) 23 Drugs: Education, Prevention and Policy 187; Lisa Williams, 'Muddy Waters?: Reassessing the Dimensions of the Normalisation Thesis in Twenty-First Century Britain' (2016) 23 Drugs: Education, Prevention & Policy 190.
[348] Cass R Sunstein, 'On the Expressive Function of Law' (1996) 144 University of Pennsylvania Law Review 2021.
[349] Mark Asbridge and others, 'Normalization and Denormalization in Different Legal Contexts: Comparing Cannabis and Tobacco' (2016) 23 Drugs: Education, Prevention & Policy 212.
[350] Voigt (n 198) 1968. In the same order of ideas, Bogart points to the importance of changing norms relating to smoking among youth, so that smoking is not anymore seen as something 'cool': Bogart (n 15) 135. See also European Commission, 'Towards a Europe free from tobacco smoke: Policy options at EU level' (2007) Green Paper COM (2007) 27 final. For a critical view on denormalisation and its stigmatising effect on people, see Voigt (n 198), 1969.
[351] See Henri Bergeron and others, *Le Biais Comportementaliste* (Presses de Sciences Po 2018); Mario J Rizzo and Glen Whitman, *Escaping Paternalism: Rationality, Behavioral Economics, and Public Policy* (Cambridge University Press 2019).
[352] Ayo (n 57); Fran Baum and Matthew Fisher, 'Why Behavioural Health Promotion Endures despite Its Failure to Reduce Health Inequities' (2014) 36 Sociology of Health & Illness 213.

economic and educational factors which substantively influence health throughout people's lives'.[353]

The risk of overplaying the role of individual characteristics to explain health outcomes is particularly important as regards obesity. Obese people are often 'prejudged as stupid, ugly, unhappy, less competent, sloppy, lazy, and lacking in self-discipline'.[354] It is clear though that the steep rise in obesity and overweight rates globally cannot be explained by individual factors, a preference for being fatter or a change in cognitive capabilities that has made people unable to control their dietary choices. The concept of 'obesogenic environment' is used to describe the structural factors behind the current growing obesity prevalence. 'Obesogenic environments are the collective physical, economic, policy, and sociocultural surroundings, opportunities, and conditions that promote obesity.'[355]

The decline in physical activity in the general population, to take one of the factors behind weight gain, is explained by various structural factors, such as the evolution in educational settings, transport and urban environments. In particular, with the servicisation of the economy, physical activity is for most people no longer part of their working life but is now considered a leisure.[356] People are not necessarily less active in their leisure time than they were in previous generations. Yet, because of the structural changes that have taken place regarding the type of work performed by individuals, people's total physical activity has declined.[357] We have gone, ironically, from a situation where people were paid to exercise to a situation where people must pay for it.[358] People's diets have not adjusted to this change. Quite the contrary, energy intake has grown.[359] Changes in economic and social life have led people to spend less time cooking and eat more out, which has affected the structure of their diets.[360] Consumers' choice has also been shaped by the increased supply of HFSS processed food on the market, a way of manufacturing food products that is both cheaper and more convenient, and which has met with people's natural propension to favour these types of tastes.[361] This has been accompanied by an increase in the portion sizes of the products sold.[362]

To conclude, one should not artificially oppose studies and scholarship looking at either the individual or the structural factors behind unhealthy lifestyles. It is simply inaccurate that a behavioural analysis of health choices necessarily results in putting the onus for change on

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[353] Muireann Quigley, 'The Politics of Nudge and Framing Behaviour Change in Health' in Holger Straßheim and Silke Beck, *Handbook of Behavioural Change and Public Policy* (Edward Elgar Publishing 2019) 199.
[354] Swinburn and others (n 214) 796.
[355] Swinburn and others (n 214) 795.
[356] Garde, *EU Law and Obesity Prevention* (n 32) 14-15.
[357] Upton and Thirlaway (n 62) 8.
[358] Etilé (n 337) 32–33.
[359] ibid 33-34.
[360] ibid 38-39.
[361] Garde, *EU Law and Obesity Prevention* (n 32) 14; Etilé (n 337) 66; Gearhardt, Joyner and Schulte (n 285) 183.
[362] Etilé (n 337) 71.

individuals alone.[363] As previously discussed, a better understanding of human behaviour may actually warrant stronger public interventions. Further, individual and structural factors largely influence each other. There is for instance a 'psychology of poverty'.[364] The present bias described in the preceding section seems to be particularly affirmed for the least well-off of people, who struggle to envisage the potential future benefits of a healthy lifestyle compared to the costs of renouncing to immediate pleasure, affecting willpower and self-control.[365] It is not that poorer people would be less virtuous, but rather that poverty forces them to focus their attention on pressing issues and diminishes opportunities to adopt a long-term perspective.

5.2. Choice (ii): autonomy and paternalism

Whichever weight is given to various causal explanations for unhealthy lifestyles, the fact remains that lifestyle choices are mainly voluntary choices. Exposure to hazard requires, on most occasions, a positive act from the individual. Moreover, harm is largely self-inflicted. This raises specific ethical questions as to the appropriate boundaries for State intervention and the space given to individual freedom an autonomy. These questions are generally central to public health,[366] which 'is more likely to result in unsought interventions into people's lives, because many suggested interventions are initiated by health providers rather than by the patients themselves'.[367]

The ethical discussion surrounding the regulation of lifestyle risks mostly revolves around the concepts of autonomy and paternalism.[368] Autonomy is 'generally understood to refer to the capacity to be one's own person, to live one's life according to reasons and motives that are taken as one's own and *not the product of manipulative or distorting external forces*'.[369] This vision of autonomy as non-interference is associated with John Stuart Mill's philosophy, the 'harm principle' in particular, the idea that other people and the State should not interfere with

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[363] This simplified reasoning appears from Quigley (n 353) 197-198: 'There is a long tradition within health policy of drawing on a range of strategies to try to change citizens' health behaviours. A particular focus has been on changing individual behaviour vis-à-vis lifestyle risks: alcohol, smoking, and diet and exercise. This broadly fits with the view that an individual's health is a question of personal responsibility, subject to lifestyle choice. This is underpinned by a commitment to upholding individual freedom and choice, in circumstances where state intervention in the lives of its citizens should be kept to a minimum. Such commitment is often to be found as a core political belief of a broader neoliberal worldview. In such circumstances, it may be resistant to change even in the face of evidence to the contrary.'

[364] Johannes Haushofer and Ernst Fehr, 'On the Psychology of Poverty' (2014) 344 Science 862.

[365] ibid; Etilé (n 337) 56; Mullainathan and Shafir (n 327).

[366] See Lindsay F Wiley, Micah L Berman and Doug Blanke, 'Who's Your Nanny? Choice, Paternalism and Public Health in the Age of Personal Responsibility' (2013) 41 The Journal of Law, Medicine & Ethics 88; Kalle Grill and Angus Dawson, 'Ethical Frameworks in Public Health Decision-Making: Defending a Value-Based and Pluralist Approach' (2017) 25 Health Care Analysis 291.

[367] Dawson and Grill (n 144) 102.

[368] See Simões (n 38); Bartlett, 'Power, Policy Ideas and Paternalism in Non-Communicable Disease Prevention' (n 36).

[369] John Christman, 'Autonomy in Moral and Political Philosophy', in Eward N Zalta (ed), *The Stanford Encyclopedia of Philosophy* (Fall 2020 Edition), <https://plato.stanford.edu/entries/autonomy-moral/> accessed 11/05/2023, emphasis added.

choices that do not harm others.[370] Actions that violate the harm principle are deemed paternalistic. Paternalism can thus be defined as the interference with someone's decision-making, against that person's will, without their consent or contrary to their preferences, with the avowed purpose of furthering *that person's own good*.[371]

The legitimacy of paternalistic interventions, especially those from government origin, is a major question of political and moral philosophy with ramifications in many fields, including law, economics and public policy.[372] While the present work does not aim at taking a stance regarding the legitimacy of the State to interfere with voluntary lifestyle choices, laying down the different normative positions adopted on this issue is nonetheless important. Indeed, these influence the views adopted by legal actors, legislators or judges, and other stakeholders.[373] They influence risk management strategies and the degree of control that a given society wants to exercise on a risk.

From a classical liberal, Millian perspective, 'the proper evaluative view of choice [is] one that examines only the quality of individual consent',[374] which means that choices made free of coercion and which do not coerce others should be respected. Leaving aside issues of harm done to others, government action should be limited to informing and educating people about risks but should not restrict choices further. [375] Questions may still arise within this tightly circumscribed scope for State intervention, as to which position to adopt where people are manipulated by other private actors, through the use of promotional or marketing techniques for instance, or the design of (obesogenic) choice environments, and how to treat the choices of individuals whose cognitive capabilities are not fully developed or normally limited. It seems hard to argue that choices made by children regarding lifestyle consumptions should be given as much consideration as those made by adults.

The liberal view may be appealing on principle. The idea of a free and self-determined life is alluring for most individuals. The clear disadvantage is that, considering the difficulty for most people to refrain from engaging in behaviours that they know will harm them in the long-term,

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[370] John S Mill, *On Liberty, Utilitarianism and Other Essays* (New Edition, Oxford University Press 2015) 12-13.
[371] Danny Scoccia, 'The Concept of Paternalism', in Kalle Grill and Jason Hanna (eds), *The Routledge Handbook of the Philosophy of Paternalism* (Routledge, Taylor & Francis Group 2018) 11.
[372] For recent defences and critiques of paternalism, see Sarah Conly, *Against Autonomy: Justifying Coercive Paternalism* (Cambridge University Press 2013); Mark D White, *The Manipulation of Choice: Ethics and Libertarian Paternalism* (Palgrave Macmillan 2013); Rizzo and Whitman (n 351). See also Grill and Hanna (n 371).
[373] Companies manufacturing unhealthy commodities are for instance more likely to stress personal responsibility while public health NGO's are more inclined to emphasise the structural causes of unhealthy lifestyles. See Wiley, Berman and Blanke (n 354); Bartlett, 'Power, Policy Ideas and Paternalism in Non-Communicable Disease Prevention' (n 36).
[374] Gregory Mitchell, 'Libertarian Paternalism is an Oxymoron' (2005) 99 Northwestern University Law Review 1245, 1260.
[375] See White (n 372) 137-149. White's solutions to influence other's choices in a non-paternalistic way are the following: provide neutral information, help people overcome their cognitive biases and hold them responsible for their choices. See also Rizzo and Whitman (n 351) 437: 'what we can do: remonstrate, reason, persuade and entreat'.

leaving people to their own devices and bearing alone the consequences of their acts is likely to lead to damaging health consequences on a wide scale. Such is the case today. This, some would argue, is paying little respect to human life and dignity.[376] For society at large, this results in significant healthcare costs and impairments which affect social and economic life.

Rather than focusing on its outcomes, this understanding of autonomy as non-interference may also be criticised substantively.[377] We cannot possibly make conscious choices all the time and may also sometimes not want to choose at all.[378] It is unlikely, to say the least, that people want and can enquire about the potential risks of all the products put on the market, and that they wish to enter into a careful deliberation as to whether those risks are worth being taken or not. '[N]ot all choices are equally valuable and being released from choices we don't really want to be making is a relief.'[379] It is also hard to qualify the choices of a person suffering from addiction as free. Interfering with these choices may therefore be construed as an actual increase of one's level of autonomy.[380]

The question of voluntariness is here key. Choices that are not truly voluntary would seem to deserve less respect. A question that has generated considerable scholarly debate is whether behavioural research, and the various phenomena uncovered, which underline the cognitive limitations in individuals, provide renewed justifications for discarding the liberal vision of autonomy and for defending paternalism.[381] If people are unable to adopt the right means to their ends and thus fail to refrain from behaviours that they wish they had not engaged into, it would seem justified to interfere. These choices would not be truly voluntary and reflect one's true preferences. Proponents of this 'new' or 'soft' paternalism, as opposed to the 'old' and 'hard' versions, defend external intervention when it aims to help people better achieve their

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[376] Sarah Conly (n 372). See also Zamir and Teichman (n 110) 167: absolutist deontology 'is internally coherent but leads to extreme, counterintuitive conclusions, which are at odds with prevailing moral judgements that legitimize a great deal of paternalism in both private and public spheres'.

[377] For a discussion of various conceptions of autonomy in a health context, see Paul E Griffiths and Caroline West, 'A Balanced Intervention Ladder: Promoting Autonomy through Public Health Action' (2015) 129 Public Health 1092. For a critique of the concept of autonomy, see Conly (n 372).

[378] Cass R Sunstein, 'Choosing Not to Choose' (2014) 64 Duke Law Journal 1; Alberto Alemanno and Anne-Lise Sibony, 'Epilogue: The Legitimacy and Practicability of EU Behavioural Policy-Making', in Alberto Alemanno and Anne-Lise Sibony (eds), *Nudge and the Law: A European Perspective* (n 53) 329-333. See also, generally, Cass R Sunstein, *On Freedom* (Princeton University Press 2019).

[379] Conly (n 372) 11.

[380] Kalle Grill and Kristin Voigt, 'The Case for Banning Cigarettes' (2016) 42 Journal of Medical Ethics 293, 295-296

[381] Behavioural findings would at least warrant an 'anti-antipaternalism – a skepticism about antipaternalism, but not an affirmative defense of paternalism': Cass R Sunstein, Christine Jolls and Richard H Thaler, 'A Behavioral Approach to Law and Economics' (1998) 50 Stanford Law Review 1471, 1541. See also Colin Camerer and others, 'Regulation for Conservatives: Behavioral Economics and the Case for "Asymmetric Paternalism"' (2003) 151 University of Pennsylvania Law Review 1211; Tor, 'The Methodology of the Behavioral Analysis of Law' (n 50) 318; Zamir and Teichman, *Behavioural Law and Economics* (n 110) 168. For Van Aaken, '[e]ven if behavioural research shows that people are only boundedly rational, it cannot discard the normative concept of autonomy, especially if the research is used for policy measures. Above a threshold of minimal conditions of rationality, autonomy and the principle of proportionality secure the liberty to pursue decisions that are not fully rational and that can even be irrational or unreasonable': Anne Van Aaken, 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' in Alemanno and Sibony, *Nudge and the Law* (n 53) 92.

own preferences.[382] This vision has been best encapsulated with the term 'libertarian paternalism', coined by Richard Thaler and Cass Sunstein, a form of paternalism that seek to make people better-off, *as judged by themselves*.[383] As appealing as this position may be, it also suffers from serious limitations. As its paternalistic counterpart, in its old version, it can be criticised for 'tak[ing] away the motivation of people to act deliberately' and affecting their capacity to make better decisions by learning, making errors and being accountable.[384] New paternalists also suffer from a considerable knowledge problem, as it is difficult, if not impossible, to access people's true hidden preferences without taking choice as a yardstick.[385]

The problem with paternalistic State interventions in lifestyles is not only their coercive aspect, but the effect that they may have on the social position of those targeted.[386]

> The drunk, the smoker, the fatty, the problem gambler, and the drug fiend have long been objects of derision. Those deemed to be out of control have been viewed as needing to be brought back into line. If they, themselves, did not have the willpower to conform, then society would have to take charge and do the job for them.[387]

Public health interventions may, consciously or not, lead to stigmatisation, reducing the sufferer 'from a whole and usual person to a tainted, discounted one'.[388] The risk is especially high for overweight and obese people, whose body is often the subject of social reprobation and who face a range of discrimination in educational, professional and other social settings.[389]

5.3. The cultural aspect of lifestyle risks

As mentioned earlier, 'the act of consumption can never be fully understood in isolation – as an autonomous act of personal volition – but must likewise be viewed through interactive lenses: consumption occurs within and is both shaped by and shaping of a series of social institutions and systems, which possess their own varied rationales'.[390] These social institutions

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[382] See Jason Hanna, 'Hard and Soft Paternalism' in Grill and Hanna (n 371); Rizzo and Whitman (n 351) 4-7.
[383] See Cass R Sunstein and Richard Thaler, 'Libertarian Paternalism Is Not an Oxymoron' (2003) 70 The University of Chicago Law Review 1159; Thaler and Sunstein (n 313). See also Sunstein, *On Freedom* (n 378).
[384] White (n 372) 119-125. See contra Zamir and Teichman (n 110) 169.
[385] See Mitchell (n 374) 1267; Mario Rizzo and Douglas Whitman, 'The Knowledge Problem of New Paternalism' (2009) 2009 Brigham Young University Law Review 905, 922; Till Grüne-Yanoff, 'Old wine in new casks: libertarian paternalism still violates liberal principles' (2012) 38 Social Choice and Welfare 635, 642-644; White (n 372) 61-80; Rizzo and Whitman (n 351) 235–280.
[386] Lupton, 'Risk as Moral Danger: The Social and Political Functions of Risk Discourse in Public Health' (n 3); Ayo (n 57).
[387] Bogart (n 15) xviii.
[388] Erving Goffman, *Stigma: Notes on the Management of Spoiled Identity* (Simon & Schuster 1963) 3; cited by Mette Hartlev, 'Stigmatisation as a Public Health Tool against Obesity - A Health and Human Rights Perspective' (2014) 21 European Journal of Health Law 365, 370.
[389] Lee F Monaghan, Rachel Colls and Bethan Evans, 'Obesity Discourse and Fat Politics: Research, Critique and Interventions' (2013) 23 Critical Public Health 249; Schorb (n 57); Michael Gard, Darren Powell and José Tenorio (eds), *Routledge Handbook of Critical Obesity Studies* (Routledge 2022); Nuttall (n 229) 117.
[390] Michelle Everson and Christian Joerges, 'Consumer Citizenship in Postnational Constellations?' (2006) EUI Working Papers, <http://www.ssrn.com/abstract=964187> accessed 11/05/2023.

and systems shape individual and collective relationships to risk,[391] and, as a result, the risks management strategies chosen.[392] '[A]lthough the physical aspects of risks do not depend on culture and values, defining what is at stake and deciding which aspects must be addressed in dealing with a risk-issue require […] the consideration of the underlying structuring values, interests and objectives.'[393] Society at large often takes strong views on what constitutes an acceptable behaviour or not, which is reflected in the risk regulatory regime adopted. Regulating lifestyle risks entails adopting a certain vision of the 'good life'. The cultural relevance of lifestyles and lifestyle risks regulation raises specific challenges for the EU, where a common approach must be devised despite the variety of practises and inclinations towards risks existing between its different peoples. Cultural diversity is not only something that must be composed with, but also a value that the Union itself seeks to preserve.[394]

That cultural aspects may enter into play when deciding on whether and how to control certain risks is perhaps best illustrated with food and alcohol. 'In collective terms the consumption of food is an indissoluble part of certain traditions and certain social practices.'[395] As previously discussed, the positive image of alcoholic beverages, which are central to many food and drink cultures, yields a direct influence on the perception of these products as less risky than they really are.[396] Alcohol, in spite of its harmfulness, is generally more lightly regulated than comparable risk factors such as illicit drugs or tobacco.[397] There is yet no clear scientific justification for making cannabis illegal but allowing the sale of alcohol.[398] This reflects the particular place that alcohol occupies in many societies, which varies across countries and periods. For a very long period, the public in the United States perceived alcohol and other drugs similarly. These were handled by the government in the same way, before a dissociation

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[391] Regarding the influence of cultural factors on risk perception, see Lupton and Tulloch (n 296) 114; Breakwell (n 13) 70-72; Zamir and Teichman, *Behavioral Law and Economics* (n 110) 124-127. As regards food risks specifically, in a European context, see Katrin Hohl and George Gaskell, 'European Public Perceptions of Food Risk: Cross-National and Methodological Comparisons' (2008) 28 Risk Analysis 311.

[392] To a certain extent, the influence of sociocultural factors can also be felt at the risk assessment level. See Petersen and Lupton (n 56) 18: 'The concept of "risk" is central to the new public health in which it is asserted that risks are sociocultural constructs; are always political in their construction, use and effects; and inevitably include moral judgments of blame. This focus on the social construction of risk is not to argue that there are no "real" dangers and threats to which humans may fall prey, causing ill health, pain or death, but rather is to contend that our understanding of these dangers and hazards, including their origin and their outcomes, are constituted through social, cultural and political processes. It is through these processes that dangers and hazards become "risks". For instance, some dangers are singled out and labelled as "risks", while others are not; this selection process is inevitably shaped by the sociocultural and political context.'

[393] Delogu (n 76) 20.

[394] Pursuant to Article 167 TFEU: 'The Union shall contribute to the flowering of the cultures of the Member States, while respecting their national and regional diversity and at the same time bringing the common cultural heritage to the fore.'

[395] Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (n 43) 546. See also Ann Grodzins Gold, 'Food Values Beyond Nutrition' in Ronald J Herring (ed), *The Oxford Handbook of Food, Politics and Society* (Oxford University Press 2013); Delogu (n 76) 20.

[396] On the various dimensions of risk perception and the characterisation of hazards by lay people, see Breakwell (n 13) 37-43.

[397] Rehm, Lachenmeier and Room (n 14). See also Room (n 18).

[398] Upton and Thirlaway (n 62) 356.

occurred in the first half of the 20th century.[399] Prohibition stopped being an option for alcohol while the 'war on drugs' never stopped intensifying.[400] These State-sponsored moral norms become deeply engrained in local cultures. Such is the case of the strict approach taken by Finland and Sweden on alcohol and the comparatively soft approach adopted by the Dutch on illicit drugs.[401]

An area which illustrates particularly well the cultural importance of lifestyle products is the EU legislation on quality schemes. These schemes protect the names of specific foodstuffs and agricultural products in order to promote their unique characteristics, usually linked to their geographical origin and the traditional aspect of their conception. There are three main types of geographical indications at the EU level. These are schemes that apply to products whose qualities are specifically linked to an area of production: the protected designation of origin (PDO) and the protected geographical indication (PGI) for food and wine, and the geographical indication (GI) for spirit drinks and aromatised wines.[402] As we shall see later, the EU regulation of products protected by quality schemes for health purposes creates tensions, as know-how and taste do not necessarily go hand in hand with nutritional quality and health (see Chapter 7, Section 3.1).

A glance at the legal register which keeps track of all the products protected by a PDO, PGI or GI show wide differences in the number of protected products across countries. This is not solely explained by differences in size or population but also reflects a different relationship to culinary traditions.[403] Italy has for instance 873 registered names, France 749 but Germany only 174. Poland has 36 registered names, Sweden 13 but Portugal 193. On can expect EU food policy to resonate differently in these various countries.

Regarding tobacco, as we have seen, consumption patterns vary widely across the EU. This affects attitudes towards tobacco and tobacco control policies. The ban on tobacco with a characterising flavour currently in force in the EU is for instance supported by a majority of the population in only 14 Member States, with levels of support varying from 74% (Finland)

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[399] Bogart (n 15) 9-13.
[400] ibid.
[401] Paulette Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (Cambridge University Press 2001).
[402] The traditional speciality guaranteed (TSG) is another EU quality scheme, applicable to food and agricultural products, which highlight the traditional aspects of these products without being linked to a specific geographical area. The main rules on EU quality schemes are contained in Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [2012] OJ L343/1; CMO Regulation; Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products [2014] OJ L84/14; Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages [2019] OJ L130/1.
[403] European Commission, 'eAmbrosia: the EU geographical indications register', <https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/geographical-indications-register/> accessed 11/05/2023.

to only 29 % (Czechia). [404] The situation is comparable concerning the potential introduction of a plain packaging requirement for tobacco products, backed this time by the population in only 13 Member States, support ranging from 72% (Ireland) to 28% (Portugal).[405] The 2021 Eurobarometer on Europeans' attitudes towards tobacco and electronic cigarettes show more generally that the population in some countries is consistently in favour of stronger tobacco control policies while the opposite is true in some others.[406]

Similar findings appear from the 2010 Eurobarometer 'EU Citizens' Attitudes Towards Alcohol'.[407] As regards alcohol use, figures for daily consumption show a remarkable gap between countries, with a high proportion of Portuguese (43%) and a quarter of Italian respondents (25%) reporting drinking daily, while the Swedish, Polish and Lithuanian alcohol consumers are the least likely to drink alcohol on a daily basis (1%).[408] At the same time, while Lithuanians and Swedes may not consume alcohol every day, they are more likely (16% and 19% respectively) than Portuguese (14%) to engage in monthly heavy episodic drinking.[409] In some countries, alcohol is consumed in small quantities, with meals, while it is consumed in greater quantities for celebratory moments in others, with different implications for health in both cases.

Regarding support for alcohol policies, the 2010 Eurobarometer also shows differences between Member States. Respondents were asked which of the two following statements they felt the closest to, that 'individuals are responsible enough to protect themselves from alcohol-related harm' or that 'public authorities have to intervene in order to protect individuals from alcohol-related harm'. While 74% of the population in Slovakia felt closest to the first statement, for instance, 66% of Italians supported the second statement.[410] Some policies, however, appear to receive widespread support across countries. This is the case for an 18-year minimum age to consume alcohol.[411]

5.4. Lifestyle risks and the commercial determinants of health

For Max Weber, one of the main characteristics of lifestyles in modern times is their embeddedness in consumption behaviours.[412] Consumption is a defining feature for one's identity and belonging to certain social groups. As regards health, lifestyle risk factors are

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[404] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 219-220.
[405] ibid 219-220.
[406] ibid.
[407] European Commission, 'EU Citizens' Attitudes Towards Alcohol' (2010), Special Eurobarometer 331, <http://www.ec.europa.eu/health/ph_determinants/life_style/alcohol/documents/ebs272_en.pdf> accessed 11/05/2023.
[408] ibid, 20. See also Eurostat, 'One in twelve adults in the EU consumes alcohol every day', <https://ec.europa.eu/eurostat/fr/web/products-eurostat-news/-/edn-20210806-1> accessed 11/05/2023.
[409] ibid.
[410] ibid 52.
[411] ibid 66
[412] Cockerham, Abel and Lüschen (n 5) 416; Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure' (n 58) 55.

products and services which are manufactured, nowadays on a massive and global scale, and which may be bought on the market, whether legally or illegally. In high-income countries especially, unhealthy lifestyle behaviours rarely occur independently of a prior purchase.

As we have seen, a lot of the transformation in people's dietary habits can be traced to the major changes in food supply that have occurred in the last decades.[413] The rise in the burden of NCDs worldwide is referred to as an 'industrial epidemic', while major transnational corporations are considered as 'vectors of disease' that put into contact the consumer (the host) and the unhealthy commodity (the agent).[414] The term 'commercial determinants of health' describes private sector activities that affect people's health positively or negatively, with a particular focus on corporation's manufacturing and marketing choices.[415]

Unhealthy commodities are a particularly lucrative business, thanks to low production costs, long shelf-life and high retail value.[416] The manufacture of soft drinks and tobacco products are amongst the most profitable industrial activities in the world.[417] In 2020, the food and drink industry (including alcohol) was the largest manufacturing sector in the EU, with a turnover of 1,205 billion euros, and the leading employer, representing 4,8 million people. 91% of this turnover originates from sales made within the EU single market.[418] Key actors of the EU food and drink industry are producers of alcoholic beverages, soft drinks, chocolate, biscuit, confectionery and savoury snacks. Further, this industry represents 5.8% of total EU exports and a trade surplus of 44 billion euros.[419] The EU controls a 18.8% share of global food and drink exports, making it the leading regional block worldwide.[420] Spirits and wine, with 12 billion euros of sales each, are central to EU exports.[421] Seven of the first 20 agri-food companies worldwide are European.[422] As regards gambling, finally, figures show that this sector is also financially important. Total revenues of the gambling market amounted to 98,6

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[413] Stefanie Vandevijvere and others, 'Increased Food Energy Supply as a Major Driver of the Obesity Epidemic: A Global Analysis' (2015) 93 Bulletin of the World Health Organization 446.
[414] Anna B Gilmore, Emily Savell and Jeff Collin, 'Public Health, Corporations and the New Responsibility Deal: Promoting Partnerships with Vectors of Disease?' (2011) 33 Journal of Public Health 2; David Stuckler and others, 'Manufacturing Epidemics: The Role of Global Producers in Increased Consumption of Unhealthy Commodities Including Processed Foods, Alcohol, and Tobacco' (2012) 9 PLOS Medicine e1001235; Rob Moodie and others, 'Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-Processed Food and Drink Industries' (2013) 381 The Lancet 670.
[415] WHO 'Commercial determinants of health' (2021), <https://www.who.int/news-room/fact-sheets/detail/commercial-determinants-of-health> accessed 11/05/2023.
[416] Stuckler (n 414).
[417] ibid.
[418] FoodDrinkEurope, 'Data & Trends EU Food & Drink Industry: 2020 Edition' (2020) 2-4, <https://www.fooddrinkeurope.eu/resource/data-trends-of-the-european-food-and-drink-industry-2020/>.
[419] ibid 18.
[420] ibid 22.
[421] ibid 20.
[422] ibid 26.

billion euros in 2019, with a growth forecasted to 111 billion in 2025. There are a total of 16 million customers for online gambling in the EU.[423]

The weight of the unhealthy sector in the EU's economy has obvious repercussions for regulation. Restrictions on the activities of these companies has significant consequences in terms of revenue and employment. Their huge financial power gives them the possibility to influence policymaking through lobbying and influence activities,[424] several example of which will be given throughout the thesis. These companies usually lay an emphasis on individual responsibility and advocate for limited public interventions aiming at informing and educating the public.[425] A recent analysis estimates that the 33 main companies involved in the manufacture of tobacco products, alcoholic drinks, soft drinks, processed food and fast-food worldwide made a profit of 99 billion dollars, resources on an order of magnitude larger than those required for NCD prevention and control on a global scale.[426]

6. Risk management (ii): the regulator's toolbox

On the basis of the risk assessment, and after having considered other legitimate factors, risk managers select appropriate prevention and control options. These regulatory mechanisms 'share the common objective of promoting healthier behaviours by reducing exposure to a given risk factor' but are 'characterized by specific features, responding to a different rationale and producing different unintended consequences'.[427] This section provides a brief presentation of these various interventions, which are part of the Union and the national regulators' toolbox, with a particular focus on behaviourally informed regulation and information disclosure requirements.

These regulatory tools are part of a health promotion policy, an effort to improve the health of the whole population.[428] 'Health promotion' should be understood broadly, as a 'process of enabling people to increase control over, and to improve, their health', moving 'beyond a focus on individual behaviour towards a wide range of social and environmental interventions'.[429] The term will not be used to refer to specific kinds of interventions which, such as education and information campaign, would only *promote* good health rather than directly regulate

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[423] European Gaming and Betting Association, 'European Online Gambling – Key Figures 2020 Edition' (2020), <https://www.egba.eu/resource-post/european-online-gambling-key-figures-2020-edition/> accessed 11/05/2023.

[424] Gilmore, Savell and Collin (n 414), 'Public Health, Corporations and the New Responsibility Deal: Promoting Partnerships with Vectors of Disease?' (2011); Stuckler and others (n 414); Moodie and others (n 414).

[425] Gilmore, Savell and Collin (n 414); Bartlett, 'Power, Policy Ideas and Paternalism in Non-Communicable Disease Prevention' (n 36).

[426] Luke N Allen, Arian Hatefi and Andrea B Feigl, 'Corporate Profits versus Spending on Non-Communicable Disease Prevention: An Unhealthy Balance' (2019) 7 The Lancet Global Health e1482, e1482.

[427] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1752.

[428] Dawson and Grill (n 144) 102.

[429] WHO, 'Health Promotion', <https://www.who.int/westernpacific/about/how-we-work/programmes/health-promotion> accessed 11/05/2023.

underlying risk factors.[430] Health promotion is not limited to awareness-raising. It does not simply increase knowledge of diseases and their causes but aims at modifying individual behaviours toward the adoption of protective lifestyles.[431]

Health promotion is a population-level intervention,[432] as opposed to individual-level interventions,[433] such as that performed by a health professional with its patients, which may involve counselling or treatment.[434] Unlike individual-level interventions, which take the physical and psychological characteristics of the individual or their life situation into account, population-level interventions target the environment, i.e. the general context in which individual choices are made.

Considering the variety of factors influencing choice, effective non-communicable disease prevention requires the adoption of multisectoral approaches, involving not only the health sectors but sectors such as education, agriculture, sports, transport, urban planning, environment, employment, trade and economic development.[435] What the present section and this thesis focus on are interventions that directly regulate the product or activity constituting a risk factor: its characteristics, its availability, its price or its use. These interventions are typically used in combination rather than separately, as part of a regulatory mix. Lifestyles cannot be improved by measures taken in isolation, there is no 'silver bullet'.[436]

6.1. Regulatory interventions

There are various types of lifestyle regulatory interventions, each of them with their pros and cons, contributing differently to the objective of reducing exposure to risk factors, relating differently to other legitimate interests, and affecting differently the various actors involved. An information disclosure requirement regarding the nutritional composition of foods puts relatively little constraints on manufacturers and promotes consumers autonomy, if understood as the capacity to make free and informed choices. It is however unlikely, as we shall see, to

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[430] See Upton and Thirlaway (n 62) 356; Baum and Fisher (n 340). In that regard, Dawson and Grill note that there are no good reasons 'to exclude by definition the possibility that health promotion could improve people's lives via some other route than empowerment': Dawson and Grill (n 144) 101.

[431] European Parliament Research Service, 'Strengthening Europe in the fight against cancer: Going further, faster' (2020) 34, <https://op.europa.eu/en/publication-detail/-/publication/d571cb5d-2ecd-11eb-b27b-01aa75ed71a1/language-en> accessed 11/05/2023.

[432] See Rayner and others, 'NCDs: Risk factors and determinants' (n 152).

[433] See Upton and Thirlaway (n 62) 68. As observed by Michie and others, this distinction, '[while] superficially appealing', cannot satisfactorily classify all interventions: Susan Michie, Maartje M van Stralen and Robert West, 'The Behaviour Change Wheel: A New Method for Characterising and Designing Behaviour Change Interventions' (2011) 6 Implementation Science 42, 43–44. A public campaign for 'Stop Smoking Services' mixes for instance both individual- and population-level elements. Such intervention will still be considered as individual-level, insofar as it puts a patient and a healthcare provider in contact, unlike the interventions presented in this section and analysed throughout the thesis.

[434] For a presentation of individual-level interventions in healthy lifestyles promotion, see Upton and Thirlaway (n 62).

[435] United Nations General Assembly (n 6) 36.

[436] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1773-1774.

result in significant behaviour change and positive health outcomes.[437] A ban, on the other hand, provided it is respected, is the most effective way to prevent a behaviour from taking place, but constitutes a highly paternalistic intervention with potentially far-reaching, and unintended, social or economic consequences. Most of these interventions, bans excluded, operate according to a 'permit but discourage' logic,[438] under which the activity in question remains lawful but consumers are, through various means, discouraged from partaking in it.

The 'Nuffield intervention ladder', a classification developed by the Nuffield Council on Bioethics,[439] is a useful way to present and rank public health interventions, in function of the intensity of the restriction operated on individual choice.[440] Table 1 classifies some typical lifestyle risks measures according to this ladder. Where possible, interventions that are part of the EU regulator's toolbox have been used, as will be further explored in Chapters 5 and 6.

Table 1: A 'Nuffield inspired' ladder of lifestyle risks interventions[441]

Level	*Description*	*Example*
Eliminate choice	Entirely eliminating choice	Ban on illicit drugs
Restrict choice	Restricting available options	Regulate ingredients used in food or tobacco products
Guide choice through disincentives	Price or other disincentives	Taxes on tobacco Minimum unit pricing for alcoholic beverages Smoke-free environments
Guide choice through incentives	Price or other incentives	Tax-break on healthy food options

[437] Upton and Thirlaway (n 62) 357. See section 6.2 in this chapter for more developments on this matter.
[438] Bogart (n 15).
[439] The Nuffield Council on Bioethics is a UK-based independent charitable body that examines and reports on ethical issues in biology and medicine: <https://www.nuffieldbioethics.org/about-us> accessed 11/05/2023.
[440] Nuffield Council on Bioethics 'Public Health: Ethical Issues' (2007) 42, <https://www.nuffieldbioethics.org/assets/pdfs/Public-health-ethical-issues.pdf> accessed 11/05/2023; see also Upton and Thirlaway (n 62) 358; Willet and others (n 140) 478.
[441] Adapted from Upton and Thirlaway (n 62) 358.

Guide choices though changing the default policy	Changing the default option	Change the default option in restaurant menus or cafeteria
Enable choice	Helping individuals change their behaviour	Advertising restrictions[442]
Provide information	Inform and educate the public	Health warnings, nutrition labelling, information campaigns
Do nothing		

According to the Nuffield Council on Bioethics:

> The range of options available to government and policy makers can be thought of as a ladder of interventions, with progressive steps from individual freedom and responsibility towards state intervention as one moves up the ladder. In considering which 'rung' is appropriate for a particular public health goal, *the benefits to individuals and society should be weighed against the erosion of individual freedom*. Economic costs and benefits would need be taken into account alongside health and societal benefits.
>
> Primarily, the function of the ladder is to compare alternative approaches in terms of their intrusiveness and likely acceptability, and not a means of allowing judgements in absolute terms. The intervention ladder is, therefore, not a formulaic device, but […] a tool for bringing into sharper focus the issues at stake.[443]

Ranking interventions according to their effect on individual freedom is not a neutral choice. Echoing some of the positions discussed in Section 5.2, the Nuffield ladder can be criticised for promoting a vision of autonomy understood primarily as non-coercion.[444] The Nuffield classification appears however particularly well suited to lifestyle risks regulation, on two grounds. First, as individual behaviour change is the objective sought in this area, it seems logical to rank interventions according to the extent to which individual choice is constrained. Second, it also easier to establish such a ranking on the basis of the effect of measures on individuals than it is to do so on the basis of their effect on economic operators. Indeed, the latter option requires, as a prerequisite, to agree on the types of costs, direct or indirect, to consider. A tobacco advertising ban or a tax on alcoholic beverages, on the one hand, may not actually give rise to costs to economic operators. Being prohibited from advertising a product does not make manufacturing that product more expensive. A tax on consumption may be ultimately borne by the consumer. These interventions are restrictive insofar as they lead to a

[442] Advertising rules does not appear in the original ladder developed by the Nuffield Council on Bioethics (n 440) 42 and that developed by Upton and Thirlaway (n 62) 358. We consider that restrictions on advertising, by limiting 'unhealthy' influences on choice, participate to enabling the healthy choice. In that, we follow Willet and others who consider that a role for the industry under the 'enable choice' level is to 'focus[…] marketing on only healthy and sustainably produced foods': Willett and others (n 140) 478.
[443] Nuffield Council on Bioethics (n 440) 42.
[444] Griffiths and West propose for instance an alternative 'balanced intervention ladder', build on 'richer accounts of autonomy': Griffiths and West (n 377).

decrease in consumption and foregone profits. Labelling obligations, on the other hand, create direct costs, printing or design costs for instance. Yet, it would make little sense to consider a labelling obligation to be more restrictive than a tax.

Ranking interventions on the basis of their restrictive effects vis-à-vis economic operators would require to tackle the question of their effectiveness. Public policy evaluation is generally a difficult endeavour, reinforced as regards lifestyle risks by the fact that healthy lifestyles cannot be promoted by individual measures taken in isolation. Measures are often adopted as part of a multi-sectoral regulatory mix, 'which makes the effectiveness of a specific intervention all the more difficult – if not impossible – to quantify'.[445]

The WHO published a guide on the 'best buys' for the prevention and control of NCDs, presenting the interventions considered to be the most cost-effective and feasible for implementation.[446] Out of 88 interventions reviewed, there are 12 'best buys' for tobacco, alcohol and diets, reproduced in Table 2 below.

Table 2: WHO 'best buys' for NCDs prevention

Objective	*Best buys*
Reduce tobacco use	Increase excise taxes and prices on tobacco products
	Implement plain/standardized packaging and/or large graphic health warnings on all tobacco packages
	Enact and enforce comprehensive bans on tobacco advertising, promotion and sponsorship

[445] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1774. See also Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 154-155.

[446] WHO, 'Tackling NCDs: 'best buys' and other recommended interventions for the prevention and control of noncommunicable diseases' (2017), <https://apps.who.int/iris/handle/10665/259232> accessed 11/05/2023. Best buys are interventions for which the analysis found 'an average cost-effectiveness ratio of ≤ $ 100 per DALY averted in low- and lower middle-income countries': ibid 3. Doubts have been raised as to the pertinence of this 'best buys' in low-income and lower-middle-income countries: see Luke N Allen and others, 'Are WHO "Best Buys" for Non-Communicable Diseases Effective in Low-Income and Lower-Middle-Income Countries? A Systematic Review' (2017) 5 The Lancet Global Health S17; Wanrudee Isaranuwatchai and others, 'Prevention of Non-Communicable Disease: Best Buys, Wasted Buys, and Contestable Buys' (2020) 368 British Medical Journal m141.

	Eliminate exposure to second-hand tobacco smoke in all indoor workplaces, public places, public transport
	Implement effective mass media campaigns that educate the public about the harms of smoking/tobacco use and second-hand smoke
Reduce the harmful use of alcohol	Increase excise taxes on alcoholic beverages
	Enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media)
	Enact and enforce restrictions on the physical availability of retailed alcohol (via reduced hours of sale)
Reduce unhealthy diet	Reduce salt intake through the reformulation of food products to contain less salt and the setting of target levels for the amount of salt in foods and meals
	Reduce salt intake through the establishment of a supportive environment in public institutions such as hospitals, schools, workplaces and nursing homes, to enable lower sodium options to be provided
	Reduce salt intake through a behaviour change communication and mass media campaign
	Reduce salt intake through the implementation of front-of pack labelling

As we shall see in Chapters 5 and 6, most of these regulatory interventions have been adopted by the EU or are currently under consideration. These are situated at different levels of the intervention ladder. It is noteworthy that measures to 'eliminate' or 'restrict' choices are not part of the WHO 'Best buys'. This might reflect the fact that bans are not considered a feasible option for tobacco, alcohol or food, although regulating ingredients is more routinely done. As regards unhealthy diets, the focus on salt intake highlights the importance of this dietary risk factor for health outcomes (see Section 4.3). For both tobacco and alcohol, tax and price measures are ranked as number one 'best buys',[447] in line with the overall evidence showing

[447] As regards diets, 'Reduce sugar consumption through effective taxation on sugar-sweetened beverages' is ranked as an 'effective intervention' even if not a 'best buy': WHO, 'Tackling NCDs: 'best buys' and other recommended interventions for the prevention and control of noncommunicable diseases' (n 446) 11.

that these forms of intervention are among the most effective ones.[448] A concern with measures that directly increase the price of unhealthy commodities, however, is their regressive effect. Low-income consumers are not only more sensitive to price increases but are also more affected by it, as they tend to have unhealthier lifestyles.[449]

Generally, any health promotion policy should be mindful of the fact that people with a lower socioeconomic status tend to have habits that are less healthy and dedicate, in proportion, a greater share of their income to the purchase of food, beverages or tobacco. Such policy should reduce existing inequalities rather than entrench them or, worse, widen them. As for climate and environmental action, the transition to healthier lifestyles should be just, transforming society and the economy in a way that is as fair and inclusive and leaves no one behind.[450] As part of the European Green Deal, the European Commission has set up a Just Transition Mechanism and Just Transition Fund, to address the social and economic effects of the green transition, focusing on the most impacted regions, industries and workers.[451] Inspiration could be drawn from such initiatives in the field of health and lifestyles.

6.2. Behaviourally informed regulation and information requirements

The various behavioural phenomena highlighted in Section 5.1.1 are not only relevant to our understanding of lifestyle behaviours but also pertinent for the adoption of effective strategies

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[448] Rayner and others (n 137) 132–133. Regarding tobacco, see MM Schaap and others, 'Effect of Nationwide Tobacco Control Policies on Smoking Cessation in High and Low Educated Groups in 18 European Countries' (2008) 17 Tobacco Control 248; Frank J Chaloupka, Ayda Yurekli and Geoffrey T Fong, 'Tobacco Taxes as a Tobacco Control Strategy' (2012) 21 Tobacco Control 172; Shannon Gravely and others, 'Implementation of Key Demand-Reduction Measures of the WHO Framework Convention on Tobacco Control and Change in Smoking Prevalence in 126 Countries: An Association Study' (2017) 2 The Lancet Public Health e166; Ariadna Feliu and others, 'Impact of Tobacco Control Policies on Smoking Prevalence and Quit Ratios in 27 European Union Countries from 2006 to 2014' (2019) 28 Tobacco Control 101. Regarding alcohol see Alexander C Wagenaar, Matthew J Salois and Kelli A Komro, 'Effects of Beverage Alcohol Price and Tax Levels on Drinking: A Meta-Analysis of 1003 Estimates from 112 Studies' (2009) 104 Addiction 179; Robyn Burton and others, 'A Rapid Evidence Review of the Effectiveness and Cost-Effectiveness of Alcohol Control Policies: An English Perspective' (2017) 389 The Lancet 1558. Regarding food, see European Commission, 'Reviews of Scientific Evidence and Policies on Nutrition and Physical Activity - Objective Area A2: Effectiveness and Efficiency of Policies and Interventions on Diet and Physical Activity' (2018) 17-20, <https://data.europa.eu/doi/10.2875/337727> accessed 11/05/2023; Hunt Allcott, Benjamin B Lockwood and Dmitry Taubinsky, 'Should We Tax Sugar-Sweetened Beverages? An Overview of Theory and Evidence' (2019) 33 Journal of Economic Perspectives 202; Barry M Popkin and Shu Wen Ng, 'Sugar-Sweetened Beverage Taxes: Lessons to Date and the Future of Taxation' (2021) 18 PLOS Medicine e1003412.

[449] Stéphane Verguet, Patrick KA Kearns and Vaughan W Rees, 'Questioning the Regressivity of Tobacco Taxes: A Distributional Accounting Impact Model of Increased Tobacco Taxation' (2021) 30 Tobacco Control 245; Hunt Allcott, Benjamin B Lockwood and Dmitry Taubinsky, 'Regressive Sin Taxes, with an Application to the Optimal Soda Tax' (2019) 134 The Quarterly Journal of Economics 1557.

[450] The International Labour Organisation defines the just transition as 'greening the economy in a way that is as fair and inclusive as possible to everyone concerned, creating decent work opportunities and leaving no one behind': see <https://www.ilo.org/global/topics/green-jobs/WCMS_824102/lang--en/index.htm> accessed 11/05/2023.

[451] European Commission, 'The Just Transition Mechanism: making sure no one is left behind', <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/finance-and-green-deal/just-transition-mechanism_en#just-transition-fund> accessed 11/05/2023.

to drive behaviour change. There has been, over the last decades, a surge of interest for behaviourally informed regulation, 'the incorporation of behavioral insights into the design of legislative and regulatory policies',[452] including in the EU.[453] Advances in behavioural research 'teach us how neglecting these insights can cause public policies to fail in achieving intended effects and why paying more attention to them may provide the key for dealing effectively with main challenges facing modern social organizations'.[454]

The main findings of behavioural research relevant to public policy may be summarised in four statements, which are all, as previously discussed, highly relevant for lifestyle behaviours: 'i) humans display a tendency to inertia and procrastination; ii) they are very sensitive to how information is presented (framing); iii) as well as to social influences; and iv) humans do not handle probabilities very well'.[455] Hence, while behavioural insights may be applicable to a range of public policy areas, they are particularly pertinent to the field of lifestyles, where behaviour change is the main regulatory objective.[456] Smoke-free environments and their 'denormalising' effect, health warnings that remind people of their healthy commitments or advertising restrictions that limit inaccurate risk perception are all examples of behaviourally informed interventions applied to lifestyles.

Behaviourally informed regulation is often conflated with the concept of *nudging*,[457] although both terms are actually not interchangeable, the latter being a subset of the former.[458] Coined by Thaler and Sunstein, the term 'nudge' was originally used to refer to *'*any aspect of the

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[452] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 178.

[453] See Alemanno and Sibony, *Nudge and The Law* (n 53); Klaus Mathis and Avishalom Tor, *Nudging - Possibilities, Limitations and Applications in European Law and Economics* (Springer International Publishing 2016); Harry Bremmers and Kai Purnhagen, *Regulating and Managing Food Safety in the EU: A Legal-Economic Perspective* (Springer International Publishing 2018); Marianna Baggio and others, 'The Evolution of Behaviourally Informed Policy-Making in the EU' (2021) 28 Journal of European Public Policy 658.

[454] Pelle Guldborg Hansen, 'The Concepts of Nudge and Nudging in Behavioural Public Policy' in Straßheim and Beck, (n 353) 63.

[455] Anne-Lise Sibony and Alberto Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' in Alemanno and Sibony, *Nudge and The Law* (n 53) 3. These four elements are taken from Cass Sunstein, 'Empirically Informed Regulation' (2011) 78 University of Chicago Law Review 1349.

[456] Regarding the application of behavioural insights to health, and lifestyles in particular, see Jean-Frédérick Ménard, 'A "Nudge" for Public Health Ethics: Libertarian Paternalism as a Framework for Ethical Analysis of Public Health Interventions?' (2010) 3 Public Health Ethics 229; Theresa M Marteau and others, 'Judging Nudging: Can Nudging Improve Population Health?' (2011) 342 British Medical Journal 263; Jennifer S Blumenthal-Barby and Hadley Burroughs, 'Seeking Better Health Care Outcomes: The Ethics of Using the "Nudge"' (2012) 12 The American Journal of Bioethics 1; Muireann Quigley, 'Nudging for Health: On Public Policy and Designing Choice Architecture' (2013) 21 Medical Law Review 588; Ivo Vlaev and others, 'The Theory and Practice of "Nudging": Changing Health Behaviors' (2016) 76 Public Administration Review 550; Muireann Quigley, 'The Politics of Nudge and Framing Behaviour Change in Health' (n 353).

[457] Sibony and Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' (n 53) 2. This conflation appears for instance in Alberto Alemanno and Alessandro Spina, 'Nudging Legally: On the Checks and Balances of Behavioral Regulation' (2014) 12 International Journal of Constitutional Law 429; Cass R Sunstein, 'Nudges.Gov: Behaviorally Informed Regulation' in Zamir and Teichman, *The Oxford Handbook of Behavioral Economics and the Law* (n 313). See also, by way of illustration, the various works mentioned at n 456.

[458] Pelle Guldborg Hansen, 'The Concepts of Nudge and Nudging in Behavioural Public Policy' (n 454).

choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their economic incentives'.[459] The concept has been subsequently refined by a number of authors.[460] Nudges are interventions that find their *raison-d'être* and justification in the bounded rationality of people and the various behavioural phenomena previously described. Rather than trying to overcome a given cognitive bias present in the *nudgee*, a nudge exploits that bias to guide choices in the direction chosen by the *nudger*.

Default rules are a typical example of a nudge. Because humans display a tendency to inertia, 'the natural propensity […] to accept [one's] environment […] as a given rather than tak[ing] affirmative choices to change it, even when it would be in [one's] best interest to do so and even when it could be done fairly easily',[461] the choice of default options takes a particular importance. Hence, a restaurant could for instance decide to put salad as a default side dish – fries would only be served upon request of the clients – in the hope that a number of them will not request a different side dish when placing their order and will therefore end up eating the salad. In this situation, clients that eat the salad have been nudged. This also highlights a key aspect of nudging: the absence of any restriction on choice or economic incentive. At no point were clients prevented from ordering fries and no incentive was offered, like a two euros rebate on their bill, to convince them to choose the salad.

Hence, nudging 'actively seeks to exploit the same kind of irrational mechanisms that produce irrational behaviour'.[462] This is not the case of behaviourally informed regulation in general. Behavioural public policy 'should be seen as a pluralist, non-deterministic and multipurpose approach that allows the application of behavioural insights "throughout the policy process" and in combination with regulatory policies'.[463] Some behavioural interventions, referred to as 'debiasing', attempt to limit the impact that cognitive biases have on individuals rather than to change behaviour by relying on these biases.[464] Cooling-off periods may for instance be used to prevent impulsive purchases. These allow consumers to take time to reflect on their purchase without guiding them in any direction. Policies adopted to counter the exploitative practices of

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[459] Thaler and Sunstein (n 313) 6.

[460] See for instance the definition given by Hansen. 'A nudge is a function of (I) any attempt at influencing people's judgment, choice or behaviour in a predictable way, that is (1) made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making posing barriers for people to perform rationally in their own self-declared interests, and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of such attempts. Thus a nudge amongst other things works independently of: (i) forbidding or adding any rationally relevant choice options, (ii) changing incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth, or (iii) the provision of factual information and rational argumentation.': Pelle Guldborg Hansen, 'The Definition of Nudge and Libertarian Paternalism: Does the Hand Fit the Glove?' (2016) 7 European Journal of Risk Regulation 155, 20.

[461] Sibony and Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' (n 53) 3.

[462] ibid 72.

[463] Benjamin Ewert, 'Moving beyond the Obsession with Nudging Individual Behaviour: Towards a Broader Understanding of Behavioural Public Policy' (2020) 35 Public Policy and Administration 337.

[464] On the difference between nudging and debiasing, see Zamir and Teichman, *Behavioral Law and Economics* (n 110) 178. See also White (n 372) 142-145; Hansen, 'The Definition of Nudge and Libertarian Paternalism: Does the Hand Fit the Glove?' (n 460) 5; Hansen, 'The Concepts of Nudge and Nudging in Behavioural Public Policy' (n 454) 72.

private market actors, such as misleading promotional techniques, are often based on behavioural insights without necessarily being nudges.[465]

Behavioural insights have had a profound impact on information-related regulatory interventions. Information disclosure requirements, which usually befall the operator that markets a given product or service, are widely used across regulatory regimes. They function as a way to ensure transparency as to the composition and characteristics of a product or service and to educate consumers about the risks to health and safety associated with it. Such interventions are often based on the premise that poor choices are caused by a lack of knowledge which can be remedied by the provision of more or better information.[466] It suits particularly well those upholding the idea of a rational, information-savvy consumer and holding liberal views on public policy.[467]

Yet, '[t]he confrontation between behavioural insights and existing rules on disclosure leads to a simple conclusion: disclosure requirements are both prevalent in legal systems and remarkably ineffective'.[468] In *More Than You Wanted to Know*, Omri Ben-Shahar and Carl Schneider lay down various reasons for this ineffectiveness, which can be summarised in the following four statements.[469] First, disclosures put a misplaced emphasis on choice, where choosing is often difficult and time-consuming. People would rather not have to make certain choices or would prefer that others decide for them. Second, people often lack the literacy required to understand the information provided to them, both linguistically and numerically. Third, people suffer from an information overload. Each disclosure tends to give too much information in itself, while the total number of disclosures keep growing. Fourth, even information that is noticed and understood does not necessarily lead to behaviour change because, among other things, people may lack motivation to act upon it. These findings are of a particular importance in the EU context, where, as we shall see, legal actors have largely embraced the vision of a rational and diligent consumer, able to navigate its way around various pieces of information. By way of consequence, policymakers have often advocated for the use

[465] This is the rationale underpinning the Claims Regulation: Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (Claims Regulation) [2006] OJ L404/9. See below Chapter 6, Section 3.2.
[466] The European Commission makes for instance a particularly optimistic assumption in its impact assessment of EU nutrition labelling legislation, when assuming that 'the same proportion of customers who read the information are influenced in their dietary choices': see European Commission, 'Impact assessment report on nutrition labelling issues accompanying the document: Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers' (Food Information Regulation impact assessment) (Staff Working Document) SEC (2008) 94, 62.
[467] See White (n 372) 139-141.
[468] Sibony and Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' (n 53) 13. See also Omri Ben-Shahar and Carl E Schneider, *More Than You Wanted to Know: The Failure of Mandated Disclosure* (Princeton University Press 2014); Zamir and Teichman, *Behavioral Law and Economics* (n 110) 175.
[469] Ben-Shahar and Schneider (n 468).

of disclosures and other information-based policies.[470] Lifestyle health promotion makes no exception.

Rather than pleading for abandoning information requirements altogether, a substantial amount of research has focused on how to improve disclosures to allow consumers to better notice, understand and process information.[471] 'Given people's limited ability to grasp large quantities of complex information, disclosures should be timely, brief, salient, and graphic (where possible)', and should also not include complex language or be presented in small prints.[472] EU tobacco health warnings, which combine a clear and unambiguous message – 'smoking kills' – with graphic depictions of the consequences of smoking – e.g. a smoker's darkened lungs – are good examples of such 'smart' disclosures (see Chapter 6, Section 3.1.2).

Health warnings bring us to a last important dimension of behaviourally informed regulation, in its nudging form especially: ethics. If based on cognitive biases that are not consciously known by individuals, these interventions may be described as manipulative,[473] where manipulation is understood as influencing someone 'by bypassing their capacity for reason, either by exploiting nonrational elements of psychological makeup or by influencing choices in a way that is not obvious to the subject'.[474] In our previous example, the 'salad nudge' adopted by the restaurant would most likely work unconsciously for those who choose the salad, unaware that their choice has been influenced in a certain direction. This would not be the case if the menu clearly stated that choosing a salad was better for the clients' health, or if the restaurant offered a two euros rebate on the bill. To address this challenge, various frameworks to ensure sufficient transparency and democratic accountability of nudges have been proposed in the literature.[475]

7. Conclusion

Tobacco and alcohol consumption, unhealthy diets, illicit drug use and gambling are lifestyles that expose individuals to a range of health risks, in the form of non-communicable diseases in particular. Embedded in an increasingly globalised net of economic relationships, lifestyle

[470] For an introduction to the EU 'information paradigm', see Anne-Lise Sibony and Geneviève Helleringer, 'EU Consumer Protection and Behavioural Sciences: Revolution or Reform?' in Alemanno and Sibony, *Nudge and The Law* (n 53) 214; Geneviève Helleringer and Anne-Lise Sibony, 'European Consumer Protection Through The Behavioral Lens' (2017) 23 Columbia Journal of European Law 607, 623–624.
[471] See Sibony and Alemanno, 'The Emergence of Behavioural Policy-Making: A European Perspective' (n 53) 13-14; Helleringer and Sibony (n 470).
[472] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 173. See also Cass Sunstein, 'Empirically Informed Regulation (n 455) 1344-1345.
[473] Luc Bovens, 'The Ethics of Nudge' in Mats J Hansson and Till Grüne-Yanoff (eds), *Preference Change: Approaches from Philosophy, Economics and Psychology* (Springer 2008); Blumenthal-Barby and Burroughs (n 456) ; Pelle Guldborg Hansen and Andreas Maaløe Jespersen, 'Nudge and the Manipulation of Choice' (2013) 4 European Journal of Risk Regulation 3; Alemanno and Spina (n 457).
[474] Blumenthal-Barby and Burroughs (n 456) 5.
[475] Blumenthal-Barby and Burroughs (n 456); Hansen and Jespersen (n 473); Alemanno and Spina (n 457). See also Cass R Sunstein, Lucia A Reisch, *Trusting Nudges: Toward A Bill of Rights for Nudging* (Routledge 2019).

behaviours shape societies and define social groups in distinctive ways. What is considered as an intolerable deviance by some may be regarded as a valuable practice by others.

Managing lifestyle risks requires to navigate these different dimensions and to arbitrate between the different values and interests present in society. The range of tools available to the regulator reflects this complexity. Different interventions may be selected, which put more or less constrains on individuals and economic operators. Any regulatory regime expresses a different compromise in this regard. Yet, lifestyle risks raise specific questions if compared to other publicly regulated risks, due in particular to the strong behavioural aspect of the risk control measures adopted and their ethical implications.

Bearing these elements in mind, the next chapter investigates the mandate bestowed upon the EU to regulate lifestyles and the powers attributed to it in this regard. It introduces the reader to the two objectives of EU regulation of lifestyle risks, protecting public health and ensuring the establishment and functioning of an internal market where commodities, persons and services circulate freely. The interactions between these two objectives constitute the guiding thread of this thesis.

Chapter 2

Regulating lifestyle risks in EU law: between health and the internal market

1. Introduction

While recognising 'the primary role and responsibility of Governments in responding to the challenge of non-communicable diseases', the UN Political Declaration on NCDs also stresses 'the important role of the international community and international cooperation in assisting Member States, particularly developing countries, in complementing national efforts to generate an effective response'.[476] It insists that action should be undertaken at all possible levels, 'local, national, regional, and global'.[477] Each of these levels has indeed a contribution to make. Some aspects of the regulation of lifestyle risks are inherently local, if a city wants for instance to revise its urban mobility scheme to favour physical activity, some others have global ramifications, such as the impact of the world trade regime on the supply of ultra-processed and unhealthy foods.

As a supranational polity of conferred powers,[478] the European Union acts on the basis of a delineated mandate, under the condition that its activity brings added value if compared to that of its Member States acting alone. This is not only a reflection of the principle of subsidiarity[479] but also derives from the federal nature of the Union.[480] Federalism operates from the assumption that action at the local level is preferable and is transferred upward only where necessary to achieve a certain objective.[481] A number of arguments can be put forward to defend this division of powers, usually built on ideas of effectiveness and legitimacy. Local government may be more effective, as public authorities have better knowledge of and expertise on local circumstances. It may also be seen as more legitimate, bringing citizens closer to the exercise of power and allowing for a better reflection of differences in policy preferences among people(s).[482] These concerns apply to all areas of government action but appear particularly pertinent as regards lifestyle risks, where practices are often defined along national or subnational lines, where the nature of the public health problem differs from one

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[476] United Nations General Assembly (n 6), paras 3-4.
[477] ibid, para 33.
[478] Article 5(2) TFEU.
[479] Article 5(3) TFEU.
[480] On the link between subsidiarity and federalism, see Robert Schütze, 'Subsidiarity after Lisbon: Reinforcing the Safeguards of Federalism?' (2009) 68 The Cambridge Law Journal 525; Xavier Groussot and Sanja Bogojević, 'Subsidiarity as a Procedural Safeguard of Federalism' in Loïc Azoulai (ed), *The Question of Competence in the European Union* (Oxford University Press 2014).
[481] Daniel Halberstam, 'Federalism: Theory, Policy, Law' in Michel Rosenfeld and Andras Sajo (eds), *The Oxford Handbook of Comparative Constitutional Law* (Oxford University Press 2012).
[482] See ibid; Roger Van den Bergh, 'Farewell Utopia? Why the European Union Should Take the Economics of Federalism Seriously' (2016) 23 Maastricht Journal of European and Comparative Law 937; Michael Faure, 'The Economics of Harmonization of Food Law in the EU' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing 2018).

State to the other, and where attitudes towards government intervention may vary.[483] Cultural differences in human behaviour and relationship to risk may warrant to adopt different risk management strategies.[484] More generally, health is one of the core interests protected by modern national welfare systems. The provision of healthcare is often seen as constituting a specific duty of States towards their population[485] and the EU lacks the institutional and financial capacity to deal with health issues.[486] From these different perspectives, there would hence be many good reasons justifying that lifestyle risks remain largely regulated at the State or local level.

Conversely, a number of arguments can be made to support EU action in the field, explaining why it got involved in the first place and why its contribution remains useful and necessary. These arguments are however too rarely laid out.[487] This is not only the case regarding lifestyle risks but is true of EU regulation in general. As Azoulai rightly puts it:

> The current legal and political discourse lacks a set of clear justifications for engaging in this [regulation], as well as a set of criteria to measure the appropriateness of the justification in each individual case. The arguments used or implied in the current practice are often not clearly identified and remain under-debated.[488]

Although the present thesis will not examine the appropriateness of EU lifestyle risks regulation 'in each individual case', this chapter aims at identifying 'a set of clear justifications' for engaging in it. This exercise serves two main purposes. It allows to better understand the form taken by the EU regulatory regime, why in particular specific powers have been granted to the EU to regulate lifestyle risks and why certain regulatory interventions have been preferred over others. It may also help increasing the legitimacy of EU action in a field where, as discussed in the previous chapter, the use of public powers remains controversial.

This chapter's main contention is that EU regulation of lifestyle risks can be explained and justified by two main rationales. A first one, historically and conceptually predominant, is that of contributing to the establishment of the EU internal market, which requires to address the externalities of Member State lifestyle risks policies and their restrictive effect on the free movement of goods, services, and people. A second one is centred around health as a standalone value. Promoting good health becomes an objective so important that it justifies for Member States to lose part of their autonomy as regards lifestyle risks regulation.

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[483] See Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 54.
[484] Regarding individual and cultural differences in human behaviour, see Breakwell (n 13) 52-84; Zamir and Teichman, *Behavioral Law and Economics* (n 110) 111-114 and 124-127.
[485] Brooks and de Ruijter (n 24) 106; Scott L Greer, 'Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union' (2021) 16 Health Economics, Policy and Law 90.
[486] Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 54; Greer, 'Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union' (n 485).
[487] A notable exception is Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 55-57
[488] Loïc Azoulai, 'The Complex Weave of Harmonization' in Anthony Arnull and Damian Chalmers (eds), *The Oxford Handbook of European Union Law* (Oxford University Press 2015) 599.

Both rationales carry a normative and a descriptive value. They provide a justification as to why the EU should be involved in lifestyles, the extent of which may be discussed. In addition, they are reflected in the EU's current doings, as will be shown throughout the thesis. Both coexist under the Union constitutional framework of competences and EU powers in lifestyle risks regulation derive from these two objectives: promoting health and ensuring the functioning of the internal market. Although these objectives may be pursued simultaneously and harmoniously, their interplay has given rise to a number of legal difficulties. Some of these difficulties are addressed in this chapter, such as the interplay between the internal market and health legal bases. A number of others are addressed later in the thesis, in Chapter 7 in particular.

2. Rationales for EU lifestyle risks regulation

2.1. Transboundary effects: the spill over of free movement

One of the arguments most frequently advanced to justify the exercise of power at the federal or central level rather than the national or local level is the existence of transboundary effects or externalities resulting from government action or inaction, which may render local regulation ineffective or deter local institutions from acting.[489] A good example is climate change.[490] The rejection of greenhouse gases in the atmosphere and the resulting rise in temperatures, among other negative consequences, affect the entire planet, even though most of the carbon dioxide and other gases emissions originate from a limited number of industrialised countries. In this case, action at the national level alone is insufficient and countries may be tempted to free ride on the efforts of others so as to reap the benefits of lower emissions without affecting the functioning of their economies. From this perspective, climate action at the EU level appears thus relatively uncontroversial. Many other contemporary risks are global in nature and require transnational cooperation to be addressed. This is the case, in public health matters, of communicable diseases. As pathogenic agents spread across borders, unilateral action is unlikely to be sufficient to control the diffusion of a disease and decisions taken in one jurisdiction may have significant consequences in others. It is thus unsurprising that '[i]nfectious disease was the founding catalyst of global health governance'.[491] The Covid-19 pandemic has provided a good illustration of this and may represent a 'founding catalyst' of a strengthened EU health governance, or, even, of a European Health Union.[492]

Conversely, it is less clear why the EU should deal with a localised form of pollution or any risk that has a strictly national relevance. Contrary to *communicable* diseases, the regulation of

[489] Faure (n 482) 267-268; Roger Van den Bergh, 'Farewell Utopia? Why the European Union Should Take the Economics of Federalism Seriously' (n 482) 941; see also Azoulai, 'The Complex Weave of Harmonization' (n 488) 599; Halberstam (n 481) 589-590.
[490] Van den Bergh, 'Farewell Utopia? Why the European Union Should Take the Economics of Federalism Seriously' (n 482) 951.
[491] Brooks and Ruijter (n 24) 106.
[492] Alberto Alemanno, 'Towards a European Health Union: Time to Level Up' (2020) 11 European Journal of Risk Regulation 721; Ilona Kickbusch and Anniek de Ruijter, 'How a European Health Union Can Strengthen Global Health' (2021) 1 The Lancet Regional Health - Europe 100025.

risks linked to *non-communicable* diseases appears prima facie to be devoid of any significant transboundary effects. The damages caused by hazardous lifestyles are inherently local in nature, limited to the individual and its surroundings, and a country's decision as regards the level of control to be attained remains largely unaffected by that of its neighbours. Conducting fully autonomous tobacco or alcohol policies at the national level does not create any major difficulty, as far as health is concerned, unlike it is the case for highly infectious diseases. As Member States remain in charge of healthcare systems and bear the costs associated with it, there is also a certain logic and coherence in entrusting them with disease prevention.

If looking beyond health, however, what connects States is the tradable nature of the products or services associated with non-communicable diseases. Trade in hazardous goods disseminates the risk. For a State, accepting that such goods enter its market means exposing its population to this risk, potentially in a less regulated form. Conversely, diverging national health standards may constitute impediments to cross-border trade, usually in the form of non-tariff barriers, as economic operators have to comply with different sets of rules and may not freely import or export goods or services that do not conform with them.[493] In the case of a ban, trade is simply made impossible. Validating or eliminating these barriers to trade requires supranational action, which will have a bearing on national lifestyle risks regulatory regimes.

Risk regulation is, in general, of utmost importance for supranational trade regimes.[494] Through free movement and the internal market, the EU has progressively been led to intervene in lifestyle risks matters. This dynamic has particularly been at play, as will appear from the next chapters, as regards alcohol and other food products. While 'not originally foreseen in the founding Treaty, today the most important and widespread form of EU regulation in the internal market is concerned with the government of risk[s]'.[495] Those arising from unhealthy lifestyles, but also those associated with unsafe food or unsafe products, with the use of GMOs, or with medicines and medical devices. The internal market has been the main driver to the emergence of EU risk policy and regulation.[496]

From this market perspective, supranational involvement is gradual. As a first step, in the absence of common rules, national rules restricting trade may be scrutinised and set aside if they do not prove to be useful for the protection of human health or if the standards applicable in different jurisdictions are given recognition beyond national borders. In the latter case however, forcing States to recognise laxer foreign standards may affect the level of public health protection and lead to a 'race to the bottom'.[497] To enable cross-border trade without undermining the control of the risks associated with unhealthy commodities, States may decide, as a second step, to adopt common rules at the supranational level, ensuring a level-playing

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[493] Hood, Rothstein and Baldwin (n 100) 6.
[494] See Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (n 40).
[495] Alberto Alemanno, 'The Shaping of European Risk Regulation by Community Courts' (2009) Jean Monnet Working Paper 18/08, 4.
[496] Weimer, *Risk Regulation in the Internal Market* (n 2) 48. See also Christian Joerges, 'Sound science in the European and global market: Karl Polanyi in Geneva' in Ellen Vos and Michelle Everson (eds), *Uncertain risks regulated* (Routledge-Cavendish 2009) 415.
[497] Faure (n 482) 270-273; Halberstam (n 481) 590-591; see also Van den Bergh, 'Farewell Utopia? Why the European Union Should Take the Economics of Federalism Seriously' (n 482) 943.

field for economic operators and a certain degree of control over regulatory choices. The regulatory competence is progressively transferred to the supranational level, although it derives primarily from a commitment to the free circulation of products and services. These two modes of economic regulation, the elimination of barriers to trade via the disapplication of national rules on the one hand and the harmonisation of national standards on the other, are central to EU lifestyle risks regulation and form the bedrock of the present thesis.

The free movement of people may also give rise to transboundary effects, triggering a need for common action. The link between the free movement of people and Union action in health has most often been made as regards communicable diseases. The progressive abolition of borders in Europe and the resulting increase in the mobility of people has increased the opportunity for the spread of infectious diseases.[498] This is one of the reasons motivating the adoption by the Union of a programme of action to tackle the AIDS epidemic in the 1990s.[499] More recently, the restrictive effect of uncoordinated national responses to the Covid-19 pandemic has prompted the Union to act to preserve the free movement of people.[500]

People suffering from cancer or diabetes cannot infect others but the cross-border movement of people may affect national action in other ways. Individuals may for instance take advantage of open borders to acquire products in countries where less stringent public health measures apply. The incentive is particularly strong if a given product cannot be sold in one's home country but is available abroad, or if there is a significant price difference between two legally accessible products. In a small country where most of the population lives close to a border, lifestyle control measures can thus easily be circumvented, which may deter that country from adopting a stricter health policy or undermine its effectiveness.

European border regions are all too familiar with this problem. Shortly after its accession to the EU in 1995, Sweden experienced a drastic increase in cross-border shopping for alcohol, its population taking advantage of the laxer rules and lower prices in place in neighbouring countries. The liberalisation of cross-border movements risked undermining the Swedish effort to limit the consumption of alcoholic beverages.[501] Another example is the Danish fat tax of 2011, repealed a bit more than a year after its adoption, on grounds, among other reasons, of

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[498] Elias Mossialos and others, 'Health Systems Governance in Europe: The Role of European Union Law and Policy' in Mossialos and others, *Health Systems Governance in Europe: The Role of European Union Law and Policy* (n 37) 53.

[499] Sébastien Guigner, 'La Dynamique d'Intégration par Sédimentation: Retour sur l'Inscription de la Santé dans les Compétences de l'Union' in Estelle Brosset (ed), *Droit Européen et Protection de la Santé – Bilan et Perspectives* (Bruylant 2015) 51; see Decision 91/317/EEC of the Council and the Ministers for Health of the Member States, meeting within the Council of 4 June 1991 adopting a plan of action in the framework of the 1991 to 1993 'Europe against AIDS' programme [1991] OJ L175/26.

[500] See in that regard Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic [2021] OJ L211/1.

[501] Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 74 and 81. A similar phenomenon took place in Finland, see Case C-394/97 *Heinonen* [1999] EU:C:1999:308, para 18.

an alleged increase in the cross-border purchases of butter and other high-saturated fat products from Germany to Sweden.[502]

As regards illicit drug trafficking, the Schengen system 'can be viewed as a compensation for freedom: the abolition of internal frontiers (including physical frontiers) among the participating states would be combined with further integration between these states in the fields of immigration and criminal law'.[503] It was important for Member States, prior to liberalising the cross-border movement of people, which would facilitate illicit drug trafficking, to ensure that such activity was effectively criminalised and to set up mechanisms for police and justice cooperation between Member States.

Interestingly enough, the free movement of people also affects national health policy on communicable diseases in a comparable way. Where measures differ between two countries – one would require all shops to be closed to stop the spread of a virus while the other one would only decide to put a cap on the number of people that can be simultaneously present in a closed environment – the population of the first country may decide to go shopping in the second country, leading to an influx of people which risks undermining the effectiveness of the latter country's policy. Such cross-border movements have been witnessed during the Covid-19 pandemic.[504] If one is to preserve the free movement of people and the possibility to engage in unrestricted cross-border shopping without undermining the level of health protection, a certain degree of coordination or harmonisation of national policies is necessary.

Under this approach, EU health law and policy may very well be limited to issues involving a cross-border dimension. This is what the 2007 White Paper 'Together for Health' alluded to when stating that:

> Member States have the *main responsibility* for health policy and provision of healthcare to European citizens. [The EU's] role is not to mirror or duplicate their work. However, there are areas where Member States cannot act alone effectively and where cooperative action at [Union] level is indispensable. These include major health threats and *issues with a crossborder or international impact*, such as pandemics and bioterrorism, *as well as those relating to free movement of goods, services and people*.[505]

2.2. Promoting good health among Europeans

Where no transboundary effects are present, it is possible to conduct a lifestyle risks policy at national level that is both effective and adapted to local circumstances and preferences. It is

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[502] Sinne Smed and others, 'The Effects of the Danish Saturated Fat Tax on Food and Nutrient Intake and Modelled Health Outcomes: An Econometric and Comparative Risk Assessment Evaluation' (2016) 70 European Journal of Clinical Nutrition 681, 685; Signild Vallgårda, Lotte Holm and Jorgen D Jensen, 'The Danish Tax on Saturated Fat: Why It Did Not Survive' (2015) 69 European Journal of Clinical Nutrition 223, 225.
[503] Valsamis Mitsilegas, *EU Criminal Law* (Hart Publishing 2009) 7.
[504] Alessio M Pacces and Maria Weimer, 'From Diversity to Coordination: A European Approach to COVID-19' (2020) 11 European Journal of Risk Regulation 283, 287.
[505] European Commission, 'Together for Health: A Strategic Approach for the EU 2008-2013' COM (2007) 630 final, 2, emphasis added.

hard to see, for instance, how enacting a local smoking ban in cafés and restaurants or a prohibition of alcohol consumption in outdoor public spaces would affect in any way free movement and the capacity of another jurisdiction to adopt similar policies, or to refrain from doing so. On all such issues, there would be a certain logic in leaving regulatory choice to the national level. Yet, even in this context, various reasons may be identified that would warrant action at the supranational level. As regards the EU, three appear particularly pertinent.

Good health may be considered so important as a value that it justifies trumping regulatory diversity, because a low standard of protection contradicts 'widely held perceptions of human rights' or simply for reason of 'equity, justice or pure paternalism'.[506] In that regard, the right to health fulfils an important function for the EU, not only as a source of legal obligations, as we shall see throughout this work, but as an overarching norm justifying to enact protective measures at the Union level. As will be discussed in the next section, 'the protection and improvement of human health [can] be viewed as a fundamental right in itself'.[507] A raison d'être for EU supranational integration may be found in the protection of fundamental rights,[508] considering especially that the burden of NCDs and other damaging health consequences arising from lifestyles is unevenly distributed both within and between Member States.[509] In a country where no rules regulating indoor smoking are in place, hence exposing the population to second-hand smoke, one could argue that this constitutes an infringement on the rights of non-smokers to live in a clean, non-harmful environment. Granting supranational bodies with an oversight on fundamental rights may appear as necessary so that the population of States which fail to adequately protect these rights are not left without remedies.

Economically speaking, promoting good health is also a sound investment for governments. Preventive action on NCDs constitutes an efficient way to reduce the significant financial burden that these diseases impose on national healthcare systems and the broader costs to

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[506] Faure (n 482) 277.

[507] de Ruijter (n 47) 19. In its Political Declaration on NCDs, the UN General Assembly reaffirms 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health': United Nations General Assembly (n 6), para 5. On the right to health in general, see Jean McHale, 'Fundamental Rights and Health Care' in Mossialos and others, *Health Systems Governance in Europe : The Role of EU Law and Policy* (n 37); Antoine Bailleux, 'L'Apport de la Charte des Droits Fondamentaux de l'Union Européenne au "Droit" à la Santé' in Brosset, *Droit Européen et Protection de la Santé – Bilan et Perspectives* (n 499); Hervey and McHale (n 37) 156-183; Calum Alasdair Young, 'Fundamental Rights and EU Health Law and Policy' in Hervey, Alasdair Young and Bishop (n 37). As regards lifestyle risks and NCDs, see Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1783-1784; Marie Elske Gispen and Brigit Toebes (eds), *Human Rights and Tobacco Control* (Edward Elgar Publishing 2020).

[508] de Ruijter (n 47) 18.

[509] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1783.

society incurred.[510] Under this 'health is wealth' approach, the positive contribution that a healthy population makes to the economy is underlined:[511]

> *Cost-effective and efficient health spending is a productive or growth-friendly type of expenditure*. It helps increase the economy's production assets (labour, capital and knowledge). It increases the quantity and the productivity of labour by increasing healthy life expectancy. […] Investing in health also helps limit future costs related to the treatment of preventable diseases. And finally, investing in health also means investing in an efficient health workforce.[512]

Health promotion is not only a way to save government revenue but also to increase it, by allowing people to live longer and more productive lives.[513] Although this vision of health may appear of a lesser worth than that focusing on the value of health per se for human flourishing, it is definitely an important dimension for the EU. The EU is not only made of an internal market but of an Economic and Monetary Union imposing on Member States to coordinate their economic policies and to follow a number of budgetary rules.[514] In the aftermath of the 2008 financial and sovereign debts crisis, the EU considerably strengthened its fiscal and economic governance instruments, so much that it was said that austerity represented the third face of EU health policy.[515] In the words of former Director-General for Health and Food Safety Anne Bucher, one 'cannot imagine a cycle of economic, fiscal and social policy coordination without health policy, which supports longer and productive working lives and aims to make essential healthcare accessible for all'.[516]

Finally, for the EU, acting in health matters may also have a strategic appeal, contributing to improving its image and increasing its legitimacy in the eyes of the public.[517] This is especially

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[510] Considering on the one hand the premature deaths linked to lifestyle consumptions and the related savings in pensions and other public expenditures for the State, and on the other hand the public revenue arising from taxes on unhealthy products or services, one may legitimately wonder whether governments do not ultimately benefit from the lifestyle health burden. This idea has been refuted on a number of occasions. As regards tobacco globally, see US National Cancer Institute and World Health Organization, 'The Economics of Tobacco and Tobacco Control' (2017) NCI Tobacco Control Monograph Series 21. On drugs in general in the French context (including tobacco, alcohol and illicit drug), see Pierre Kopp, 'Le Coût Social des Drogues en France' (2015) Note 2015-04, <https://www.ofdt.fr/BDD/publications/docs/eisxpkv9.pdf#page=6> accessed 11/05/2023.

[511] Sébastien Guigner, 'De « La Santé dans Toutes les Politiques » à « Toutes les Politiques dans la Santé » : le Régime de Visibilité de la Prise en Compte de la Santé dans les Politiques de l'Union Européenne' (2016) 34 Sciences Sociales et santé 71, 71-79.

[512] European Commission, 'Investing in Health' (Staff Working Document) SWD (2013) 43 final, 11, emphasis added.

[513] See above (n 510).

[514] See art 5 TFEU.

[515] See Scott L Greer, The Three Faces of European Union Health Policy: Policy, Markets, and Austerity' (2014) 33 Policy and Society 13. See also Greer, 'Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union' (n 485) 94-96.

[516] European Commission, '*European Semester: Health reforms need to continue'* (2019) Health-EU newsletter 236 – Focus, <https://ec.europa.eu/health/eunewsletter/236/newsletter_en> accessed 11/05/2023.

[517] Guigner, 'De « La Santé dans Toutes les Politiques » à « Toutes les Politiques dans la Santé » : le Régime de Visibilité de la Prise en Compte de la Santé dans les Politiques de l'Union Européenne' (n 511). See also Somek (n 57) 12: 'For an organization such as the European Union that notoriously lacks appeal to ordinary people, posturing as being concerned about the well-being of citizens plays part of a strategy to look "nice"'.

pertinent for the EU, which is often criticised for being too 'economic' and too remote from citizens' concerns. As said by former EU Commissioner for Health David Byrne:

> Health is a preoccupation of Europeans. We need to get it right on health, if we are to get it right on a new Europe that means something to our citizens. […] Indeed our citizens are telling us that the European Union should not only be preoccupied with better markets, predictable rules, stable international relations, sustainable jobs and public finances. They are telling us that there can be no Europe without a Europe of Health.[518]

This concern for EU's image and appeal was behind the launch of a European programme against cancer,[519] one of the first public health policies devised at the Union level. Amidst the budgetary crisis of the mid-1980s, at a time when the European integration process had come to a stalemate, this programme was considered as way to bridge the gap existing between the EU and its citizens and to improve the EU's image. The then French President François Mitterrand was especially vocal in pushing for a 'People's Europe', a plan to reinforce the legitimacy of European integration by responding 'to the expectations of the people of Europe by adopting measures to strengthen and promote its identity and its image both for its citizens and for the rest of the world'.[520] This resulted in the adoption of the first EU measures in the field of tobacco, which represented a significant improvement for some of the Member States that had no such rule in place at the time.

This shows that, although the internal market has been the driving force behind the emergence of EU lifestyle risks regulation, EU involvement also proceeded early from non-market considerations. Health objectives have been progressively incorporated into the regulation of the EU internal market.

> [W]hilst initially [internal market] legislations were for the most part concerned with "product regulation," and were justified by the need to prevent obstacles (nontariff barriers) to the free movement of goods deriving from regulatory diversity, successive legislations have been increasingly focused on "process regulation" (emission quality standards, maximum exposure levels, maximum residue limits of veterinary medicinal products, food production requirements, etc.), and thus aimed overtly at "protection" goals rather than free movement objectives.[521]

As we shall see in Chapter 5 and 6, such a dynamic has been at play in the emergence and development of EU lifestyle risks policy. This policy blends health and market objectives with, arguably, protection goals being increasingly overtly put first.

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[518] David Byrne, 'Future priorities in EU health policies' (2002) Speech at the European Health Forum Gastein, <https://ec.europa.eu/commission/presscorner/api/files/document/print/en/speech_02_426/SPEECH_02_426_EN.pdf> accessed 11/05/2023.

[519] Council of the European Union, Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council of 7 July 1986, on a programme of action of the European Communities against cancer [1986] OJ C184/19.

[520] European Council, Fontainebleau 25-26 June 1984, Conclusions of the Presidency, 8. See Guigner, 'La Dynamique d'Intégration par Sédimentation: Retour sur l'Inscription de la Santé dans les Compétences de l'Union' (n 499) 38-43; de Ruijter (n 47) 72.

[521] Alberto Alemanno, 'Regulating the European Risk Society', in Alberto Alemanno and others (eds), *Better Business Regulation in a Risk Society* (Springer New York 2013) 39.

3. EU competence to regulate lifestyle risks

To the dual market and health rationale behind EU involvement in lifestyle risks regulation corresponds a dual set of competences under the EU Treaties. Schematically speaking, while some of EU powers as regards lifestyle risks derive from its commitment to free movement and the establishment and functioning of the internal market, others proceed from the objective of ensuring that a high level of health protection is ensured in the EU. This results in a fragmented legal landscape, a characteristic which is true of EU health law in general.[522] Identifying the relevant competence framework in the field of lifestyle risks requires to go beyond the simple 'health' label.

The protection of human health is one of the EU's fundamental objectives. EU competence in public health is wide in scope and covers, implicitly or explicitly, all aspects of the regulation of lifestyle-related health risks. The EU is empowered to devise a health promotion policy aimed at diminishing the prevalence of unhealthy lifestyles in the European population. Yet, this broad and clear mandate is not matched with corresponding legislative powers, which would allow the EU to adopt direct harmonisation measures in that field.

As regards free movement and the internal market, the situation is almost reversed. The Union has been granted with broad powers, both to strike down national rules that impair free movement and to adopt harmonisation measures providing for a level-playing field for economic operators. These powers are however narrower in scope, as they only allow the EU to regulate lifestyle risks, directly or indirectly,[523] to the extent that it benefits the free movement of goods, services, or people. Further, the apparent contradiction between what the EU can undertake under its internal market competence and what it is prevented to do under its public health competence leads to problems of clarity and legitimacy of Union action.

3.1. Health: an important objective with constrained powers

The protection of human health is one of the core objectives of the European Union. According to Article 3 TEU, '[t]he Union's aim is to promote peace, its values and the *well-being* of its peoples'.[524] Further, pursuant to Article 9 TFEU, '[i]n defining and implementing its policies

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[522] See Tamara K Hervey and Bart Van Hercke, 'Health care and the EU: the law and policy patchwork' in Mossialos and others, *Health Systems Governance in Europe : The Role of EU Law and Policy* (n 37) 84-133; Hervey and McHale (n 37) 30-70.

[523] Direct regulation refers to acts adopted by the EU institutions in the field of lifestyle risks while indirect regulation refers to the effect of free movement provisions on Member States' capacity to conduct their lifestyle risks policy. Both types of EU interventions are important from the perspective of risk regulation, as they shape the regulatory environment within which lifestyle behaviours occur. Further, '[b]oth what EU law allows itself, and what it prevents in Member States, are part of the division of powers': Gareth Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' in Sacha Garben and Inge Govaere (eds), *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future* (Hart Publishing 2017) 76.

[524] Emphasis added. Although the objectives contained in Article 3 TEU do not have an independent function in the EU legal order – they do not impose legal obligations on Member States or confer rights on individuals – this does not mean that they are devoid of any legal effect. They are particularly relevant 'for the interpretation of the

and activities, the Union *shall take into account* requirements linked to the promotion of a high level of […] human health',[525] an obligation reiterated and reinforced in Article 168(1) TFEU and Article 35 of the Charter of Fundamental Rights of the European Union (CFR or 'the Charter'), under which '[a] high level of human health protection *shall be ensured* in the definition and implementation of all Union policies and activities'.[526]

These various horizontal clauses reflect an 'health in all policies' approach to policymaking, meaning 'the recognition that a broader range of factors, other than those traditionally addressed within the "health" field, affect population health'.[527] While not being specific to it, this commitment is of particular importance for the EU, whose action follows a competence catalogue which cannot fully reflect the plurality of social phenomena.[528] Health may be affected by other policies pursing other objectives, which should also contribute to the general objective of human health protection.

The precise meaning of the mainstreaming obligation contained in Articles 9 and 168(1) TFEU and Article 35 of the Charter remains somewhat unclear and open to different interpretations.[529] It can be construed as requiring the EU to take positive action to address the causes of ill-health, including lifestyle risk factors,[530] and as preventing any backsliding from taking place, whereby the EU would adopt measures lowering the level of protection previously reached.[531] The reference to a 'high level' does not entail an obligation for the EU to reach the highest level of protection that is technically possible to attain.[532] The EU legislator keeps a margin of discretion in this regard. These three provisions can be relied upon in court, as tools to defend EU action against legal challenges or, on the contrary, so as to challenge an EU provision that would contradict the objective of reaching a high level of public health protection, although

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Treaty provisions that are intended to give effect to them'. See Marcus Klamert, 'Article 3 TEU', in Manuel Kellerbauer, Marcus Klamert and Jonathan Tomkin (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (Oxford University Press 2019) 32.

[525] Emphasis added.

[526] Emphasis added.

[527] Oliver Bartlett and Anja Naumann, 'Reinterpreting the Health in All Policies Obligation in Article 168 TFEU: The First Step towards Making Enforcement a Realistic Prospect' (2021) 16 Health Economics, Policy and Law 8, 8.

[528] The Union competence framework is based on categories of competences corresponding to different policy areas. Under Article 2 TFEU, the EU is granted with three main categories of competences, exclusive, shared and 'complementary', to which correspond different legislative powers and a different pre-emptive effect on the competence of Member States.

[529] Bartlett and Naumann (n 527) 12–16.

[530] de Ruijter (n 47) 40-41; Alasdair Young (n 507) 90-91. This can also be inferred from other internationally recognised rights to health, such as Article 11 of the European Social Charter and Article 25 of the Universal Declaration of Human Rights.

[531] See Bailleux (n 507) 127-128; Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 15.

[532] Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 14; Estelle Brosset 'Article 35. Protection de la santé' in Fabrice Picod, Cecilia Rizcallah and Sébastien Van Drooghenbroeck, *Charte des Droits Fondamentaux de l'Union Européenne : Commentaire Article par Article* (Bruylant 2019).

the potentialities appear limited as regards the latter.[533] The reference to the health mainstreaming obligation in Article 35 CFR, which is most often referred to as the 'right to health' in an EU law context, may give further symbolic importance to this obligation but it is doubtful that it confers greater legal value.[534]

Health has a 'mixed competence structure' under the TFEU.[535] Article 6(a) TFEU grants a competence to the Union to carry out actions to support, coordinate or supplement the actions of the Member States as regards the 'protection and improvement of human health'. Under Article 4(2) (k), the Union also shares competence with the Member States in the area of 'common safety concerns in public health matters'. These do not however include aspects related to health promotion and lifestyles.[536] No authoritative legal text defines health under EU law.[537] According to Anniek de Ruijter:

> [T]he concept of human health in the EU policy and legal context refers to the normal functioning of the (human) species and also to a more subjective expression of a (social) state of physical and mental well-being, depending on individual and social (national) backgrounds.[538]

This definition is close to that given by the WHO, which, although not directly applicable under EU law, finds its way in the Union legal order through the European Social Charter of the Council of Europe.[539] Regardless of the definition chosen, there is little doubt that lifestyle health promotion falls within the scope of the 'protection and improvement of human health'.

Article 168 TFEU is the specific 'public health' legal basis contained in the TFEU. It lays down the objectives of EU health policy and the specific powers granted to the Union to achieve these objectives. It should be borne in mind that 'public health' and 'human health' have the same meaning under EU law and can be used interchangeably,[540] both referring to the above definition of health. According to Article 168(1):

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[533] Bartlett and Naumann (n 527).
[534] Hervey and McHale (n 37) 182–183. This is reinforced by the fact that Article 35 CFR should be classified as a 'principle' and not a 'right' under the Charter: see art 52 CFR. In this regard, see Bailleux (n 507) 122. See also the Explanations relating to the Charter of Fundamental Rights on Article 35, mentioning the '*principles* set out in this Article', emphasis added: Explanations relating to the Charter of Fundamental Rights [2007] OJ C303/17.
[535] Garben, 'Article 168 TFEU' in Kellerbauer, Klamert and Tomkin (n 524) 1448.
[536] This concerns '(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives', '(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health' and '(c) measures setting high standards of quality and safety for medicinal products and devices for medical use': art 168(4) TFEU.
[537] de Ruijter (n 47) 53.
[538] ibid 57-58.
[539] Bartlett and Naumann (n 527) 12. Although the EU is not a party to the European Social Charter (ESC), Article 35 of the Charter of Fundamental Rights of the European Union must be interpreted in light of Articles 11 and 13 of the ESC: see the Explanations relating to the Charter of Fundamental Rights. Under the ESC, 'health means physical and mental well-being, in accordance with the definition of health in the Constitution of the World Health Organisation (WHO)': Council of Europe, *European Social Charter Collected Texts* (7th edition, Council of Europe 2015) 240, 295.
[540] de Ruijter (n 47) 55. This appears clearly from the various judgements analysed in Chapter 4.

> Union action, which shall complement national policies, shall be directed towards improving public health, *preventing physical and mental illness and diseases*, and *obviating sources of danger to physical and mental health*. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their *prevention*, as well *as health information and education*, and monitoring, early warning of and combating serious cross-border threats to health.
>
> The Union shall complement the Member States' action in *reducing drugs-related health damage*, including information and prevention.[541]

Union action is centred on 'public health' issues, understood as the management of health risks and the prevention of disease,[542] as opposed to 'healthcare', the provision of health services and medical care,[543] an area which remains more firmly within the ambit of Member State competence.[544] Aside from the general reference to 'physical and mental illness and diseases' and to 'sources of danger to physical and mental health', which are wide enough to cover all kinds of health hazards, lifestyle risks are directly referred to in Article 168(1) through the mention of 'drugs-related health damage'. The importance of lifestyle risks for EU health policy appears more clearly from Article 168(5), which grants the power to the Union to adopt 'measures which have as their *direct objective* the protection of public health regarding *tobacco and the abuse of alcohol*'.[545] This reference to tobacco and alcohol was introduced by the Lisbon Treaty and remains the only explicit mention of these two risk factors ever made in the EU Treaties.[546] None of the other risk factors identified and studied in this thesis are singled out in this way.

It is thus clear from Article 168 TFEU that the prevention of health damages associated with hazardous lifestyles is one of the EU's main health priorities. As previously mentioned, health falls predominantly within the category of complementary competences, which implies that Union action in that field is limited to measures that 'support, coordinate or supplement' those adopted by the Member States and that Union action may not supersede their competence.[547] According to Article 2(5) TFEU, '[l]egally binding acts of the Union adopted on the basis of [complementary competences] *shall not entail harmonisation* of Member States' laws or regulations',[548] a prohibition reiterated as regards health at Article 168(5) TFEU, which

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[541] Art 168(1) TFEU, emphasis added.
[542] Greer, 'The Three Faces of European Union Health Policy: Policy, Markets, and Austerity' (n 515) 13; Hervey and McHale (n 37) 69.
[543] For the difference between 'public health' and 'health-care', see de Ruijter (n 47) 62-63.
[544] Under Article 168(7) TFEU: 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.'
[545] Art 168(5) TFEU, emphasis added. On the meaning of 'direct objective', see Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 62-63.
[546] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1760.
[547] Art 2(5) TFEU.
[548] Emphasis added.

'*exclud[es] any harmonisation* of the laws and regulations of the Member States'.[549] In that field, the EU may only adopt incentive measures[550] or recommendations.[551] A derogation exists for the 'common safety concerns in public health matters' referred to at Article 4(2)(k) TFEU, in relation to which the Union may adopt harmonisation measures.[552] These common safety concerns include food safety but do not extend, as explained in Chapter 1 (Section 2) to the aspects studied in this thesis.[553]

As regards lifestyle risks, the Union may therefore adopt incentive measures and recommendations but may not adopt measures entailing the harmonisation of Member States' laws and regulations. What does that mean for EU lifestyle risks policy and the capacity of the Union to enact effective control measures? The answer is clear for recommendations, legal acts of the Union that have no binding force,[554] and through which the Union can therefore not adopt control measures but merely recommend their adoption.

What the prohibition of harmonisation contained in Articles 2(5) and 168(5) TFEU concretely entails for the EU legislator remains to this day unclear, as does the nature of complementary competences.[555] At the very least, it should be understood as prohibiting *de jure* harmonisation, the harmonisation of existing national provisions, and could even be interpreted as denying all pre-emptive effect to Union legislation which is of non-harmonising nature.[556] One may consider with Bartlett that 'the prohibition on harmonisation means that Article 168(5) TFEU confers no authority upon the EU to engage in any type of […] prevention that would prevent the Member States from enacting their own policy on the same topic'.[557] Hence, the EU cannot

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[549] Emphasis added.
[550] Article 168(5) refers both to 'incentive measures' and 'measures'. Following Bartlett's contextual and historical interpretation of this provision, on may conclude that these two terms refer to the same type of act, which excludes harmonisation, and that the use of both results from poor drafting: Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 60.
[551] Art 168(6) TFEU.
[552] Art 168(4).
[553] Art 168(4)(b) refers to 'measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health'. This provision serves for instance as a legal basis for the General Food Law Regulation.
[554] Art 288 TFEU.
[555] See Robert Schütze, 'Co-operative Federalism Constitutionalized: The Emergence of Complementary Competences in the EC Legal Order' (2006) 31 European Law Review 167. The Working Group V of the European Convention in charge of drafting the Treaty establishing a Constitution for Europe, from which the competence categories contained in Title I of the TFEU are directly inspired, saw complementary competences as 'provisions giving authority to the Union to adopt certain measures of low intensity with respect to policies which continue to be the responsibility of the Member States': Final Report of Working Group V 'Complementary Competencies' (2002) CONV 375/1/02, 3, <http://european-convention.europa.eu/pdf/reg/en/02/cv00/cv00375-re01.en02.pdf> accessed 11/05/2023. See Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 58.
[556] See Schütze, 'Co-operative Federalism Constitutionalized: The Emergence of Complementary Competences in the EC Legal Order' (n 555); Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 63-64; Robert Schütze, 'Classifying EU Competences: German Constitutional Lessons?' in Garben and Govaere, *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future* (n 523) 50-51.
[557] Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 64.

dictate, under its general public health competence, whether tobacco products must carry a health warning, whether alcohol advertising should be prohibited on TV or whether a certain food may be placed on the market.

Through incentive measure, which may have binding force,[558] the EU can spend 'small sums of money to promote European networks that connect people and organizations, put items on the agenda for the future, and […] produce research'.[559] It can engage in benchmarking exercises and facilitate the sharing of information and best practices. This form of intervention is not devoid of any influence and may contribute positively to lifestyle health promotion,[560] but is nonetheless limited in nature.

As discussed at the beginning of this section, 'public health is affected by almost every policy in government, and almost every policy in government could potentially be seen as more or less successful public health policy'.[561] Other legal bases belonging to other policy areas and other categories of competence could also be pertinent for lifestyle risks regulation and allow the Union to enact more forceful measures. The choice of legal basis, it must be recalled, 'has constitutional significance'.[562] It 'may not depend simply on an institution's conviction as to the objective pursued but must be based on objective factors which are amenable to judicial review', including 'in particular the aim and content of the measure'.[563] Following these principles, an analysis of the relevant TFEU provisions does not alter the conclusion that the Union is generally deprived of any direct and general harmonisation powers applicable to health and lifestyle risks.[564]

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[558] ibid 60.

[559] Greer, 'The Three Faces of European Union Health Policy: Policy, Markets, and Austerity' (n 515) 15. See also Greer, 'Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union' (n 485) 93.

[560] Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (n 29) 61–62.

[561] Scott L Greer, 'Introduction - What is Public Health Policy?' in Greer and Kurzer (n 37) 1. See also de Ruijter (n 47) 52.

[562] Opinion 2/00 *Cartagena Protocol* [2001] EU:C:2001:664, para 5.

[563] Case C-300/89 *Commission v Council* [1991] EU:C:1991:244, para 10.

[564] The analysis is limited to legal bases that belong to fields closely related to health, where health protection is explicitly referred to as an objective of Union action. Provisions belonging to policy fields where EU action may only have an indirect or incident impact on health are left aside for practical and conceptual reasons. See in that regard Hervey, Young and Bishop (n 37) 18. Indeed, all policies can potentially have an impact on health. Such is the case of Article 121 TFEU, which relates to the coordination of Member States' economic policies and empowers the Council to adopt economic policy guidelines in the form of country specific recommendations (CSRs) to Member States. These CSRs address the question of the sustainability of national healthcare systems and include recommendations related to people's lifestyles. See Natasha Azzopardi-Muscat and others, 'EU Country Specific Recommendations for Health Systems in the European Semester Process: Trends, Discourse and Predictors' (2015) 119 Health Policy 375; Stéphane De La Rosa, 'Le Programme Santé de la Commission : Véritable Politique Européenne de Santé ou Simple Appui aux Politiques Nationales ?' (2017) 4 Revue des Affaires Européennes 597. Another field of EU policy related to health and lifestyles is the common agricultural policy (CAP). What Article 39 TFEU shows, however, is that health promotion and protection are not part of the CAP's objectives. The CAP has come under a lot of criticisms for neglecting that aspect, and EU action in the field has actually been mostly detrimental to health rather than protective of health. See Ffion Lloyd-Williams and others, 'Estimating the Cardiovascular Mortality Burden Attributable to the European Common Agricultural Policy on Dietary Saturated Fats' (2008) 86 Bulletin of the World Health Organization 535; Nikolai Pushkarev,

Under Article 153 TFEU on social policy, the Union may adopt harmonisation measures aimed at improving 'the working environment to protect workers' health and safety'.[565] This legal basis has been used to legislate in the field of lifestyle risks but is limited to aspects related to the health of workers. Directive 89/654/EEC requires for instance employers to introduce appropriate measures for the 'protection of non-smokers against discomfort caused by tobacco smoke.'[566] Article 153 TFEU could also be employed to adopt measures encouraging physical activity at work, a useful objective if considering that the tertiarisation of work is one of the structural forces at play behind the general decline in physical activity in society.[567]

Article 191 TFEU on environment mentions the protection human health as one of the main objectives of Union policy in that field.[568] This makes sense, as many activities are equally detrimental to the environment and to human health.[569] To the knowledge of the author, there is no case-law that would shed light on the relationship between health and environmental concerns in the choice of legal basis. To the extent that a lifestyle risks measure with a predominantly environmental objective also benefits human health, Article 192 TFEU could constitute a suitable legal basis.[570] Such could be the case of a rule addressing the pollution resulting from cigarette use, which could also affect the consumption of the product. The potential of that provision still remains limited however, if considering that lifestyle risks regulation is primarily concerned with harm to human health.

Union competence on consumer protection is also relevant, since, under this policy, 'the Union shall contribute to protecting the *health*, safety and economic interests of consumers'.[571] Under Article 169 TFEU, however, the EU is granted with powers similar to that applicable to public health. Article 169(2)(b) allows the EU to adopt measures 'which support, supplement and monitor the policy pursued by the Member States', hence excluding harmonisation, and Article 169(2)(a) refers to measures adopted pursuant to Article 114 TFEU, an important provision which is covered in the next section.

'A CAP for Healthy Living Mainstreaming Health into the EU Common Agricultural Policy' (2015) 2 AIMS Public Health 844; Christopher A Birt, 'Food and Agriculture Policy in Europe' (2016) 3 AIMS Public Health 131; James McEldowney, 'EU Agricultural Policy and Health: Some Historical and Contemporary Issues' (2020) European Parliament Research Service.

[565] Art 153(1)(a) TFEU, harmonisation powers are granted pursuant to Article 153(2)(b).

[566] See Council Directive 89/654/EEC of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) [1989] OJ L393/1, annex I, para 16.3 and annex II, para 11.3.

[567] Garde, *EU Law and Obesity Prevention* (n 32) 321-326.

[568] Under Art 191 TFUE, 'Union policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment, protecting human health […]'. 'Environment' is in itself a contested concept, 'ripe for discussion': see Nicolas de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford University Press 2014) 5-7.

[569] De Sadeleer, *EU Environmental Law and the Internal Market* (n 568) 36–37; David Langlet and Said Mahmoudi, *EU Environmental Law and Policy* (Oxford University Press 2016) 35.

[570] This derives from the application of the centre of gravity doctrine, see below section 3.2.

[571] Art 169 TFEU, emphasis added.

Under Article 165 TFEU on education, vocational training, youth and sport, the Union 'shall contribute to the promotion of European sporting issues, while taking account of the specific nature of sport, its structures based on voluntary activity and its social and educational function'.[572] Its action on sport shall be aimed at 'developing the European dimension in sport, by promoting fairness and openness in sporting competitions and cooperation between bodies responsible for sports, and by protecting the physical and moral integrity of sportsmen and sportswomen, especially the youngest sportsmen and sportswomen'.[573] Although no direct reference to physical activity and the health dimension of sport is made in that provision, Article 165 has been used to adopt measures with a clear health purpose.[574] In any case, education, vocational training, youth and sport are fields belonging to the complementary competences of the EU,[575] for which the adoption of harmonisation measures is not possible.[576]

Finally, a last area of Union competence must be addressed. Under Article 83 TFEU on judicial cooperation in criminal matters, the EU is empowered to 'establish minimum rules concerning the definition of criminal offences and sanctions in the areas of particularly serious crime with a cross-border dimension', including in the area of 'illicit drug trafficking'.[577] This provision allows the EU to adopt measures as regards a specific category of lifestyle risks factors, illicit drugs, and places constraints on the nature of the measures that can be adopted. These can only relate to criminal offences and sanctions, a very strong form of regulation of human behaviour. Although, as we shall see in Chapter 5, EU policy in the field of illicit drugs contains human health aspects, it remains primarily related to criminal law and criminal justice matters.

3.2. Internal market: a (too) broad legislative competence (?)

Under Article 3 TEU, the Union 'shall establish an internal market', defined in Article 26(2) TFEU as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured'. The TFEU contains a number of specific internal market provisions, found primarily in its Title II and IV,[578] dealing respectively with the free movement of goods and the free movement of persons, services, and capital. Member State measures that restrict free movement are in principle prohibited under the TFEU, unless they pursue a legitimate public policy objective. One of these objectives is the protection of human health, as appears from Articles 36 and 52(1) TFEU. Hence, for instance, national rules which would prevent alcoholic beverages originating from another Member State to be freely marketed on the domestic market, because, say, they do not conform to the applicable health labelling requirements or are accompanied by unlawful advertising, are in principle prohibited

[572] Art 165(1).
[573] Art 165(2) TFEU.
[574] See Council Recommendation of 26 November 2013 on promoting health-enhancing physical activity across sectors [2013] OJ C354/1.
[575] Art 6(e) TFEU.
[576] Art 165(4) TFEU.
[577] Art 83(1) TFEU.
[578] To which is usually added Article 110 TFEU, see Chapter 3.

under free movement provisions, unless it can be shown that these rules serve to protect public health. The application of free movement provisions to Member State lifestyle risks measures, although it does not constitute a 'EU health policy' *stricto sensu*, places constraints on national health policies and shapes the national regulatory landscape. It has therefore profound implications for health promotion in the EU, as will be analysed in detail in Chapter 3 and 4.

The internal market is not only a place of 'de-regulation' but also of 're-regulation'. It is an area of shared competence,[579] meaning that the Union may legislate and adopt legally binding acts in that area.[580] Under Article 26(1) TFEU, the 'Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties'. As public health constitutes a valid ground of justification to defend national lifestyle risks measures limiting the cross-border movement of goods, persons, or services, free movement provisions alone do not suffice to guarantee the establishment and the proper functioning of the internal market. Diverging national standards may survive, limiting the integration of the various national markets into a single European market. The solution is to adopt common measures at the European level, harmonising national rules into a single European one, so that free movement is no longer impaired.

This is the function of Article 114 TFEU, which empowers the Union to adopt 'measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market'.[581] A common European standard on alcohol labelling, to follow on the example given above, allows for all alcoholic beverages produced in the EU to be freely marketed in all national markets, as far as labelling is concerned. Crucially, what this example shows is that internal market harmonisation measures, in a field such as lifestyle risks, are always of a dual nature: market-related but also health-related. This duality appears clearly from Article 114(3) TFEU, which requires that the European Commission, in its legislative proposals envisaged under Article 114 'concerning health, safety, environmental protection and consumer protection, […] take as a base a high level of protection'. By harmonising standards, an internal market exercise, the EU must also set the content of these standards, which then becomes a public health exercise.

In addition to Article 114, the TFEU contains specific harmonisation provisions related to the right of establishment of self-employed persons and the freedom to provide services. Pursuant to Article 53(1) TFEU, the Union may adopt directives 'for the coordination of the provisions laid down by law, regulation or administrative action in Member States concerning the taking-up and pursuit of activities as self-employed persons', a power which also applies, by virtue of Article 62 TFEU, to matters pertaining to the free movement of services. Article 113 TFEU also grants power to the Union in the field of indirect taxation, to 'adopt provisions for the

[579] Art 4(2)(a) TFEU.
[580] Art 2(2) TFEU.
[581] Art 114(1) TFEU.

harmonisation of legislation concerning turnover taxes, excise duties and other forms of indirect taxation to the extent that such harmonisation is necessary to ensure the establishment and the functioning of the internal market and to avoid distortion of competition'.

Considering the limitations of Article 168 TFEU and other health-related legal bases,[582] the only possible route for the EU to enact harmonisation measures which have as their direct objective the promotion of healthy lifestyles is through Article 114 TFEU and, where pertinent, through Articles 53(1) and 62 TFEU.[583] For specific tax measures, Article 113 TFEU is also available. As will be shown in Chapter 5 and 6, these provisions, Article 114 TFEU especially, have allowed the EU to adopt a wide range of lifestyle risks control measures.[584] Yet, while being broad in scope, Article 114 TFEU does not provide the EU with an unlimited competence. As ruled by the Court of Justice in the landmark *Tobacco Advertising* case, Article 114 TFEU does not grant the EU with a 'general power to regulate the internal market'.[585] To be lawfully adopted under that provision, measures 'must *genuinely* have as [their] object the improvement of the conditions for the establishment and functioning of the internal market.'[586] For a measure to be considered as a genuine contribution to the internal market, two conditions must be fulfilled. First, there needs to be actual divergences between the laws of the Member States which create obstacles to free movement or distortions of competition[587] or future

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[582] Article 352 TFEU, the 'flexibility clause', which was used to adopt harmonisation measures in the early days of EU health policy, is no longer an available option. Since the Lisbon Treaty revision, 'measures based on this Article shall not entail harmonisation of Member States' laws or regulations in cases where the Treaties exclude such harmonisation', which is the case of health.

[583] The Tobacco Products Directive is for instance based on these three provisions: Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (Tobacco Products Directive) [2014] OJ L127/1. The AVMS Directive is solely based on Articles 53(1) and 62 TFEU: Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services (AVMS) Directive) [2010] OJ L95/1. Considering that Articles 53(1) and 62 TFEU pursue an internal market objective similar to that of Article 114 TFEU and that their use is subject to similar conditions, assessed jointly by the Court of Justice, these two provisions will not be analysed separately from Article 114 TFEU throughout the thesis: see *Tobacco Advertising* (n 25), para 87. All remarks made on Article 114 TFEU can be considered applicable to Articles 53(1) and 62 TFEU.

[584] Among others, the following pieces of lifestyle legislation are based on Article 114 TFEU: Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (Tobacco Advertising Directive) [2003] OJ L152/16; Claims Regulation; Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (Food Information Regulation) OJ L304/18; Tobacco Products Directive.

[585] *Tobacco Advertising* (n 25), para 83.

[586] *Tobacco Advertising* (n 25), para 84, emphasis added

[587] Case C-58/08 *Vodafone e.a.* [2010] EU:C:2010:321, para 32. The most recent cases do not explicitly refer to these two concepts of 'obstacles to free movement' and 'distortions of competition' but tend to refer to those under the common term of 'obstacles to trade'. Yet, through a direct reference to paragraph 32 of the *Vodafone* case, these cases can be considered as upholding the difference between 'obstacles' and 'distortions': see *Philip Morris* (n 28), paras 58-59; Case C-358/14 *Poland v European Parliament and Council* [2016] EU:C:2016:323, paras 32-33. See also Case C-482/17 *Czech Republic v Parliament and Council* [2019] EU:C:2019:321, Opinion

divergences likely to give rise to such obstacles or distortions.[588] Second, the adopted measure must remove these obstacles or distortions.[589] What these two conditions precisely entail and how they have shaped EU lifestyle risks policy will be further analysed in Chapter 7.

In order to be lawfully adopted, harmonisation measures in the field of lifestyle risks which purport to protect public health must thus necessarily pursue a goal of market integration. This goes for Articles 114, 53(1) and 62 TFEU, but also for Article 113 TFEU, which allows the Union to adopt harmonisation measures in the field of taxation 'to the extent that such harmonisation is necessary to ensure the establishment and the functioning of the internal market and to avoid distortion of competition'. Hence, implicitly or explicitly, all EU lifestyle risks harmonisation measures follow a double objective: internal market and health.[590]

A limit to the use of Article 114 TFEU to adopt such measures could have arisen from Article 168 TFEU, which, save for specific exceptions, prevents the Union from adopting harmonisation measures in the field of health. This is what Germany argued in *Tobacco Advertising*, claiming that Directive 98/43/EC on the advertising and sponsorship of tobacco products was a public health measure which could not have been lawfully adopted under Article 114 TFEU.[591] According to Germany, 'recourse to Article [114 TFEU] is not possible where the centre of gravity of a measure is focused not on promoting the internal market but on protecting public health',[592] which it considered was the case with the directive at stake, introducing a general ban on tobacco advertising and sponsorship in the EU.

The Court rejected that argument and ruled that:

> [P]rovided that the conditions for recourse to Articles [114, 53(1) and 62 TFEU] as a legal basis are fulfilled, the [Union] legislature cannot be prevented from relying on that legal basis *on the ground that public health protection is a decisive factor in the choices to be made*.[593]

For the Court, Article 168(5) TFEU cannot be interpreted as preventing the EU legislator from adopting harmonisation measures having health as an objective under other provisions. The only limit to the use of Article 114 TFEU, and related legal bases, is to be found in the conditions for recourse to these provisions, outlined above. As long as these are fulfilled, the importance of the public health objective is irrelevant to the legality of the act.[594] The

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of Advocate General Sharpston, para 44, referring to the elimination of 'obstacles to free movement' and 'distortions in competition'.

[588] *Philip Morris* (n 28), para 59; *Poland v Parliament and Council* (n 587), para 33.

[589] *Tobacco Advertising* (n 25), paras 84, 95; *Tobacco Advertising II* (n 26), para 69.

[590] See e.g Claims Regulation, art 1(1); AVMS Directive, recital 104; Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco (Tobacco Excise Duties Directive) [2011] OJ L176/24, recital 2; Food Information Regulation, art 3; Tobacco Products Directive, art 1.

[591] Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products [1998] OJ L213/9. See further Chapter 6 Section 2.1.

[592] *Tobacco Advertising* (n 25), para 32.

[593] ibid, para 88, emphasis added.

[594] Sacha Garben, 'Supporting policies' in Pieter Jan Kuijper and Fabian Amtenbrink (eds), *The Law of the European Union* (Fifth Edition, Kluwer Law International 2018) 1211.

importance of the Court's ruling for the development of EU lifestyle risks policy, and EU health policy in general, cannot be overstated. The Court allowed the EU legislature to make up for its lack of harmonisation powers in public health through the use of its internal market competence.

As already discussed above, that measures adopted pursuant to Article 114 TFEU may have a bearing on health is not in itself objectionable. Article 114 TFEU is purposive in nature: it seeks the achievement of an objective but does not regulate any particular area.[595] As observed by Advocate General Fennelly, this competence 'is not limited in advance by reference to a particular subject-matter defined *ratione materiae*'.[596] To exclude from its scope the areas where the EU is not granted harmonisation powers would considerably weaken its function. This is even more true in relation to health, an interest that is often put forward by Member States to justify their national restrictive measures. Moreover, Article 114(3) TFEU itself foresees the integration of health concerns within internal market measures. If the Treaty drafters wanted to exclude health from the reach of Article 114 TFEU, they could have explicitly done so, as provided under the second paragraph of that provision, which states that Article 114 TFEU 'shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons'.

That being said, the Court in *Tobacco Advertising* could have decided to rely on the centre of gravity doctrine, according to which 'if examination of [an EU] act shows that it has a twofold purpose or twofold component and if one of these is identifiable as main or predominant, whereas the other is merely incidental, the act must be founded on a sole legal basis, that is, the one required by the main or predominant purpose or component'.[597] Following this approach, another purpose than a strictly internal market one, such as health, could be validly pursued by a measure adopted via Article 114 TFEU under the condition that this purpose remains of a lesser weight than the internal market component of the measure. This was essentially the point that Germany was making in *Tobacco Advertising*, when arguing that 'the legislative history of the Directive and its content and purpose show that the centre of gravity of the measure is public health protection'.[598]

Yet, in that judgement, the Court refused to discuss the respective importance of the internal market and public health objectives present in Directive 98/43/EC on tobacco advertising. Had it done so, it would have probably concluded that health was prevailing, for it is clear that a piece of legislation setting up a wide ban on tobacco advertising and sponsorship is more concerned with the protection of health than the free movement of tobacco products. The Court,

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[595] For a critical approach towards purposive legal bases, see Gareth Davies, 'Democracy and Legitimacy in the Shadow of Purposive Competence' (2015) 21 European Law Journal 2.
[596] Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising)* [2000] EU:C:2000:324, Opinion of Advocate General Fennelly, para 62. See also Davies, 'Democracy and Legitimacy in the Shadow of Purposive Competence' (n 595) 3: 'a defining characteristic of pure purposive power is that while it is constrained to follow specific goals, it is not constrained in the subject matter or the breadth of its impact'.
[597] *British American Tobacco* (n 27), para 94.
[598] *Tobacco Advertising* (n 25), para 34.

however, had good reasons to refrain from engaging in a centre of gravity reasoning. This is not because, as Advocate General Fennelly argued, a centre of gravity test should only be applied in cases where the competing legal bases allow for harmonisation,[599] which was not the case in the situation at hand, but rather because the very idea of a applying a centre of gravity test to internal market legislation adopted under Article 114 TFEU seems ill-suited. '[I]t is of the essence of any internal-market measure that it pursues, quite legitimately, two objectives - one the removal of obstacles to trade or distortions of competition; the other (the means of achieving the first) the adoption of harmonised EU measures to replace national measures in the field in question'.[600] Every time an EU measure harmonises national health standards, an obstacle to trade is lifted and *at the same time* a new standard of health protection is created. These two objectives cannot legally be severed and the rest is a matter of political choices that should escape the Court's review.[601] 'Internal market legislation is always also 'about something else', and that something else may in fact be the main reason why the internal market measure was adopted.'[602]

From the perspective of Article 114 TFEU and the internal market, the Court's approach appears to be the correct one. Yet, the use of EU internal market powers to harmonise matters which, according to the legal bases relevant to these specific fields, should remain free from

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[599] *Tobacco Advertising*, Opinion of Advocate General Fennelly (n 596), paras 68-69. This argument is problematic insofar as it undermines the role of legal bases in the EU legal order, which is precisely to prevent the EU from acting in areas where powers have not explicitly been granted to it. Contrary to what is held by Fennelly, it appears even more important to perform a centre of gravity test where the choice is not between two legal bases that equally allow for harmonisation but between legal bases that do not attribute the same kind of powers to the EU. In some of its writings, Bruno de Witte considers that the Court upheld the view of AG Fennelly in *Tobacco Advertising*, although this cannot be explicitly read from the decision: see Bruno de Witte, 'A Competence to Protect: the Pursuit of Non-Market Aims through Internal Market Legislation', in Philip Syrpis (ed), *The Judiciary, the Legislature and the EU Internal Market* (Cambridge University Press 2012) 35; Bruno de Witte, 'Non-Market Values in Internal Market Legislation', in Niamh Nic Shuibhne (ed), *Regulating the Internal Market* (Edward Elgar Publishing 2006) 75. Bruno de Witte's view on the matter seems to have evolved since he more recently wrote that 'in its *Tobacco Advertising* judgment, the Court at no point sought to determine whether the health protection objective of the directive was dominant or ancillary to the internal market objective': Bruno de Witte, 'Exclusive Member State Competences - Is There Such a Thing?' in Garben and Govaere, *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future* (n 523) 63.

[600] *Tobacco Advertising*, Opinion of Advocate General Fennelly (n 596), para 75.

[601] René Barents, 'The Internal Market Unlimited: Some Observations on the Legal Basis of Community Legislation' (1993) 30 Common Market Law Review 85, 101. This argument was further unpacked by Advocate General Poiares Maduro in Case C-58/08 *Vodafone Ltd* [2009] EU:C:2009:596, para 9: 'Article [114] can, indeed, provide the basis for an intensification of regulation in addition to deregulatory measures. This is, in principle, to be decided by the political process. Indeed, Article [114](3) specifically provides that legislation for which it provides the legal basis should pursue a high level of health, safety, environmental and consumer protection. Such goals must, however, be part of an overall legislative framework which has as its object the establishment and functioning of the internal market by means of the approximation and harmonisation of Member State laws, regulations or administrative actions. In other words, the [Union] measure must contribute to market integration even if it does not need to be limited to what is strictly necessary to further market integration. Although furthering market integration is a necessary requirement for the [Union] to be competent under Article [114], the exercise of its competence must not be limited to the goal of market integration. If it were, it would put into question the pursuit of other legitimate regulatory goals which the States could no longer pursue on their own.'

[602] De Witte, 'Exclusive Member State Competences - Is There Such a Thing?' (n 599) 63.

EU harmonisation, is not without raising question as to the legitimacy of Union action. It sits uneasily with the principle of conferral, according to which 'the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein'.[603] Union action in the field of lifestyle risks gives rise to a competence creep, understood as 'a process whereby the powers of the EU [are] perceived as expanding in covert or somehow unclear ways, including into areas where Member States were supposed to remain fully in charge'.[604] This is more generally true of health, which, '[i]n light of the degree and extent of EU action in this field', is probably 'of all the supporting policy areas […] the one that is the most difficult to distinguish from a shared competence'.[605]

The contradiction between the legislative practice in the area of lifestyle risks and the content of Article 168(5) TFEU illustrates an incoherence that goes deeper in the EU Treaty system. The idea of categorising competences in different policy areas attached to specific legal bases goes against the purposive nature of Article 114 TFEU.[606] In fact that provision 'makes a mockery of the carefully drawn restrictions in provisions such as Article 168.'[607] The drafting of Article 168(5) TFEU can thus be qualified as 'cynical',[608] insofar as 'the [EU] legislator may need to justify politically desired European "health measures" by means of the economic vocabulary of the internal market'.[609] The legal consequences of this discrepancy are immense, as the analysis contained in Chapter 7 will endeavour to show.

4. Conclusion

Health and the internal market are the two faces of EU lifestyles risks regulation. Free movement has played a key role in the emergence of the EU risk regulatory regime and represents a powerful justification for its existence. The establishment of the internal market

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[603] Article 5(2) TEU. See Alan Dashwood, 'The Limits of European Community Powers' (1996) 21 European Law Review 113; Graine De Burca and Bruno De Witte, 'The delimitation of powers between the EU and its Member States' in Anthony Arnull and Daniel Wincott (eds), *Accountability and Legitimacy in the European Union* (Oxford University Press, 2002); Stephen Weatherill, 'Better competence monitoring' (2005) 30 European Law Review 23; Michael Dougan, 'Legal developments' (2010) 48 Journal of Common Market Studies (2010) 163.

[604] Sacha Garben and Inge Govaere, 'The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future' in Garben and Govaere, *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future* (n 523) 7.

[605] Garben, 'Supporting policies' (n 594) 1208. The case of health is particularly controversial if considering that the introduction with the Maastricht Treaty of the first health legal basis in the EEC Treaty, which contained already an express exclusion of harmonisation, was seen by the most reluctant Member States as a way to stop the expansion of Union legislation in this area: Guigner, 'La Dynamique d'Intégration par Sédimentation: Retour sur l'Inscription de la Santé dans les Compétences de l'Union' (n 499) 58-60. Needless to say that these Member States have failed in this regard.

[606] See Loïc Azoulai, 'The question of competence' in Azoulai, *The Question of Competence in the European Union* (n 480) 11: '[…] there is no doubt that changes introduced by the Lisbon Treaty contain a direct challenge to the predominant functional and constitutional conceptions of the European legal order of the last 50 years'.

[607] Stephen Weatherill, *The Internal Market as a Legal Concept* (Oxford University Press 2017) 171.

[608] Robert Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (Oxford University Press, 2009) 282.

[609] ibid 283.

requires to eliminate the barriers to trade resulting from national risk control measures. The EU has been granted with sweeping legislative and judicial powers to do so. In parallel to this market objective, the Union pursues a broad public health objective, aiming at protecting and improving human health, within which the promotion of healthy lifestyles features prominently. The EU, as other 'post-national risk governance regimes', is 'at one and the same time, a modern normative commitment to the establishment of a global economy, with all the risks that that entails, as well as a manifestation of an unprecedented ambition to control or govern that same risk'.[610]

Regarding national measures, these two Treaty-sanctioned goals compete with each other. Health functions as a limit to the internal market. Through the application of free movement provisions, the EU has gained an oversight on national risk regulation, as regards in particular the assessment and the management of lifestyle risks. The confrontation of these two objectives influences the functioning and the content of national risk regulatory regimes. This is the focus of Chapter 3 and 4.

At the EU level, the two objectives are no longer opposed. The adoption of common European standards facilitates free movement while at the same time allowing the EU to set the content of a genuine lifestyle risks policy. The internal market harmonisation powers compensate for the lack of public health harmonisation powers. Chapter 5 and 6 present the aims of that EU policy and the various regulatory tools adopted by the EU to promote healthier lifestyles.

The dual, hybrid nature of EU lifestyle risks regulation creates a number of legal frictions, starting with the apparent contradiction between the existence of a large body of law in an area of complementary competence where Member State action is not supposed to be displaced. The interplay between market and health gives rise to a number of other legal problems, addressed in Chapter 7, the final chapter of the thesis, which affect the content and the functioning of the EU risk regulatory regime.

[610] Michelle Everson, 'Three Intimate Tales of Law and Science : Hope, Despair and Transcendence' in Vos and Everson (eds), *Uncertain risks regulated* (n 496) 348.

Part II

Member State regulation of lifestyle risks: health promotion as a limit to the EU internal market

Chapter 3

Member State measures as restrictions to free movement

1. Introduction

It is a common observation made by EU law professors and students that so much of the internal market case-law is about 'sins'.[611] National measures applicable to alcoholic beverages have given some of its landmark cases to the field, *Dassonville* and *Cassis de Dijon*, but also *Commission v Germany (Beer Purity)* and, more recently, *Scotch Whisky*.[612] Such is also the case, as we shall see, for food products and gambling services. That alcohol, food, and gambling form such a large part of the free movement case-law is not surprising. Although they are most often not primarily linked, if at all, to cross-border trade, national measure aimed at controlling lifestyle-related health risks reduce trading opportunities and often give rise to obstacles to the free flow of goods, services, or persons.

This chapter provides an overview of the various categories of measures enacted at the national level to tackle those risks and analyses, for each of them, the extent to which they constitute a restriction to free movement prohibited under the TFEU. This matters for two reasons. First, where a restriction to free movement is created, only measures that pursue a legitimate purpose and are proportionate can be lawfully adopted. Being classified as a restriction to free movement brings a national measure under the purview of EU law, which has important implications for the national regulatory process, as will be addressed in Chapter 4. Second, because the harmonisation competence of the EU is limited to measures that bring a contribution to the internal market, determining what constitutes an obstacle to free movement is crucial for EU policy and the rules that may be adopted. This will be investigated in greater detail in Chapter 7.

After clarifying the conditions under which free movement provisions are applicable to national lifestyle measures, the main type of regulatory instruments typically used in relation to lifestyle risks are analysed. These are addressed by category and not under each free movement provision taken separately. The categories used are, as much as possible, those that derive from the TFEU provisions or the Court of Justice case-law, such as selling arrangements or product requirements, and not those of the 'intervention ladder' introduced in Chapter 1. The reason is that specific legal consequences are attached to these categories, which renders a separate assessment necessary. These are presented in a descending order, addressing first the measures that have generated the most difficult legal questions and, often, a substantial part of the case-law.

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[611] See Floris De Witte, 'Sex, Drugs & EU Law: The Recognition of Moral and Ethical Diversity in EU Law' (2013) 50 Common Market Law Review 1545.

[612] Case 8/74 *Dassonville* [1974] EU:C:1974:82 ; Case 120/78 *Rewe v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*) [1979] EU:C:1979:42; Case 178/84 *Commission v Germany (Beer purity)* [1987] EU:C:1987:126; Case C-333/14 *The Scotch Whisky Association* [2015] EU:C:2015:845.

2. Applicability and scope of free movement provisions

National lifestyle risks control measures may constitute restrictions to the free movement of goods and services, and to the freedom of legal and natural persons to establish themselves in another Member State to engage in such trade in goods or services. Various provisions contained in the TFEU are relevant in this regard. For these provisions to apply, a number of conditions must be met.

2.1. Relevant free movement provisions and their applicability

2.1.1. The concepts of goods, services, and establishment

Title II of the TFEU contains the provisions applicable to the free movement of goods, from Article 28 to Article 37. Among these provisions, Article 34 TFEU, which prohibits quantitative restrictions to imports and measures having equivalent effect, and Article 37 TFEU, dealing with the operation of commercial monopolies, are the two most relevant provisions as regards national lifestyle risks regulation. Article 30 TFEU, prohibiting customs duties on imports and exports and charges having equivalent effect, and Article 35 TFEU, prohibiting quantitative restrictions to exports, have not found any specific application in relation to lifestyles and will therefore not be dealt with in this chapter. The role of Article 36 TFEU, which allows Member States to derogate from the prohibitions contained in Articles 34 and 35 TFEU is analysed in detail in Chapter 4. Article 110 TFEU, finally, which prohibits discriminatory or protectionist internal taxation, while formally not part of Title II on the free movement of goods, also concerns the free circulation of products and is highly relevant to national lifestyle risks measures.

Under Articles 28 and 29 TFEU, provisions on the free movement of goods apply to products originating in Member States and to products coming from third countries which are in free circulation in Member States, the latter meaning that 'import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied in that Member State [unless they have] benefited from a total or partial drawback of such duties or charges'.[613]

Under the definition provided by the Court, 'goods' are 'products which can be *valued in money* and which are capable, as such, of forming the *subject of commercial transactions*'.[614] There is therefore no doubt that tobacco products, alcoholic beverages and other foodstuffs constitute goods within the meaning of Article 34 to 37 TFEU. The same can be said of Article 110 which applies to 'products'.

[613] Article 29 TFEU.
[614] Case 7/68 *Commission v Italy* [1968] EU:C:1968:51, emphasis added.

Article 49 TFEU prohibits restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State. Freedom of establishment includes 'the right to take up and pursue activities as self-employed persons and to set up and manage undertakings'.[615] Freedom of establishment generally means the right of self-employed persons or companies to set up a place of business and pursue an economic activity in another Member State, on a long-term basis:

> The concept of establishment within the meaning of the Treaty is […] *a very broad one*, allowing a [Union] national to participate, *on a stable and continuous basis*, in the economic life of a Member State other than his State of origin and to profit therefrom, so contributing to economic and social interpenetration within the Community in the sphere of activities as self-employed persons.[616]

Under Article 56 TFEU, 'restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended', 'services' within the meaning of the Treaties only applying to activities 'normally provided for remuneration'.[617]

The difference between services and establishment is essentially temporal. While freedom of establishment allows a foreign national to participate in the economic life of another Member State 'on a stable and continuous basis',[618] the freedom to provide services 'envisage[s] that he is to pursue his activity there on a temporary basis'.[619] This has not proved to be a decisive question in relation to lifestyle risks measures, as Article 49 TFEU has mostly been applied in the field of gambling and generally simultaneously with Article 56 TFEU.

2.1.2. The requirement of a Member State measure and a cross-border situation

Apart from what constitutes the definition of 'goods, 'establishment' and 'services', there are generally two main conditions for the application of free movement provisions. The first is the presence of a cross-border element. Free movement rules apply to trade between Member States, meaning that purely internal situations fall outside their scope of application.[620]

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[615] Article 49 TFEU.

[616] Case C-55/95 *Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano* [1995] EU:C:1995:411, para 25, emphasis added.

[617] Article 57 TFEU. The service cannot be provided entirely for free but the provider must not necessarily seek to make a profit, see Case C-281/06 *Jundt* [2007] EU:C:2007:816, para 33. Remuneration can be indirect, meaning that 'Article [57] does not require the service to be paid for by those for whom it is performed', Case 352/85 *Bond van Adverteerders v State of the Netherlands* [1988] EU:C:1988:196, para 16. In that regard, see Joined Cases C-51/96 and C-191/97 *Deliège* [2000] EU:C:2000:199 and Case C-159/90 *Society for the Protection of Unborn Children Ireland v Grogan and Others* [1991] EU:C:1991:378.

[618] *Gebhard* (n 616), para 25.

[619] ibid, para 26. The temporary nature of the activities in question 'has to be determined in the light, not only of the duration of the provision of the service in question but also of its regularity, periodicity or continuity', see ibid, para 27. See also Case C-215/01 *Schnitzer* [2003] EU:C:2003:662, paras 30-32.

[620] In relation to free movement of goods, see Joined Cases C-321 to 324/94 *Pistre* [1997] EU:C:1997:229, para 44. In relation to freedom of establishment and freedom to provide services, see Case C-268/15 *Ullens de Schooten* [2016] EU:C:2016:874, para 47. This is unless provided otherwise in an act of secondary law. The provisions of Chapter III of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on

However, it is not because all the facts of a case are confined to a single Member State that the Court will not apply free movement.[621] The Court takes an expansive view of what constitutes a cross-border situation, as exemplified by a recent ruling the field of gambling, *Bonver Win*.[622]

In *Bonver Win*, the eponym Czech company had been stripped of its gambling licence to operate games of chance following the entry into force of a Czech rule applicable to all service providers operating in that Member State. Despite not being itself in a cross-border situation, Bonver Win challenged this piece of legislation as being contrary to Article 56 TFEU, arguing that the provision applied since some of its customers were nationals from other Member States. Asked to give a preliminary ruling on this question, the Court answered, first, that a cross-border situation cannot be presumed to exist on the sole ground that nationals from other Member States may avail themselves of service opportunities: 'a mere assertion by a service provider that some of its customers come from a Member State other than that in which it is established is not sufficient to establish the existence of a cross-border situation capable of falling within the scope of Article 56 TFEU'.[623] It nonetheless rejected any possibility of relying on the number of customers originating from another Member State to establish a cross-border situation,[624] staying faithful to its long-standing position that no quantitative criterion should be relied upon when deciding on the application of free movement rules.[625] Turning to the specific circumstances of the case, the Court found that that Article 56 should apply as:

> [I]t [was] apparent from the request for a preliminary ruling that the town of Děčín [where Bonver Win was established], which is located approximately 25 km from the German border, is a place that is enjoyed by German nationals and Bonver Win ha[d], in the context of the national proceedings, *provided evidence* which seeks to demonstrate that some of its customers were persons from other Member States, which means that it cannot be argued that the existence of foreign customers is purely hypothetical.[626]

The second condition for free movement provisions to apply is that a given measure is attributable to a Member State. Member States are the addressees of free movement provisions which do not, in principle, apply to private parties' actions. Here again, the Court takes a broad view of what constitutes a Member State measure, meaning that an action by a nominally private party may in certain circumstances trigger the application of internal market freedoms.

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services in the internal market [2006] OJ L376/36 (Services Directive), on freedom of establishment of providers, are for instance also applicable to purely international situations, see Joined Cases C-360/15 and C-31/16 *X and Visser* [2018] EU:C:2018:44, para 110.

[621] *Pistre* (n 620) 44. See also Case C-184/96 *Commission v France (Foie gras)* [1998] EU:C:1998:495 para 17.

[622] Case C-311/19 *Bonver Win* [2020] EU:C:2020:981.

[623] ibid, para 25.

[624] ibid, para 26-29.

[625] For a discussion of this issue, see Harri Kalimo and Max S Jansson, 'De Minimis Meets Market Access: Transformations in the Substance and the Syntax of EU Free Movement Law?' (2014) 51 Common Market Law Review 523. This formalistic position from the Court may appear surprising, outdated even, in today's data-driven world, considering especially that a quantitative assessment is part of the Court's analysis under Article 101 TFEU and as we shall see below, Article 110 TFEU. Nonetheless, the rejection of an effect-based approach as regards free movement rules, to the exception of Article 110 TFEU, fits well with the recognition by the Court of these provisions as 'fundamental freedoms': see Case 240/83 *ADBHU* [1985] EU:C:1985:59, para 9.

[626] *Bonver Win* (n 622), para 32, emphasis added.

Free movement of goods applies to professional regulatory bodies[627] and private bodies supported by the State.[628] It also applies to situations where a private conduct impedes free movement and the State fails to act to stop the nuisance.[629] Regarding freedom of establishment and the freedom to provide services, the Court has consistently ruled that Articles 49 and 56 TFEU apply not only 'to the action of public authorities but extend also to rules of any other nature aimed at regulating in a collective manner gainful employment, self-employment and the provision of services',[630] including those of trade unions.[631] Purely private measures, whereby a company or group of companies would for instance, on their own motion, decide to comply with certain quality requirements for foods or to refrain from certain kinds of advertising, do not fall within the ambit of free movement rules. They may however constitute anti-competitive behaviours prohibited by EU competition rules, which fall beyond the scope of the present enquiry.

2.2. Gambling and illicit drugs: what constitutes an economic activity?

It is implicit in the concepts of 'goods', 'services' and 'establishment' that internal market freedoms apply to economic activities. This has not given rise to any difficulty regarding trade in tobacco products, alcoholic beverages, and other foodstuffs. It has however been argued, unsuccessfully, that gambling did not constitute an economic activity. Illicit drugs, on the other hand, are excluded from the scope of application of free movement provisions, precisely because their commerce does not constitute a lawful economic activity.

2.2.1. Gambling

Under the case-law of the Court of Justice, gambling is defined as a 'a game of chance with the hope of winning',[632] as opposed to a game of skill. A 'sum of money' needs to be at stake, meaning for instance that electronic games, such as computer games, which are not played for the prospect of winning a sum of money do not constitute gambling in the sense of the Court's case-law.[633] In *Familiapress*, the Court considered that a competition allowing successful participants in crossword puzzles contained in a magazine to enter a draw and win a monetary prize did not constitute gambling since the draws were organised on a small scale, with little at

[627] Case C-171/11 *Fra.bo* [2012] EU:C:2012:453.
[628] Case 249/81 *Commission v Ireland ('Buy Irish')* [1982] EU:C:1982:402; Case 222/82 *Apple and Pear Development Council* [1983] EU:C:1983:370, para 17.
[629] See Case C-112/00, *Schmidberger* [2003] EU:C:2003:333 and Case C-265/95 *Commission v. France 'Angry farmers* [1997] EU:C:1997:595. For a discussion of the application of Article 34 to the acts of private parties see Laurence W Gormley, 'Private Parties and the Free Movement of Goods: Responsible, Irresponsible, or a Lack of Principles?' (2015) 38 Fordham International Law Journal 993.
[630] Case C-438/05 *The International Transport Workers' Federation and The Finnish Seamen's Union* (*Viking)* [2007] EU:C:2007:772, para 33.
[631] See *Viking* (n 630) ; Case C-341/05 *Laval un Partneri* [2007] EU:C:2007:809.
[632] Case C-275/92 *H.M. Customs and Excise v Schindler* [1994] EU:C:1994:119, para 27.
[633] Case C-65/05 *Commission v Greece* [2006] EU:C:2006:673, para 36.

stake, and did not 'constitute an economic activity in their own right but […] merely one aspect of the editorial content of a magazine'.[634]

According to consistent case-law 'activities which consist in allowing users to participate, for remuneration, in betting or gaming constitute 'services' for the purposes of Article [56 TFEU]'.[635] In the seminal *Schindler* case,[636] a number of national governments argued that free movement provisions should not apply to lotteries. They considered, first, that lotteries did not constitute an economic activity since these had traditionally been prohibited or operated either directly by public authorities or under their control, solely in the public interest, and, second, that lotteries had no economic purpose, since they were based on chance, but constituted mere recreation or amusement.[637] Unimpressed by these arguments, the Court answered the following:

> Admittedly, as some Member States point out, lotteries are subject to particularly strict regulation and close control by the public authorities in the various Member States of the Community. *However, they are not totally prohibited in those States*. On the contrary, they are commonplace.
>
> In these circumstances, lotteries cannot be regarded as activities whose harmful nature causes them to be prohibited in all the Member States and *whose position under Community law may be likened to that of activities involving illegal products*, even though, as the Belgian and Luxembourg Governments point out, the law of certain Member States treats gaming contracts as void.[638]

In subsequent cases, the Court confirmed the application of free movement provisions to other comparable forms of gambling, including sports betting[639] and online gambling in general.[640] Regarding sports betting, the Court acknowledged that these were not games of pure chance but considered that they nonetheless offered 'like games of chance, an expectation of cash winnings in return for a stake and involved the same risks of crime and fraud and may have the same damaging individual and social consequences' than other forms of gambling.[641]

Member State measures regulating the operation of gambling activities generally give rise to restrictions to the freedom to provide services within the meaning of Article 56 TFEU. They may also constitute restriction to the freedom of gambling operators to establish themselves in another Member State, within the meaning of Article 49 TFEU.[642] Which of these two

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[634] Case C-368/95 *Vereinigte Familiapress Zeitungsverlags- und vertriebs GmbH v Bauer Verlag* [1997] EU:C:1997:325, para 23.
[635] Case C-470/11 *Garkalns SIA* [2012] EU:C:2012:505, para 24. See in particular *Schindler* (n 632), para 25 and Case C-67/98 *Zenatti* [1999] EU:C:1999:514, para 24.
[636] *Schindler* (n 632), para 16.
[637] ibid, para 16.
[638] ibid, paras 31-32.
[639] *Zenatti* (n 635), para 16.
[640] Case C-243/01 *Gambelli and Others* [2003] EU:C:2003:597, para 54.
[641] *Zenatti* (n 635), para 18. The Court thereby answered to the argument made by Mr Zenatti 'that the taking of bets on sporting events cannot be equated with the running of lotteries, with which *Schindler* was concerned, in particular because bets do not amount to games of pure chance but require the person laying the bet to use his skill in predicting results', ibid, para 13.
[642] See e.g. Case C-225/15 *Politanò* [2016] EU:C:2016:645.

provisions applies depends on the circumstances of the case at hand. According to the Court's classic formula, 'where a national measure relates to several fundamental freedoms at the same time, the Court will in principle examine the measure in relation to only one of those freedoms if it appears, in the circumstances of the case, that the other freedoms are entirely secondary in relation to the first and may be considered together with it'.[643] In some cases, the Court makes a simultaneous application of both provisions.[644] Whether the freedom to provide services or freedom of establishment applies in a given case does not generally affect the qualification of a measure as a restriction to free movement, as the concept of restriction is understood similarly under both provisions, but can affect the outcome of the case at the stage of justification.

Member State measures on gambling may also constitute restrictions to the free movement of goods where they affect the devices that underlie the provision of a gambling service. In *Läärä*, the Court of Justice confirmed that free movement of goods provisions could apply to the importation of slot machines.[645] However, following the general rule outlined in the precedent paragraph, the Court is likely in gambling cases to consider that the free movement of goods is secondary to the freedom to provide services, as it is the activity of gambling which is targeted by national rules rather than the gambling devices themselves. In *Schindler* for instance, the Court ruled regarding lottery materials – leaflets, tickets – that 'the importation and distribution of [such] objects [were] not ends in themselves' but constituted only 'specific steps in the organization or operation of a lottery'.[646] These could not 'be considered independently of the lottery to which they relate'[647] and national rules preventing their imports did therefore not fall under Article 34 TFEU.[648] In *Anomar* and *Berlington*, the Court considered that the operation of slot or gaming machines, even though it is linked to operations to import them, comes under the provisions of the Treaty relating to the freedom to provide services.[649]

2.2.2. Illicit drugs

Unlike gambling, illicit drugs are excluded from the normal functioning of the internal market. According to the Court, 'drugs which are not confined within channels of distribution strictly controlled by the competent authorities for use for medical and scientific purposes are subject, by definition, to a total prohibition of importation and distribution in all the Member States'.[650]

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[643] Case C-42/07 *Liga Portuguesa de Futebol Profissional and Bwin International* [2009] EU:C:2009:519, para 47. See also Case C-90/20 *DocMorris* [2021] EU:C:2021:609, para 30.
[644] See *Gambelli* (n 640); Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica* [2007] EU:C:2007:133 ; Joined Cases C-72/10 and C-77/10 *Costa and Cifone* [2012] EU:C:2012:80 ; Case C-463/13 *Stanley International Betting and Stanleybet Malta* [2015] EU:C:2015:25 ; Case C-375/17 *Stanley International Betting and Stanleybet Malta* [2018] EU:C:2018:1026.
[645] Case C-124/97 *Läära and Others* [1999] EU:C:1999:435, paras 20-26.
[646] *Schindler* (n 632), para 22.
[647] ibid.
[648] ibid, para 24.
[649] Case C-6/01 *Anomar e.a.* [2003] EU:C:2003:446, para 55 ; Case C-98/14 *Berlington Hungary e.a* [2015] EU:C:2015:386, para 31.
[650] Case 221/81 *Wolf v Hauptzollamt Düsseldorf* [1982] EU:C:1982:363, para 10 ; Case C-137/09 *Josemans* [2010] EU:C:2010:774, para 41; Case C-663/18 *B S and C A (CBD)* [2020] EU:C:2020:938, para 61.

It follows from this statement that Member States' measures applicable to illicit drugs do not fall under the scope of the customs union provisions,[651] of the provisions governing the EU VAT system,[652] or free movement provisions in general.[653] Conversely, since their commerce is not prohibited, drugs used for pharmaceutical or medical purposes are covered by Article 34 TFEU.[654] In the *CBD* case, the Court ruled that Articles 34 and 36 TFEU applied to cannabidiol, or CBD, a substance derived from the cannabis plant also available in synthetic form, as CBD did not have psychotropic effects and was lawfully produced and marketed in the Member State where it originated (see further developments in Chapter 5, Section 3.1.1).[655]

Setting the boundary between legal and illegal activities, where free movement starts and where it ends, is not always straightforward. This can be seen with the *Josemans* case, where the Dutch unique tolerance policy on drugs came under the Court's scrutiny. In the Netherlands, cannabis is considered an illicit drug under the law, but authorities apply a policy of tolerance regarding its consumption and sale. In certain specific licenced catering establishments, so-the called 'coffee-shops', small quantities of cannabis can be sold to consumers in controlled conditions. This possibility, unique in the EU,[656] attracts cannabis consumers from other Member States, a 'drug tourism' that creates a nuisance for Dutch municipalities, especially those situated near international borders. To counter the nefarious effect of this drug tourism, the border town of Maastricht had decided to limit access to its coffee-shops to persons residing in the Netherlands, prohibiting access to residents of other Member States. This, it was claimed, was a discriminatory rule restricting the freedom of coffee-shops to provide services to non-residents. Regarding the status of cannabis in the Netherlands and a possible application of free movement rules, the Court took a position in line with its previous case-law and ruled that:

> As narcotic drugs which are not distributed through such strictly controlled channels are prohibited from being released into the economic and commercial channels of the European Union, a coffee-shop proprietor cannot rely on the freedoms of movement or the principle of non-discrimination, in so far as concerns the marketing of cannabis, to object to municipal rules such as those at issue in the main proceedings.[657]

Although the Netherlands applies a policy of tolerance, the legal situation of cannabis is not fundamentally altered.[658] It remains prohibited. An interesting twist of the case was that Dutch coffee-shops also sold food and non-alcoholic beverages, an activity to which the Court considered the freedom to provide services to be applicable.[659] The rule adopted by the city of

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[651] *Wolf* (n 650); Case 50/80 *Horvath v Hauptzollamt Hamburg-Jonas* [1981] EU:C:1981:34.
[652] Case 294/82 *Einberger v Hauptzollamt Freiburg* [1984] EU:C:1984:81; Case 289/86 *Happy Family v Inspecteur der Omzetbelasting* [1988] EU:C:1988:360.
[653] *Josemans* (n 650), para 42.
[654] Case 324/93 *The Queen v Secretary of State for the Home Department, ex parte Evans Medical and Macfarlan Smith* [1995] EU:C:1995:84, para 20.
[655] *CBD* (n 650), paras 77-78.
[656] See the discussion Chapter 5, Section 2.6.
[657] *Josemans* (n 650), para 42.
[658] ibid, para 43.
[659] ibid, para 46. This went against the opinion of Advocate General Bot. In view of 'the very negligible and ancillary proportion of sales of lawful consumer products' in coffee shops – 'the purpose of coffee shops is not to

Maastricht was found to be indirectly discriminatory towards non-nationals and therefore in breach of Article 56 TFEU.[660]

Declining to apply free movement provisions to the trade in illicit drugs was emphatically defended by Advocate General Bot in *Josemans*. He considers that:

> [T]he activity of selling cannabis *does not in any way contribute to the well-being of the citizens of the Union*, gives rise to serious public order problems and undermines a legitimate economy by allowing criminal organisations to penetrate the market. Anyone who cultivates, produces, transports, imports, exports, offers or sells narcotic products for whatever purpose *is clearly operating so far outside the legal economic sphere of the internal market* that, rather than benefiting from the advantages derived from the common market, he can only be subject to criminal prosecution.[661]
>
> [A]s a result of the exercise of the fundamental freedoms, *the trade in a narcotic product would be given legitimacy*. Such reasoning must be rejected, since it could apply equally to human trafficking, prostitution of minors or child pornography, and this would constitute an unacceptable breach in the construction of an area of freedom, security and justice based on the rule of law and respect for fundamental rights.[662]

Although Bot's opinion appears strongly influenced by his own moral considerations regarding the consumption of cannabis, and drugs in general – is the cultivation of cannabis for sale *really* comparable to the sexual exploitation of minors? – what appears from the case-law on illicit drugs and gambling, and from free movement law in general, is that the decisive legal criterion regarding the application of free movement provisions is not the morally questionable nature of an activity[663] but rather the illegal nature of a given product or service in *all Member States*.

One may therefore wonder what would happen if one Member State undertook to legalise the sale and consumption of a given drug, cannabis for instance, on its territory. Would that suffice to trigger the application of free movement law and hence subject other Member States' rules to the Court's scrutiny? Or would this occur only if a significant number of Member States opted for such policy? This would also depend on the evolution of Union rules regarding trade

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be a place for consumption like others where people come to have a fizzy drink or to buy a sandwich, but to be a very specific place where they are able to buy and consume cannabis' – Advocate General Bot considered that 'it would be artificial to split up the examination of the conformity of the contested measure having regard to those two kinds of activity' and that such an approach 'would run the risk that the rules of the Treaty could ultimately serve the interests of the drug trade', Case C-137/09 *Josemans* [2010] EU:C:2010:433 Opinion of Advocate General Bot, paras 107-111.

[660] *Josemans* (n 650), paras 58-59.

[661] *Josemans*, Opinion of Advocate General Bot (n 659), para 103, emphasis added.

[662] ibid, para 105, emphasis added.

[663] It is an established principle that 'it is not for the Court to substitute its own assessment for that of the legislatures of the Member States where an allegedly immoral activity is practised legally', Case C-268/99 *Jany and Others* [2001] EU:C:2001:616, para 56. In this case, the Court observed for instance regarding prostitution that '[f]ar from being prohibited in all Member States, [it] is tolerated, even regulated, by most of those States, notably the Member State concerned in the present case', para 57. For more general observations on the application of free movement law in areas of moral concern, see Dimitrios Doukas 'Morality, Free Movement and Judicial Restraint at the European Court of Justice', in Panos Koutrakos, Niamh Nic Shuibhne and Phil Syrpis (eds), *Exceptions from EU Free Movement Law : Derogation, Justification and Proportionality* (Hart Publishing 2016) 146.

in drugs (see Chapter 5, Section 3.1), as their illegal nature does not only derive from national law but from EU and international law as well. This means that a Member State's unilateral decision to legalise a given drug may not alter the Court's position regarding the lack of applicability of free movement provisions.

2.3. Article 34 TFEU and the concept of measures having equivalent effect

Free movement provisions generally prohibit the adoption of measures that are restrictive of cross-border trade. Regarding the freedom of establishment and the freedom to provide services, all measures 'which prohibit, impede or render less attractive the exercise of the freedoms guaranteed by Articles 49 TFEU and 56 TFEU must be regarded as restrictions'.[664] This broad test applies to any kind of national measure coming within the material scope of these two articles, regardless of its nature. Determining what constitutes a restriction under Article 34 TFEU is a far less straightforward exercise. It has given rise to abundant case-law and scholarly discussions, which are briefly presented here and explored further in the remainder of the Chapter.[665] For the sake of clarity, Articles 37 and 110 TFEU are treated in separate sub-sections.

Regarding Article 34 TFEU, although the case-law is still marred with uncertainty, the following can be said regarding the definition of what constitutes a measure having equivalent effect to a quantitative restriction on imports. According to the classical *Dassonville* formula, the concept of measure having equivalent effect covers 'any measure of the Member States that is capable of hindering, directly or indirectly, actually or potentially, intra-Union trade'.[666] This definition is an 'abstract (jurisdictional) definition' which 'must always be matched and mediated by – at least – one of the three substantive principles listed by the Court'.[667] These

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[664] *Stanley International Betting* [2015] (n 644), para 45. For an overview of what constitute, generally, restrictions to the freedom to provide services and the freedom of establishment, see Catherine Barnard, *The Substantive Law of the EU* (6th edition, Oxford University Press 2019) 297-307, 406-422, 432-441.

[665] In a vast literature, see Miguel Poiares Maduro, *We The Court : The European Court of Justice and The European Economic Constitution* (Hart Publishing 1998); Miguel Poiares Maduro and Loïc Azoulai (eds), *The Past and Future of EU Law: The Classics of EU Law Revisited on the 50th Anniversary of the Rome Treaty* (Hart Publishing 2010) 433–473; Robert Schütze, *From International to Federal Market: The Changing Structure of European Law* (Oxford University Press 2017); Fabian Amtenbrink and others (eds), *The Internal Market and the Future of European Integration: Essays in Honour of Laurence W. Gormley* (Cambridge University Press 2019); Panos Koutrakos, 'On Groceries Alcohol and Olive Oil More on Free Movement of Goods after Keck' (2001) 26 European Law Review 391; Eleanor Spaventa, 'Leaving Keck behind? The Free Movement of Goods after the Rulings in Commission v Italy and Mickelsson and Ross' (2009) 34 European Law Review 914; Laurence W Gormley, 'Free Movement of Goods and Their Use - What Is the Use of It?' (2010) 33 Fordham International Law Journal 1589; Anne-Lise Sibony, 'Can Market Access Be Taken Seriously?' (2012) 2012 European Journal of Consumer Law - Revue Européenne de Droit de la Consommation 323; Laurence W Gormley, 'Inconsistencies and Misconceptions in the Free Movement of Goods' (2015) 40 European Law Review 925; Ioannis Lianos, 'In Memoriam Keck the Reformation of the EU Law on the Free Movement of Goods' (2015) 40 European Law Review 225; Robert Schütze, 'Of types and tests: towards a unitary doctrinal framework for article 34 TFEU?' (2016) 41 European Law Review 826.

[666] Case C-591/17 *Austria v Germany* [2019] EU:C:2019:504, para 120. See *Dassonville* (n 612), para 5.

[667] Robert Schütze, 'Of types and tests: towards a unitary doctrinal framework for article 34 TFEU?' (n 665) 835. In some judgments however, the Court qualifies national measures of measures having equivalent effect against

three substantive principles, or tests, which were summarised by the Court in the *Trailers* judgment,[668] are usually attached to different categories of measures.

The first of these categories covers 'product requirements', 'rules that lay down requirements to be met by […] goods (such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging)'.[669] For these, the principle of mutual recognition applies, meaning that 'in the absence of harmonisation of national legislation, obstacles to the free movement of goods which are the consequence of applying, to goods coming from other Member States where they are lawfully manufactured and marketed, rules that lay down requirements to be met by such goods constitute measures of equivalent effect to quantitative restrictions even if those rules apply to all products alike'.[670]

The second category contains national rules restricting or prohibiting certain selling arrangements. These rules do not regulate the characteristics of products but the way they are sold, they are 'provisions concerning inter alia the place and times of sale of certain products and advertising of those products as well as certain marketing methods to be provisions governing selling arrangements'.[671] A discrimination test applies to this category of measures, whereby such rules do not constitute measures having equivalent effect if, according to the (in)famous *Keck* ruling, they 'apply to all relevant traders operating within the national territory and that they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States'.[672]

Finally, a 'market access' test applies to all other national rules: rules 'which hinder[…] access of products originating in other Member States to the market of a Member State'[673] constitute measures having equivalent effect to quantitative restriction on imports.

Throughout its case-law, the Court has tended to apply these three tests, mutual recognition, non-discrimination and market access, separately to each of these three categories of measures, product requirements, selling arrangements and other measures. In some cases, however, the Court seemed to apply a unitary framework, whereby the three tests are successively applied to a given national measure, meaning that any such measure escapes the qualification of measure having equivalent effect if it does not discriminate, directly or indirectly, against goods from other Member States, if it does not impede the mutual recognition and if it does not hinder the access of goods to the market of the Member State of import.[674] This can be seen in *ANETT*, where the Court observed, regarding the Spanish system of retail sales licences for tobacco

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the sole *Dassonville* formula, see Case C-573/12 *Ålands Vindkraft* [2014] EU:C:2014:2037, paras 65-67; Case C-602/19 *Kohlpharma* [2020] EU:C:2020:804, paras 38-39.

[668] Case C-110/05 *Commission v Italy (Trailers)* [2009] EU:C:2009:66.

[669] Case C-267/91 *Keck and Mithouard* [1993] EU:C:1993:905, para 15.

[670] *Trailers* (n 668), para 35. See also *Cassis de Dijon* (n 612), paras 6, 14 and 15.

[671] Case C-71/02 *Karner* [2004] EU:C:2004:181, para 38.

[672] *Trailers* (n 668), para 36, see also *Keck and Mithouard* (n 669), para 16.

[673] *Trailers* (n 668), para 37.

[674] On this unitary framework, see Schütze 'Of types and tests: towards a unitary doctrinal framework for article 34 TFEU?' (n 665).

products, that 'nothing indicates that the national legislation at issue has the object or effect of treating tobacco coming from other Member States *less favourably* [nor] does it concern *the requirements* that those products must meet' but added that 'it is still necessary to examine whether this legislation *hinders the access* of tobacco products coming from other Member States to the Spanish market'.[675] This can also be seen in the recent *Austria v Germany* judgment, where the Court declared, after restating the *Dassonville* formula, that 'a measure, even if it has neither the object nor the effect of treating goods coming from other Member States less favourably, also falls within the scope of the concept of a "measure having equivalent effect to quantitative restrictions", within the meaning of Article 34 TFEU, if it hinders access to the market of a Member State of products originating in other Member States'.[676]

Adopting this unitary framework would simplify the application of Article 34 TFEU and bring it closer to that of Articles 49 and 56 TFEU, subjecting all national rules to a restriction approach whereby any measure that is restrictive of free movement, in one way or another, is prohibited. For product requirements, this solution would not change anything on substance, as these requirements represent measure having equivalent effect in all circumstances. For selling arrangements, a unitary framework would mean the final demise of *Keck*[677] and could lead to a change of outcome for some specific types of measures. Certain selling arrangements that are genuinely non-discriminatory, directly or indirectly, could still be considered as measures having equivalent effect if they hindered the access of imported products to the domestic market. The Court has however until now refrained from wholly embracing the unitary framework and continues to apply the *Keck* solution to measures classified as selling arrangements.[678] This is therefore the approach that will be followed when analysing national lifestyle risks measures.

3. National measures on economic incentives: price and tax measures

Price and tax measures are widely seen as the most effective form of regulation to deter people from smoking or using tobacco products and equally effective as an alcohol control policy, something that the Court of Justice has recognised on multiple occasions by stating that 'fiscal

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[675] Case C-156/10 *ANETT* [2012] EU:C:2012:241, paras 36-37, emphasis added. For a similar 'unitary view', see Case C-333/14 *The Scotch Whisky Association* [2015] EU:C:2015:527, Opinion of Advocate General Bot, para 58: 'I infer from that standard formula that a national measure may constitute an obstacle not only when, as a selling arrangement, it is discriminatory, in law or in fact, but also when, irrespective of its nature, it impedes access to the market of the Member State concerned'.

[676] *Austria v Germany* (n 666), para 121.

[677] For recent judicial uncertainties surrounding the application of the *Keck* case-law, see Schütze 'Of types and tests: towards a unitary doctrinal framework for article 34 TFEU?' (n 665) 838-840. For further predictions or calls for the disappearance of *Keck* see Spaventa 'Leaving Keck behind? The Free Movement of Goods after the Rulings in Commission v Italy and Mickelsson and Ross' (n 665); Gormley, 'Inconsistencies and Misconceptions in the Free Movement of Goods' (n 665); Lianos (n 665).

[678] See, very recently, *DocMorris* (n 643), para 35.

legislation is an important and effective instrument for discouraging consumption of those products and, therefore, for the protection of public health'.[679]

National price and tax measures have yielded a high number of cases with regards to national lifestyle risks regulatory measures, in relation to alcohol and tobacco in particular. These measures may constitute restrictions to the free movement of goods and services within the meaning of Articles 34 and 56 TFEU and, regarding the internal taxation of tobacco products, alcoholic beverages and other foodstuffs, measures prohibited by Article 110 TFEU. The major difference between these three provisions, from the perspective of Member States and public health, is that national rules which fall foul of the requirements of Article 110 TFEU may not be 'saved' under justification, which is particularly restrictive of national regulatory autonomy and potentially prejudicial to public health.

3.1. Price measures

In order to deter the consumption of certain products, altogether or in excess, Member States might adopt measures that regulate the price at which these products are sold. These measures usually seek to eliminate products that are too cheap from the market. They can take various forms: rules that directly set a minimum or maximum retail price, rules on minimum or maximum profit margins and rules on resale price maintenance, whereby the retailer is prevented from selling a product at a different price from the one set by the manufacturer.[680] This latter type of measure is used to prevent retailers from offering discounts on products. The circumstances in which various price measures can constitute a measure having equivalent effect within the meaning of Article 34 TFEU has given rise to a steady stream of, sometimes contradictory, case-law.

In the early *Van Tiggele* judgment, the Court ruled that '[w]hilst national price-control rules applicable without distinction to domestic products and imported products *cannot in general produce [a restrictive effect] they may do so in certain specific cases*'.[681] Such an effect may arise in particular where the price or the profit margin is set at a level which puts imported products at a disadvantage, 'either because they cannot profitably be marketed in the conditions laid down or because the competitive advantage conferred by lower cost prices is cancelled out.'[682] This was the case with the Dutch measure at stake establishing a system of minimum retail prices for spirits, which was found to put imported products at a disadvantage by preventing their lower cost price from being reflected in the retail selling price.[683] The same

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[679] Case C-140/05 *Valeško* [2006] EU:C:2006:647, para 58. See also *Scotch Whisky* (n 612), para 44.
[680] See European Commission, Commission Notice: Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) [2021] OJ C100/38, 53-55
[681] Case 88/77 *Van Tiggele* [1978] EU:C:1978:10, para 13, emphasis added.
[682] *Van Tiggele* (n 681), para 14. See also Joined Cases 16 to 20/79 *Danis* [1979] EU:C:1979:248, para 7.
[683] *Van Tiggele* (n 681), para 18. For a maximum profit margin, see also Case 116/84 *Roelstraete* [1985] EU:C:1985:237, para 21 and Case 188/86 *Ministère public v Lefèvre* [1987] EU:C:1987:327, para 13.

conclusion is drawn in case of a maximum selling price which prevents or renders more difficult the import of a product whose cost price is above the set price.[684]

The Court in *Van Tiggele* also gave two examples of price measures that are not capable of putting imported products at a disadvantage: rules on retail price maintenance, where 'a national provision […] prohibits without distinction the retail sale of domestic products and imported products at prices below the purchase price paid by the retailer', and rules that set 'a minimum profit margin at a specific amount and not as a percentage of the cost price', where 'the amount of the profit margin constitutes a relatively insignificant part of the final retail price'.[685]

Regarding retail price maintenance, the Court declared in *INNO v ATAB* and *Van de Haar*, which both dealt with measures prohibiting the sales of tobacco at a different price from the one set by the manufacturers or importers, that this type of measures 'whereby the prices are freely chosen by the manufacturer or the importer […] and imposed on the consumer by a national legislative measure', provided it is applied without distinction to domestic products and imported products alike, 'generally has exclusively internal effects', although the possibility of an effect on intra-Union trade could not be excluded.[686]

The picture that emerges from these early cases is that price measures are not held to have restrictive effects on trade, provided they apply equally to foreign and domestic products, unless the level at which the price or profit margin is set puts imported products at a disadvantage, in which case the measure constitutes a measure having equivalent effect prohibited by Article 34 TFEU. Any restrictive effect is especially unlikely where the retail price is freely set by the manufacturer or importer. This line of case-law essentially subjects price measures to a discrimination test,[687] an approach confirmed post-*Keck* where such measures were classified as selling arrangements.[688]

In *Scotch Whisky*, however, the Court came to change its view. At stake was yet another type of price measure: the Scottish minimum unit pricing (MUP) rule for alcoholic beverages, whereby it is not a final retail price that is set but a minimum price per unit of alcohol contained in each beverage. In this case, the MUP was set at 0,50 pounds. Contrary to previous case-law, the Court did not investigate a potential adverse effect putting imported products at a disadvantage. It simply applied a market access test and concluded that:

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[684] Case 65/75 *Tasca* [1976] EU:C:1976:30.
[685] *Van Tiggele* (n 681), paras 16-17.
[686] Case 3/77 *INNO v ATAB* [1977] EU:C:1977:185, paras 53-54. See also Joined Cases 177 and 178/82 *Van de Haar* [1984] EU:C:1984:144, paras 20-21.
[687] See *Scotch Whisky*, Opinion of Advocate General Bot (n 675), para 65. See also the analysis of the arguments put forward by the European Commission in this case in Angus MacCulloch, 'State Intervention in Pricing: An Intersection of EU Free Movement and Competition Law' (2017) 42 European Law Review 190, 202–203.
[688] In LIBRO, the price measures was found to put imported products at a disadvantage, see Case C-531/07 *Fachverband der Buch- und Medienwirtschaft (LIBRO)* [2009] EU:C:2009:276, paras 21-22. For a price measure classified as a non-discriminatory and therefore valid selling arrangement, see Case C-63/94 *Belgapom v ITM and Vocarex* [1995] EU:C:1995:270.

> [T]he fact that the legislation at issue in the main proceedings prevents the lower cost price of imported products being reflected in the selling price to the consumer means, *by itself*, that that legislation is capable of hindering the access to the United Kingdom market of alcoholic drinks that are lawfully marketed in Member States other than the United Kingdom of Great Britain and Northern Ireland, and constitutes therefore a measure having an effect equivalent to a quantitative restriction within the meaning of Article 34 TFEU.[689]

The advantage of applying a market access test for the Court is that no effect specific to imported products needs to be shown for a price measure to constitute a measure having equivalent effect to a quantitative restriction. The difficulty inherent to that type of assessment appears from the Opinion of Advocate General Bot, where, although sharing the Court's view on the application of a market access test, the Advocate General, for the sake of completeness, still analysed the measure as a selling arrangement. To prove that the MUP was putting imported products at a disadvantage, Advocate General Bot had to rely on statistics showing that a higher percentage of wines imported from Member States than of wine from the United Kingdom were sold at a price below the MUP.[690]

Scotch Whisky, like *Van Tiggele*, concerned a measure where importers or manufacturers were not anymore free to set their prices. The question remained opened after this judgment as to what would be made of retail price maintenance measures of the kind analysed in *INNO v ATAB* and *Van de Haar*. The Court provided the answer in *Colruyt*, where the Belgian measure prohibited retailers from selling tobacco products at a retail price lower than the price indicated by the manufacturer or importer on the revenue stamp affixed to those products. The Court considered that such rule was a selling arrangement which applied to all relevant traders operating within the national territory and, since the price could still be set freely by importers, which was not of such a kind as to prevent or impede access to the Belgian market for tobacco products from another Member State any more than it did for domestic tobacco products, hence escaping the prohibition contained in Article 34 TFEU.[691]

The divergence between the solution adopted in *Scotch Whisky*, where the Court applied a market access test, and *Colruyt*, where the Court applied a discrimination test, appears unsatisfactory for at least two reasons. First, sorting price measures in different categories does not stand conceptually. If price measures 'do not concern the characteristics of those goods, but solely the arrangements under which they may be sold, [and therefore] must be regarded

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[689] *Scotch Whisky Association* (n 616), para 32, emphasis added.
[690] *Scotch Whisky*, Opinion of Advocate General Bot (n 675), para 66.
[691] Case C-221/15 *Etablissements Fr. Colruyt* [2016] EU:C:2016:704, paras 37-40. See also the supplementary argument put forward by Advocate General Wahl in his opinion, Case C-221/15 *Colruyt* [2016] EU:C:2016:288, Opinion of Advocate General Wahl, para 56: 'Second, although the retailers' ability to set prices of tobacco products is severely reduced, that ability is not completely eliminated. Indeed, at least in theory, nothing prevents retailers (especially large retailers) from negotiating with manufacturers or importers (including parallel importers) with a view to setting a price for the products lower than that usually practised. Provided the manufacturer or importer agrees to affix a revenue stamp with a lower price, the sale of tobacco products at that lower price is, and should be, permissible.' For a critical reading of both the Court and the Advocate General's reasonings, see Oliver Bartlett, 'The CJEU Assesses Another Minimum Pricing Measure Without Properly Contextualising It' (2016) 7 European Journal of Risk Regulation 810.

as concerning selling arrangements',[692] then this should be the case for all price measures, regardless of their nature. An MUP is as much a measure that concerns the way goods are sold as a retail price maintenance measure is. Second, by classifying price measures differently, and thus applying a different legal test, in function of whether importers or manufacturers are free to set their price or not, the Court draws a strict line which does not reflect the potential restrictive effects of retail price measures.[693] The possibility for such measures, in certain circumstances, to hinder access to the market of import cannot be excluded out of hand. This is after all what the Court itself said in *INNO v ATAB* and *Van de Haar*.

It should be borne in mind that the Court's judgment in *Colruyt* was handed down less than a year after the judgment in *Scotch Whisky*, by a different chamber. It is hence possible that the difference in outcomes reflects a divergence in the chambers' views rather than a global position from the Court. In *Deutsche Parkinson*, a judgment delivered only some weeks after the one in *Colruyt*, yet another chamber from the Court analysed the compatibility with Article 34 TFEU of a measure setting a fixed price for medicinal products, hence a far more restrictive measure than the one at stake in *Colruyt*, based on its discriminatory effect against imported products.[694] A certain degree of uncertainty therefore remains as to what test applies to price measures. What is known is that any price measure that puts imported products at a disadvantage, preventing them for instance from exploiting the competitive advantage arising from their lower price, is caught by Article 34 TFEU. Moreover, as we shall see in Chapter 5, EU rules on excise duty for tobacco products currently prevent Member States from adopting measures setting a minimum retail selling price for this category of products.

3.2. Taxation

Another, indirect way to increase the price of harmful products or services to limit their consumption is to adopt tax measures. While taxation policy remains largely in the hands of Member States, it must nonetheless be exercised in compliance with internal market freedoms, with regards in particular, as far as goods are concerned, to Article 110 TFEU. National tax measures applicable to services may also fall under the purview of Article 56 TFEU.

3.2.1. Article 110 TFEU

Article 110 TFEU aims at ensuring that internal taxation remains neutral vis-à-vis imported goods and does not favour domestic production at the expense of foreign products. As such, it brings limits to Member States' discretionary powers when enacting tax measures that seek to limit the consumption of tobacco products, alcoholic beverages or unhealthy foods.

According to Article 110 TFEU:

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[692] *Colruyt* (n 691), para 37.
[693] Oliver Bartlett, 'The CJEU Assesses Another Minimum Pricing Measure Without Properly Contextualising It' (n 691).
[694] Case C-148/15 *Deutsche Parkinson Vereinigung* [2016] EU:C:2016:776, paras 24-26.

> No Member State shall impose, directly or indirectly, on the products of other Member States any internal taxation of any kind *in excess* of that imposed directly or indirectly on *similar* domestic products.
>
> Furthermore, no Member State shall impose on the products of other Member States any internal taxation of such a nature as to afford *indirect protection* to other products.[695]

The two paragraphs of Article 110 TFEU address different situations. Article 110(1) TFEU is essentially concerned with discrimination. Member States may not enact measures that would result in foreign products being more heavily taxed than similar domestic products. Article 110(2) TFEU, however, is broader in scope, as it prevents Member States from using their taxation as a protectionist tool. Article 110(1) TFEU applies to situations where domestic and foreign products are similar while Article 110(2) TFEU applies to situations where those are in competition. There can be no application of Article 110 TFEU when no competitive link exists between two categories of products.

As the Court recalled on multiple occasions, 'the aim of Article [110 TFEU] as a whole is to ensure free movement of goods between the Member States in normal conditions of competition by the *elimination of all forms of protection* which result from the application of internal taxation which discriminates against products from other Member States and to guarantee the *complete neutrality* of internal taxation as regards competition between domestic products and imported products.'[696] When Member State enact taxation measures to discourage the consumption of certain products, as it is often done when these present a risk to human health, they must ensure that these measures do not provide any sort of protection to their domestic productions.

In the following developments are addressed the main questions surrounding the application of Article 110 TFEU and its effect on national taxation policy, taking examples mostly from the field of alcohol taxation, where the Court's case-law is particularly abundant.

3.2.1.1. The meaning of internal taxation under Article 110 TFEU

Article 110 TFEU applies solely to indirect taxation imposed on products.[697] The term indirect refers there to the fact that companies collect a tax which is partially or fully reflected in the selling price of goods. This tax is hence indirectly levied on consumers. According to the Court, Article 110 TFEU 'must be interpreted widely so as to cover all taxation procedures which, directly or indirectly, undermine the equal treatment of domestic products and imported products'. The prohibition contained in that article 'must therefore apply whenever a fiscal charge is likely to discourage imports of goods originating in other Member States to the benefit of domestic production'.[698]

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[695] Emphasis added.
[696] Case 106/84 *Commission v Denmark* [1986] EU:C:1986:99, para 10, emphasis added.
[697] Joined Cases C-393/04 and C-41/05 *Air Liquide Industries Belgium* [2006] EU:C:2006:403, para 57.
[698] Case C-221/06 *Stadtgemeinde Frohnleiten and Gemeindebetriebe Frohnleiten* [2007] EU:C:2007:657, para 40.

Articles 30 and 110 TFEU are mutually exclusive,[699] the application of one automatically precluding the application of the other. Article 30 TFEU applies to charges incurred at the moment or by reason of the crossing of a frontier and is generally borne solely by imported or exported products. Article 110 TFEU applies to charges incurred within a Member State and is generally imposed on both imported and domestic products. In cases where a Member State adopts a taxation scheme which imposes a charge on an imported product in a situation where there is no identical or similar domestic product, it is still considered to be internal taxation within the meaning of Article 110 'if it relates to a general system of internal dues applied systematically to categories of products in accordance with objective criteria irrespective of the origin of the products'.[700] However, if a Member State uses the revenue of such a system of internal dues, applied to both domestic and imported products, to fully offset the burden borne by domestic products, resulting in practice in a charge only impacting foreign products, it is then considered to be a charge having an effect equivalent to a customs duty within the meaning of Article 30 TFEU.[701]

The consequences of falling within the scope of one article or the other are not only formal. Both charges having equivalent effect and protective taxation are prohibited, but while any charge, however small, must be removed, a system of taxation that favours domestic products does not necessarily need to be eliminated. It must simply be adjusted so as to remove its protective effect.[702]

Articles 110 and 34 TFEU are also mutually exclusive.[703] The boundary between the two provisions is easier to navigate since Article 34 TFEU does not apply, in principle, to obstacles of a fiscal nature.[704] The Court once suggested that an excessive level of a tax may constitute a measure having equivalent effect within the meaning of Article 34 TFEU,[705] but this was effectively ruled out.[706]

3.2.1.2. Differentiating Articles 110(1) and 110(2) TFEU

The two paragraphs of Article 110 TFEU cover different situations and should therefore, in principle, be applied separately. This has not, however, always been the Court's practice, which

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[699] Case 10/65 *Deutschmann v Bundesrepublik Deutschland* [1965] EU:C:1965:75; Case C-39/17 *Lubrizol France* [2018] EU:C:2018:438, para 25.
[700] Case 193/85 *Co-Frutta v Amministrazione delle finanze dello Stato* [1987] EU:C:1987:210, para 10.
[701] Case C-76/17 *Petrotel-Lukoil and Georgescu* EU:C:2018:139, para 24.
[702] Barnard (n 664) 63-64.
[703] Case C-313/05 *Brzezinski,* EU:C:2007:33, para 50; Case C-198/14 *Visnapuu* [2015] EU:C:2015:751, para 50.
[704] ibid.
[705] Case C-47/88 *Commission v Denmark* [1990] EU:C:1990:449, para 10-13.
[706] *Brzezinski* (n 703), para 50. See however *Austria v Germany* (n 666) and the commentary by Augustin Chapuis-Doppler and Vincent Delhomme, 'Non-discrimination and free movement in a Member State to Member State fiscal dispute: Case C-591/17 Austria v. Germany' (2019) 26 Maastricht Journal of European and Comparative Law 849, 855. In this case, the Court applies Article 34 TFEU to a fiscal charge for the use of motorways which, while not directly levied on goods, indirectly affects cross-border trade in goods.

has at times applied the article in its entirety, without distinguishing between the two paragraphs.[707]

This practice appears particularly clearly in a series of three judgements rendered in the 1980s dealing with Danish, French and Italian taxes on spirits.[708] The legislations at stake resulted in the differential taxation of various spirits which the Commission deemed to favour national production. The Court followed a similar approach in all three cases. It made no distinction between the discriminatory nature of the taxation systems and their protective effect. To fall foul of Article 110 TFEU, it is enough that 'it is impossible reasonably to contest that without exception [imported products] are in at least partial competition with the domestic products',[709] and that 'there is a difference in the rate or the detailed rules for levying the tax and […] that difference is likely to favour a given domestic production'.[710]

This line of reasoning will cease to be applied in later cases, a welcome change since, as argued in greater details below, Article 110(1) and (2) cover two fundamentally different situations and should lead to the application of two different legal tests. Discrimination arises when two similar products are taxed differently. Protection, however, should be proven by means of an effect-based test showing that the difference in taxation is likely to lead to an advantage for the domestic production.

3.2.1.3. Article 110(1) TFEU – Discriminatory taxation

The first paragraph of Article 110 TFEU prohibits 'any tax provision whose effect is to impose, by whatever mechanism, higher taxation on imported goods than on domestic products'.[711] This implies 'the comparison of tax burdens, whether in terms of the rate, the mode of assessment or other detailed rules for the application thereof".[712]

3.2.1.3.1. Notion of similarity

To apply the first paragraph of Article 110 TFEU, the products at stake must be similar. This has been interpreted widely by the Court. Similar does not mean that products must be identical but that they have a similar and comparable use.[713] For alcoholic beverages, 'it is necessary first to consider certain objective characteristics of both categories of beverages, such as their origin, the method of manufacture and their organoleptic properties, in particular taste and alcohol content, and secondly to consider whether or not both categories of beverages are

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[707] For an early occurrence, see Case 16/69 *Commission v Italy* [1969] EU:C:1969:47.
[708] Case 169/78 *Commission v Italy* [1980] EU:C:1980:52 ; Case 168/78 *Commission v France* [1980] EU:C:1980:51 ; Case 171/78 *Commission v Denmark* [1980] EU:C:1980:54.
[709] *Commission v France* (n 708), para 39 ; *Commission v Denmark* (n 708), para 34 ; *Commission v Italy* (n 708), para 33.
[710] *Commission v France* (n 708), *Commission v Denmark* (n 708) and *Commission v Italy* (n 708), para 13. See also Case 319/81 *Commission v Italy* [1983] EU:C:1983:71, para 16.
[711] *Commission v Denmark* (n 696), para 10.
[712] *Commission v Denmark* (n 708), para 7.
[713] *Commission v France* (n 708), para 5.

capable of meeting the same need from the point of view of consumers.'[714] Importantly, the fact that a beverage is less popular than an another does not mean that it cannot fulfil the same consumer needs. This question 'must be assessed on the basis not of existing consumer habits but of the prospective development of those habits and, essentially, on the basis of objective characteristics'.[715]

In its early case-law, the Court considered that the formal customs classification of products was an important factor to take into consideration.[716] This position was later abandoned. The Court now takes of the view that this classification 'cannot provide conclusive evidence with regard to the appraisal of the criterion of similarity laid down in the first paragraph of Article [110]'.[717] The *Commission v Denmark* and *John Walker* cases,[718] handed down the same day and dealing both with aspects of the Danish taxation system on alcoholic beverages, provide a good illustration of the detailed nature of the test applied by the Court.

In *Commission v Denmark*, the Court examined the difference in taxation between wine made from grapes and wine made from other fruits. It ruled that these were similar products.[719] The Court examined these two different wines in two of their forms, as table wines and as liquor wines. Regarding table wines, the Court noted that fruit and grape wines were manufactured from the same kind of basic products, agricultural products, and by the same process, natural fermentation.[720] It added that their organoleptic properties, in particular their taste and their alcohol content, were similar.[721] It also concluded that they could meet the same consumer needs since they could be consumed in the same way, 'namely to quench thirst, as refreshments and at meal times'.[722] In their liquor form, the Court noted that fruit and grape wines were manufactured identically, 'since the end product is invariably obtained by the addition of ethyl alcohol following initial fermentation for some length of time and, in some cases, by the addition of other substances, such as juice or honey', and were both consumed as aperitifs or dessert wines.[723]

The difference in taxation between fruit wine of the liqueur type and whisky was at stake in *John Walker*, products that the Court ultimately found to be dissimilar.[724] The Court considered that the two categories of beverages exhibit 'manifestly different characteristics' since fruit wine of the liqueur type is made of fruit and results from a process of natural fermentation

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[714] *Commission v Denmark* (n 696), para 12; Case 243/84 *Walker v Ministeriet for Skatter og Afgifter (John Walker)* [1986] EU:C:1986:100, para 11.
[715] *Commission v Denmark* (n 696), para 15.
[716] Case 45/75 *Rewe-Zentrale v Hauptzollamt Landau-Pfalz* [1976] EU:C:1976:22, para 12.
[717] *Commission v Denmark* (n 696), para 17. See also *Commission v Italy* (n 798), para 31.
[718] *Commission v Denmark* (n 696) and *John Walker* (n 714).
[719] *Commission v Denmark* (n 696), para 19.
[720] *Commission v Denmark* (n 696), para 14.
[721] ibid.
[722] *Commission v Denmark* (n 696), para 15.
[723] *Commission v Denmark* (n 696), para 16.
[724] *John Walker* (n 714), para 14.

whereas whisky is made from cereal and obtained by distillation.[725] It found their organoleptic properties to be different and also pointed at the large differences in their alcoholic strength, 40% by volume for whisky while liqueur wines do not exceed 20% by volume.[726] According to the Court, the fact that the two products could be consumed in the same way, 'as an aperitif diluted with water or with fruit juice', was not enough to render the two products similar since their intrinsic characteristics were fundamentally different.[727]

As appears from these two judgments, there is no silver bullet that can be used to determine if two products are similar. The Court looks at a number of criteria which, taken together, provide the necessary evidence and adjudicates on a case-by-case basis. The Court has taken position on a variety of alcoholic beverages. In *Roders*, it concluded that sherry was not similar to table wine,[728] vermouth was not similar to fruit wines,[729] and that champagne was not similar to other sparkling fruit wines, on the ground, inter alia, that 'the consumption of champagne is usually associated with special occasions.'[730] Regarding tobacco, the Court found dark-tobacco and light-tobacco cigarettes to be similar products.[731] In *Commission v Italy*, the Court considered that fruits typically grown in Italy, such as 'apples, pears, peaches, plums, apricots, cherries, oranges and mandarins',[732] were not similar to bananas:[733] 'the higher water content of pears and other fruits typically grown in Italy give them thirst-quenching properties which bananas do not possess', whereas 'banana is regarded, at least on the Italian market, as a foodstuff which is particularly nutritious, of a high energy content and well-suited for infants'.[734]

3.2.1.3.2. Breach of Article 110(1) TFEU

Discrimination is the key criterion against which a taxation system is assessed under Article 110(1) TFEU. Both directly and indirectly discriminatory measures are prohibited.[735] Possible discrimination should derive 'exclusively from the difference in the tax burden borne by the two categories of products, whether it is the result of the rate of tax, the mode of assessment or other detailed implementing rules'.[736]

Direct discrimination arises when the difference in tax burden derives from a dissimilar treatment on grounds of origin. This can be seen in *Commission v Italy*, where the taxation

[725] *John Walker* (n 714), para 12.
[726] ibid.
[727] *John Walker* (n 714), para 13.
[728] Joined Cases C-367/93 to C-377/93 *Roders and Others v Inspecteur der Invoerrechten en Accijnzen* [1995] EU:C:1995:261, para 32.
[729] ibid. para 33.
[730] ibid. para 35.
[731] Case C-302/00 *Commission v France* [2002] EU:C:2002:123, paras 22-29.
[732] Case 184/85 *Commission v Italy* [1987] EU:C:1987:207, para 3.
[733] ibid, para 10.
[734] ibid.
[735] Case 148/77 *Hansen v Hauptzollamt Flensburg* [1978] EU:C:1978:173, para 19.
[736] *Commission v. Denmark* (n 696), para 19.

method applied to imported potable spirits and domestic ones was different.[737] Article 110(1) TFEU does not prohibit a system whereby the respective revenues arising from the, similar, taxation of domestic and imported products are used for different purposes,[738] and does not prohibit reverse discrimination where imported products bear a lower tax burden than domestic ones.[739]

Indirect discrimination usually arises in cases where similar products are taxed differently on other grounds than their origin, but the products more heavily taxed are solely or predominantly imported products.[740] This can be seen in *Commission v France* where a different tax rate applied to dark-tobacco and light-tobacco cigarettes. The Court noted that 'cigarettes falling within the most favourable tax category come almost exclusively from domestic production whereas almost all imported products come within the least advantageous category', resulting therefore in discriminatory taxation.[741]

As with other internal market freedoms, there is no 'de minimis' threshold. Any system providing a tax advantage to domestic products, however slight, falls foul of Article 110(1) TFEU.[742]

3.2.1.4. Article 110(2) TFEU – Protective taxation

Article 110(2) TFEU covers situations where the taxation on a given imported product provides indirect protection to a domestic product in competition. It is 'intended to cover all forms of indirect tax protection in the case of products which, without being similar within the meaning of the first paragraph of Article [110 TFEU], are nevertheless in competition, even partial, indirect or potential competition, with each other'.[743]

3.2.1.4.1. Notion of 'products in competition'

To determine whether two products are in competition, the Court uses a test which presents many similarities with the one used for similar products. It looks at the manufacturing process, the composition of products and consumer behaviour. The British 'beer and wine' saga provides a good illustration of the Court's analysis.

In *Commission v United Kingdom (beer and wine I)*,[744] the Court found it difficult to answer definitively on the competitive relationship between beer and wine. As there was little doubt

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[737] *Commission v Italy* (n 707). See also *Rewe-Zentrale* (n 716), para 17.
[738] *Rewe-Zentrale* (n 716), para 17.
[739] Case 86/78 *Peureux* [1979] EU:C:1979:64, para 32.
[740] *Commission v Denmark* (n 708), para 36 ; *Commission v Italy* (n 710), para 18 ; Case 277/83 *Commission v Italy* [1985] EU:C:1985:285, para 15; *Commission v Denmark* (n 696), para 21; Case C-230/89 *Commission v Greece* [1991] EU:C:1991:156, para 10.
[741] *Commission v France* (n 731), para 30.
[742] *Commission v Italy* (n 740), para 17.
[743] *Co-Frutta* (n 700), para 19. See also Case 356/85 *Commission* v *Belgium* [1987] EU:C:1987:353, para 7; *Roders* (n 728), para 38; Case C-167/05 *Commission v Sweden* [2008] EU:C:2008:202, para 41.
[744] Case 170/78 *Commission v United Kingdom (beer and wine I)* [1980] EU:C:1980:53.

that beer and wine were quite different products if looking at their composition, manufacturing process and organoleptic properties,[745] the discussion revolved mostly around consumer habits. The main argument developed by the United Kingdom in favour of the non-existence of a competitive relationship between the two products was that 'in accordance with long established tradition in the United Kingdom, beer is a popular drink consumed preferably in public-houses or in connexion with work; domestic consumption and consumption with meals is negligible [whereas] the consumption of wine is more unusual and special from the point of view of social custom.'[746] According to the Court, however, one cannot restrict its analyses to consumer habits in a particular country or region in order to measure the degree of substitution between the two beverages: 'those habits, which are essentially variable in time and space, cannot be considered to be a fixed rule; the tax policy of a Member State must not therefore crystallize given consumer habits so as to consolidate an advantage acquired by national industries concerned to comply with them'.[747]

The Court was of the opinion that a certain degree of substitution between the two beverages exists, and that beer and wine could meet identical needs, to a certain extent.[748] It could not however reach a definitive conclusion and asked the Commission and the United Kingdom to try solving the issue or to present new observations to the Court.[749] The case came back before the Court three years later. In *Commission v United Kingdom (beer and wine II)*,[750] the Court finally judged that a competitive relationship existed between beer and the types of wines 'which are the most accessible to the public at large, that is to say, generally speaking, the lightest and cheapest varieties'.[751]

Regarding other products, the Court considers that there are, for all spirits, 'common characteristics which are sufficiently pronounced to accept that in all cases there is at least partial or potential competition'.[752] A competitive relationship also exists between bananas and other table fruits.[753]

3.2.1.4.2. Breach of Article 110(2) TFEU

Once the competitive relationship between two categories of products has been established, it must be shown that the application of the internal taxation protects domestic production. In that regard, the case-law has evolved from a formal approach, briefly touched upon when discussing

[745] ibid. para 15.
[746] ibid. para 13.
[747] ibid. para 14. See also *Commission v Italy* (n 710), para 9.
[748] *Commission v United Kingdom (beer and wine I)* (n 744), para 14.
[749] ibid. para 24.
[750] Case 170/78 *Commission v United Kingdom (beer and wine II)* [1983] EU:C:1983:202.
[751] ibid. para 12. See also *Commission* v *Belgium* (n 743), para 10; *Commission v Sweden* (n 743), para 43.
[752] *Commission v France* (n 708), para 12; *Commission v Denmark* (n 708), para 12; *Commission v Italy* (n 708), para 12; *Commission v Italy* (n 710), para 16.
[753] *Commission v Italy* (n 732), para 12.

the global approach to Article 110 TFEU, to a more effects-based approach, arguably closer to the spirit of Article 110(2) TFEU.

In early cases, if a different tax rate was applied to competing domestic and imported products, the taxation was found to be protective.[754] This resulted partly, as already explained above, from the simultaneous application of Article 110(1) and (2) TFEU. This approach appears clearly from the British beer and wine cases. In *Commission v United Kingdom (beer and wine I)*, the Court held that the protective effect did not need to be shown statistically but needed simply to be 'likely' to derive from the tax system in question.[755] It added that it was 'impossible to require the Commission to supply statistical data on the actual foundation of the protective effect of the tax system complained of'.[756] In *Commission v United Kingdom (beer and wine II)* the Court established that wine bore a tax burden which, by reference to alcoholic strength, was more than twice as heavy as that borne by beer.[757] The information provided to the Court did not allow to establish precisely the influence of this tax difference on the respective prices of the two products,[758] so the Court decided that the difference in tax burden was enough to identify a protective effect.[759]

There is a lot to criticise in the approach taken in these two cases, which amounts to rendering nugatory the clear differences existing between the two paragraphs of Article 110 TFEU and thus excessively constrains Member States in the exercise of their fiscal competence. The first paragraph prohibits any difference taxation while the second prohibits a difference only insofar as it leads to a protective effect to the benefit of domestic production. While there appears to be no valid reason for taxing differently similar products on the basis of their origin, taxing different products differently constitutes the very essence of fiscal policy. EU law should only outlaw an established protective effect.

The Court fortunately changed its approach in *Commission v Belgium*.[760] It held that 'any assessment of the compatibility of a given tax with the second paragraph of Article [110 TFEU] must take account of the impact of that tax on the competitive relationship between the products concerned', looking essentially at whether this tax can reduce the potential consumption of imported products to the advantage of competing domestic products.[761] In this regard, the price

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[754] *Commission v Denmark* (n 708), paras 35-36; *Commission v France* (n 708), para 41; *Commission v Italy* (n 708), para 35; *Commission v United Kingdom (beer and wine I)* (n 744), para 24; *Commission v Italy* (n 710), para 18.
[755] *Commission v United Kingdom (beer and wine I)* (n 744), para 10.
[756] ibid.
[757] *Commission v United Kingdom (beer and wine II)* (n 750), para 21.
[758] ibid.
[759] ibid, paras 26-27.
[760] *Commission* v *Belgium* (n 743). The formal approach was however still used in the latter case *Commission v Greece* (n 740), para 10.
[761] *Commission* v *Belgium* (n 743), para 15. See also *Roders* (n 728) para 39; *Commission v Sweden* (n 743), para 52.

difference between the products at stake is an element that cannot be disregarded. [762] In this judgment, the Court offered a detailed analysis that contrasts sharply with its preceding case-law. The Commission claimed that the higher taxation of wine compared to beer constituted a breach of Article 110(2) TFEU. Looking at the prices of the two products, the Court observed that ordinary wine was sold at a price approximately four times higher than that of beer, and that, in such a situation, the Commission had failed to establish how a difference of 6% in VAT rates between beer and wine could influence consumer behaviour.[763] The Court acknowledged that a deceleration of the rise in wine consumption had been observed after the introduction of the tax increase but considered that no causal connection had been established between the two.[764] No protective effect was found in this case.

The contrast could hence not be clearer with previous cases where only the existence of a difference in tax burden was enough to establish a breach of Article 110(2) TFEU. The evidential requirement falling on the Commission is arguably quite hard to discharge. It must show that the difference in tax burden leads to a high enough change in the price gap between the two products compared. The bigger the gap originally is, the less a tax difference is susceptible to substantially alter their competitive relationship and the less it is likely to affect consumer choice. Further, the Commission must also produce evidence that a change in patterns of consumptions to the detriment of the imported product has occurred and establish a causal connection between this change and the tax increase.

This position has been reiterated in another beer and wine case, *Commision v Sweden*. The application of a different tax rate favourable to beer only led to a marginal change in the price difference between the two products, which the Court considered 'not liable to influence consumer behaviour in the sector concerned'.[765] It added that 'the statistical information submitted by the Commission regarding sales of the products in question shows, at most, a certain sensitivity on the part of consumers to variations in the price of those products over a short period, but not long-term changes in consumer habits in favour of beer and to the detriment of wine.'[766]

3.2.1.5. Justification

Once a breach of Article 110 TFEU has been found, can a Member State avail itself of any justification based on the protection of a public interest, such as the protection of human health? Article 110 itself does not foresee any grounds of justification and the Court confirmed, if need

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[762] *Commission* v *Belgium* (n 743), para 16. See also *Roders* (n 728), para 39; *Commission v Sweden* (n 743), para 53.
[763] *Commission* v *Belgium* (n 743), para 18.
[764] ibid, para 20.
[765] *Commission v Sweden* (n 743), paras 56-57. Advocate General Mengozzi took the opposite view in this case: see Case C-167/05 *Commission v Sweden* [2007] EU:C:2007:436, Opinion of Advocate General Mengozzi, in particular paras 71-72.
[766] *Commission v Sweden* (n 743), para 59.

be, that Article 36 TFEU cannot be used in this context.[767] In *Commission v France*, the French government relied on public health to try defending its measures, unsuccessfully.[768] Advocate General Van Themaat alluded to this defence in its joined opinion in *Commission v Denmark* and *John Walker*, seemingly endorsing the Danish argument that taxing whisky more heavily than liqueur wines served to curtail the consumption of beverages with the highest alcohol content.[769] This was however absent from the final judgment in the two cases. It has been argued that indirectly discriminatory taxation under Article 110(1) TFEU could be justified,[770] but it is hard to find any case-law confirming that view.

Rather than formally recognising the possibility of justifying a breach of Article 110, the Court has made use of the concept of 'objective criterion' which, if fulfilled, makes a national measure compatible with Article 110 TFEU. This seems, at first sight, to resemble the mandatory requirements doctrine under Article 34 TFEU. A closer look shows that it is in reality quite different.

The Court has repeated on multiple occasions that Article 110 TFEU does not 'restrict the freedom of each Member State to lay down tax arrangements which differentiate between certain products on the basis of objective criteria, such as the nature of the raw materials used or the production processes employed' if this differentiation 'pursues objectives of economic policy which are themselves compatible with the requirements of the Treaty and its secondary legislation'.[771] In *Commission v France*, the Court recognised the possibility to favour traditional and customary products coming from regions which are economically disadvantaged.[772] In *Bergandi*, the Court considered discouraging the use of certain game machines and encouraging the use of others was a 'legitimate social purpose'.[773]

However, the Court has also repeatedly insisted that for such an objective criterion to apply, the tax system in question needed to be devoid of 'any form of discrimination, direct or indirect, in regard to imports from other Member States or any form of protection of competing domestic products'[774] In *John Walker* for instance, the Court found that Article 110(2) TFEU did not preclude differential taxation based on objective criteria if both categories of products, the one benefitting and the one negatively affected by the tax difference, contained a significant proportion of domestic products.[775] There lies the problem, for if this condition is met, there cannot be any protective effect and hence no breach of Article 110(2) TFEU anyway. Taken at face value, the objective criterion does not therefore add much to the application of Article 110

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[767] *Commission v France* (n 731), paras 32-33.
[768] ibid.
[769] Case 106/84 *Commission v Denmark* and Case 243/84 *John Walker* [1985] EU:C:1985:481, Joined Opinion of Advocate General VerLoren van Themaat, 5.2, para (f).
[770] Barnard (n 664) 59.
[771] *Commission v Denmark* (n 696), para 20; *John Walker* (n 714), para 22; *Hansen* (n 735), para 16.
[772] Case 196/85 *Commission v France* [1987] EU:C:1987:18, para 9.
[773] Case 252/86 *Bergandi* [1988] EU:C:1988:112, para 30.
[774] *Commission v Denmark* (n 696), para 20; *John Walker* (n 714), para 22. See also ibid, para 31; *Commission v France* (n 772), para 10.
[775] *John Walker* (n 714), para 23.

TFEU. In a rather tautological exercise, the Court interprets Article 110 TFEU as not precluding Member States to enact fiscal measures when the circumstances that contravene that article are not met.[776]

The Court's position can also be read in a different manner, as an intrusion in Member State's fiscal choices that is not foreseen by Article 110 TFEU. Indeed, the Court seems to require that Member States, even when no breach of Article 110 TFEU is materially possible, only enact tax measures that differentiate between products on the basis of an objective criterion. This is a peculiar reading of that provision. When Member States do not discriminate against imported products or do not protect their domestic production, they should be left free to organise their internal taxation as they see fit, under the requirement of their domestic legal orders. It is in any case not up to the Court of Justice to decide on the compliance of that arrangement with an objective criterion.

It is submitted that the added value of the objective criterion doctrine lies in reality in the way the Court applies it. Where it identifies an objective criterion, the Court generally dispenses itself from an actual analysis of the discriminatory or protective nature of the measure at stake. It does not analyse the measure in detail[777] or even bypasses the application of Article 110 entirely.[778] On the other hand, if the Court sees a prima facie discrimination case, it looks at the measure more closely.[779] From this perspective, whenever the Court refuses to analyse a measure containing discriminatory or protective aspects on grounds of the objective criteria pursued,[780] this starts resembling like a system of justification.

The recognition by the Court of the possibility for Member States to avail themselves of certain defences under Article 110 TFEU would be a welcome development, not only from a public health perspective but also as regards other public interests. Taxation being by nature a discriminatory exercise – goods, people, companies are taxed differently on grounds of their characteristics – it is good that Member States are able to make legitimate fiscal policy choices even if this leads to a discriminatory or protective effect towards imports. However, the way in which the Court has used the objective criteria doctrine is problematic. It is conceptually illogical, it is a factor of legal uncertainty, and it does not allow to draw a proper balance between the public interest at stake and the effect of the measure on trade. The Court should rather proceed like it does under Article 34 TFEU: presence of a discrimination or protective effect, possible justification, proportionality of the measure.

3.2.1.6. A case study on food taxes

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[776] See also Martin Hedemann-Robinson, 'Indirect Discrimination: Article 95(1) EC Back to Front and Inside Out?' (1995) 1 European Public Law 439, 458–460.
[777] *John Walker* (n 714), para 23.
[778] *Commission v France* (n 772), paras 7-11; *Bergandi* (n 773), paras 28-32
[779] *Commission v Denmark* (n 696), para 11.
[780] For some examples, see Martin Hedemann-Robinson (n 776) 460-468.

By way of conclusion, the degree to which Article 110 TFEU represents a constraint for Member States in the setting up of 'sin taxes' can be investigated through a case study of recent national regulatory initiatives regarding the taxation of unhealthy foodstuffs. Taxes on fat and sugar have become popular in the EU, in countries such as Denmark, France, Hungary, Poland or Portugal.[781] None of these initiatives seem to have led to direct or indirect actions before the Court of Justice.

As an illustration of what could be the fate of these taxes under Article 110 TFEU, an analysis is offered of the recent French tax on sugary drinks. The French tax on sweetened soft drinks was first introduced in 2012 and strengthened in 2018.[782] It applies to sweetened non-alcoholic beverages such as water, sodas and fruit juices. The tax increases as more sugar is added –in 2020, its amount is for instance set at 14 eurocents per litre of drink where 100 grammes of sugar have been added – and is paid by manufacturers, processors and importers of drinks sold in France.[783] Some drinks do not fall within the scope of the tax, such as syrups, soups or smoothies, or are exempted from it, such as soya drinks containing a minimum of 2,9 % of soya proteins.[784]

This measure could be analysed both under Article 110(1) TFEU and 110(2) TFEU. If considering smoothies, there is little doubt that they are similar to fruit juices, capable of meeting the same need from the point of view of consumers, or at the very least in competition with them. Under Article 110(1) TFEU, indirect discrimination against imported products would occur if fruit juices, to which the tax applies, happened to originate predominantly from other Member States and if smoothies, exempted from the tax, were mostly produced domestically. Under Article 110(2) TFEU, a disgruntled foreign producer of fruit juices, or the Commission, would face an additional burden of proof and would need to show that the price difference resulting from the different tax rates applicable to the two categories of products is liable to influence consumer behaviour to the detriment of juices. If it were the case that fruit juices and smoothies were both produced and imported in France in comparable quantities, no discriminatory or protective effect would be found.

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[781] See for general legal aspects, Alberto Alemanno and Ignacio Carreño, 'Fat Taxes in the EU Between Fiscal Austerity and the Fight Against Obesity' (2011) 2 European Journal of Risk Regulation 571; Alberto Alemanno and Ignacio Carreño, 'Fat Taxes" in Europe – A Legal and Policy Analysis under EU and WTO Law' (2013) 8 European Food and Feed Law Review 97. For some elements on the effect of these taxes on diet and health, see Barry M Popkin and Shu Wen Ng, 'Sugar-Sweetened Beverage Taxes: Lessons to Date and the Future of Taxation' (2021) 18 PLOS Medicine; Hunt Allcott, Benjamin B Lockwood and Dmitry Taubinsky, 'Should We Tax Sugar-Sweetened Beverages? An Overview of Theory and Evidence' (2019) 33 Journal of Economic Perspectives 202; Sara Capacci and others, 'The Impact of the French Soda Tax on Prices and Purchases. An Ex Post Evaluation' (2019) 14 PLoS ONE; Sinne Smed and others, 'The Effects of the Danish Saturated Fat Tax on Food and Nutrient Intake and Modelled Health Outcomes: An Econometric and Comparative Risk Assessment Evaluation' (2016) 70 European Journal of Clinical Nutrition 681.

[782] Capacci and others (n 781). The study provides good evidence that the tax was fully transmitted to consumer prices of soft drinks but suggest a very small reduction in soft drink purchases. It was done however before the rates were increased in 2018.

[783] Code général des impôts, art 1613 ter.

[784] For greater details, see <https://bofip.impots.gouv.fr/bofip/11674-PGP.html/identifiant%3DBOI-TCA-BNA-10-20191230#Champ_dapplication_10> accessed 11/05/2023.

What this example shows is that, when enacting a tax on fat or sugar, Member States have to ensure that it is designed in such a way so as not to lead to a discriminatory or protective effect, even inadvertently. The overall public health justification of the tax scheme would not provide any ground to defend the measure, as Article 110 TFEU knows no formal derogation. A justification through the use of the Court's objective criteria doctrine offers an uncertain path. Following strictly the Court's approach, no safe harbour exists where the tax measure leads to 'any form of discrimination, direct or indirect, in regard to imports from other Member States or any form of protection of competing domestic products', even if this is not the intended effect of the tax in question.

Coming back to the French example: regardless of the good reasons to tax smoothies and fruit juices differently – smoothies were for instance considered healthier and worthy of an exemption – if juices were predominantly imported and smoothies produced in France, a strict application of Article 110 TFEU would render the French tax unlawful. It would be so unless the Court itself felt that this differentiation was based on an objective criterion, in which case it could decide altogether not to investigate whether the measure leads to a discriminatory or protective effect.

Although Article 110 TFEU has not yielded a lot of case-law in recent years and does not seem to have caused difficulties in any of the recent attempts by Member States to set up sugar or fat taxes, it is a requirement of EU law that Member States should keep in mind whenever setting such schemes, especially if planning to introduce different exemptions. The more universal a fat or sugar tax is, the less it is likely to fall foul of Article 110 TFEU.

3.2.2. Article 56 TFEU

Differently to the free movement of goods, no specific provision is applicable to national tax measures on services, which must be analysed with regards the general prohibition contained in Article 56 TFEU.

It is clear that discriminatory tax arrangements constitute a breach of Article 56 TFEU. This could be seen in *Commission v Spain*, where a rule granting a fiscal exemption to the sole benefit of charitable bodies engaged in gambling activities established in Spain, hence excluding those established in other Member States was considered a discriminatory tax arrangement falling foul of the prohibition contained in Article 56 TFEU.[785] Similarly, in *Lindman*, the Finnish rule exempting individuals' winnings from games of chance organised in that Member State, to the exclusion of those that were not licensed in Finland, was found to be discriminatory and in breach of Article 56 TFEU.[786]

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[785] Case C-153/08 *Commission v Spain* [2009] EU:C:2009:618, para 34.

[786] Case C-142/02 *Lindman* [2003] EU:C:2003:613, para 21. For a non-discriminatory tax arrangement in gambling not breaching Article 56 TFEU, see Case C-788/18 *Stanleyparma and Stanleybet Malta* [2020] EU:C:2020:110.

As any tax is liable to impede or render less attractive the exercise of a service activity, all tax measures from the Member States could potentially constitute restrictions to the freedom to provide services. In *Mobistar*, however, the Court ruled, regarding a municipal tax on telecommunication infrastructure, that 'measures, the only effect of which is to create additional costs in respect of the service in question and which affect in the same way the provision of services between Member States and that within one Member State, do not fall within the scope of Article [56 TFEU] of the Treaty'.[787] Non-discriminatory taxation that merely makes the provision of a service more costly does not constitute a restriction to the free movement of services.

What should be said, however, of a tax set at a level so high that it effectively discourages the provision of a service? This was the situation in *Berlington,* where Hungary had introduced a five-fold increase in the tax to be paid on slot machines operated in amusement arcades. This tax increase did not apply to casinos. The applicants alleged that this measure, 'by drastically increasing the amount of taxes on the operation of slot machines in amusement arcades, ha[d] hindered profitable operation of those machines by operators of amusement arcades and ha[d] thus granted *de facto exclusivity* for that activity to casino operators'.[788] It was claimed in particular that the tax rate was so high that, based on the average monthly revenue of slot machines, this would result in operating them at loss. While, leaving the final assessment to the national court, the Court confirmed that, were the tax increase to produce an effect comparable to that of prohibiting the operation of slot machines outside casinos, this would constitute a restriction on the freedom to provide services.[789]

4. Monopolies, licences, and authorisations

In order to better control the dissemination of harmful products or activities, Member States may adopt rules that restrict the possibility for operators to engage in their trade, in the form of monopolies, licences, or authorisations. These usually seek to limit the possibility to import, produce or sell certain goods or services. Monopolies grant exclusive rights, meaning that there is only one active operator for a given activity on the market. Through a system of licences, the State organises the market with only a limited number of operators. Finally, a system of authorisation does not limit the number of active operators but seeks to ensure that they meet certain criteria or that the products or services put on the market are not too harmful.

From the perspective of consumers, and on the basis of the categories used in the intervention ladder, these rules can be considered as mixing elements that 'guide choice' and 'enable choice', insofar as they make access to the product or service in question more difficult, by restraining the number of operators active on the market or the number of retail outlets offering them for sales.

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[787] Joined Cases C-544/03 and C-545/03 *Mobistar and Belgacom Mobile* [2005] EU:C:2005:518, para 31. See also *Berlington* (n 649), para 35; *Austria v Germany* (n 666), para 137; Case C-482/18 *Google Ireland* [2020] EU:C:2020:141, para 26.
[788] *Berlington* (n 649), para 39.
[789] *Berlington* (n 649), para 41.

These measures may constitute restrictions to the free movement of goods and services within the meaning of Article 34 and 56 TFEU and, as regards the operation of state monopolies of a commercial character, measures prohibited by Article 37 TFEU. As it is the case for Article 110 TFEU, national rules which fall foul of the requirements of Article 37 TFEU may not be 'justified', which raises specific questions as regards national regulatory autonomy and the protection of public health.

4.1. Monopolies

State monopolies date back from a time when States were heavily involved in the economy. Monopolies usually applied to strategic productions, those involving a public interest, such as public health, and giving rise to significant tax revenue for the State.[790] Due to the influence of EU law, there are nowadays few public monopolies left in the EU. Under the Treaty, commercial monopolies related to goods are governed by Article 37 TFEU, which has been applied in a number of cases involving Member States monopolies on tobacco products and alcoholic beverages. Gambling monopolies fall under the scope of Article 56 TFEU.

4.1.1. Tobacco and alcohol: Article 37 TFEU

State monopolies of a commercial character, that control the import, export, wholesale, or retail sale of goods, fall under the purview of Article 37 TFEU. According to the first two paragraphs of that provision:

> 1. Member States shall adjust any State monopolies of a commercial character so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States.
>
> The provisions of this Article shall apply to any body through which a Member State, in law or in fact, either directly or indirectly supervises, determines or appreciably influences imports or exports between Member States. These provisions shall likewise apply to monopolies delegated by the State to others.
>
> 2. Member States shall refrain from introducing any new measure which is contrary to the principles laid down in paragraph 1 or which restricts the scope of the articles dealing with the prohibition of customs duties and quantitative restrictions between Member States.

Generally speaking, Article 37 TFEU applies in circumstances where the State grants exclusive purchase or sales rights to a public undertaking or institution or, by means of delegation, to a private organisation, thus enabling the control of imports or exports.[791] It covers monopoly 'of a commercial character', which means that production monopoly alone do not come within its scope.[792] It applies to goods only and not to the free movement of services or capital.[793]

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[790] See Graham Butler, 'State Monopolies and the Free Movement of Goods in EU Law: Getting Beyond Obscure Clarity' (2021) 48 Legal Issues of Economic Integration 285, 285.
[791] European Commission, Commission Notice: Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (n 680) 80.
[792] Peter J Oliver (ed), *Oliver on Free Movement of Goods in the European Union* (Hart Publishing 2010) 415.
[793] Case 155/73 *Sacchi* [1974] EU:C:1974:40.

Article 37, if compared to other free movement provisions, distinguishes itself with a peculiar structure and a rather obscure drafting.[794] While Article 37(1) TFEU prohibits discrimination between domestic and foreign goods in the operation of commercial monopolies, Article 37(2) TFEU invites Member States to refrain from introducing new measures that would result in such discrimination or would restrict 'the scope of the articles dealing with the prohibition of customs duties and quantitative restrictions between Member States'. This second paragraph finds its origin in the Treaty of Rome,[795] which prevented Member States from introducing new restrictive measures before the expiration of the 12-year transitional period foreseen for the completion of the common market. Despite subsequent amendments to what is now the TFEU, the paragraph was never removed. The Court does not usually differentiate between the two paragraphs and makes a general application of Article 37 TFEU. Some have read in the reference to quantitative *restrictions* contained in Article 37(2) TFEU the sign that the prohibition contained in Article 37 TFEU would go beyond discrimination, including, in a similar fashion to Article 34 TFEU, measures that do not put imported goods at a disadvantage but nonetheless hinder their free movement.[796] This interpretation of Article 37 TFEU, as we shall see below, has however always been rejected. As the Court has repeated on multiple accounts, Article 37 TFEU does not require the abolition of monopolies having a commercial character but only that they do not lead to any discrimination between nationals of Member States.[797]

According to the Court, 'the purpose of Article 37 of the Treaty is to reconcile the possibility for Member States to maintain certain monopolies of a commercial character as instruments for the pursuit of public interest aims with the requirements of the establishment and functioning of the common market.'[798] The legitimacy of monopolies, for instance monopolies on the retail sales of alcoholic beverages enacted 'to protect public health against the harm caused by alcohol',[799] is therefore recognised.

4.1.1.1. The scope of Article 37 TFEU

One of the main questions regarding the application of Article 37 TFEU is the determination of its scope vis-à-vis Article 34 TFEU. While both provisions are concerned with obstacles to the free movement of goods, the prohibition contained in Article 34 TFEU, which applies to non-discriminatory measures hindering access to the market, is broader than the one contained

[794] See Butler (n 790) 287-288.
[795] Article 37 EEC.
[796] Butler (n 790) 301.
[797] Case 59-75 *Manghera e.a.* [1976] EU:C:1976:14, para 5; Case 91/78 *Hansen* [1979] EU:C:1979:65, para 8; Case 78/82 *Commission v Italy* [1983] EU:C:1983:159, para 11; Case C-387/93 *Banchero* [1995] EU:C:1995:439, para 27 ; Case C-189/95 *Franzen* [1997] EU:C:1997:504, para 38.
[798] *Franzen* (n 797), para 39.
[799] *Franzen* (n 797), para 41. See also Case C-198/14 *Visnapuu* [2015] EU:C:2015:463, Opinion of Advocate General Bot, paras 157-160.

in Article 37 TFEU.[800] It is therefore important to delimit the respective scope of these two provisions and to identify possible overlaps between them.

As regards the material scope of Article 37 TFEU, the issue has been well summarised by Advocate General Bot in *Visnapuu*:

> Should the scope of that provision be limited to the specific function of the monopoly, namely its exclusive right? Does a national rule which, exceeds, in strict terms, the exercise of the exclusive right attributed to the monopoly, but which is related to the existence and operation of that monopoly because it is intrinsically connected with the specific function assigned to that monopoly, fall within the scope of application of that provision?[801]

In early cases, the scope of Article 37 TFEU was broadly interpreted by the Court as 'not limited to imports or exports which are directly subject to the monopoly but cover[ing] *all measures which are connected with its existence* and affect trade between Member States in certain products, whether or not subject to the monopoly'.[802] In *Cinzano*, *Rewe-Zentrale* and *Miritz*, duties applied on imported products that were linked to the German monopoly on alcohol were found to fall within the scope of Article 37 TFEU.[803] In *Rewe-Zentrale*, the Court considered that Article 37 TFEU covered 'charges which would result in discrimination against imported products as compared with national products coming under the monopoly',[804] even though the imported products themselves did not come under the monopoly. This broad understanding allowed the Court to make a simultaneous application of Articles 37 TFEU and 110 TFEU.[805]

Shortly after, the Court proceeded to a narrowing down of the scope of Article 37 TFEU, yet leaving a degree of uncertainty as to which test to apply. In *Cassis de Dijon*, the infamous German measure setting a minimum alcoholic content for spirits was part of the Law on the Monopoly in Spirits but applied to imports regardless of whether they were covered by the monopoly in question or not. Since the measure did not 'concern the exercise by a public monopoly of its specific function — namely, its exclusive right', [806] the Court refused to apply Article 37 and applied Article 34 instead. In *Grandes distilleries Peureux* and *Peureux*, released only some months after *Cassis de Dijon*, the Court held that 'the rules contained in Article 37 [TFEU] concern only activities *intrinsically connected* with the specific business of the monopoly and are irrelevant to national provisions which have no connexion with such specific business',[807] a middle-ground between the stricter *Cassis* line and the original broader understanding of Article 37 TFEU. In *Peureux*, the Court found that a charge levied on

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[800] See Case C-170/04 *Rosengren e.a.* [2006] EU:C:2006:213, Opinion of Advocate General Tizzano, para 65.
[801] *Visnapuu*, Opinion of Advocate General Bot (n 799), para 123.
[802] Case 13/70 *Cinzano & CIA GmbH v Hauptzollamt Saarbrücken* [1970] EU:C:1970:110, para 5; *Rewe-Zentrale* (n 716), para 26; Case 91/75, *Hauptzollamt Göttingen and Bundesfinanzminister v Wolfgang Miritz GmbH & Co* [1976] ECLI:EU:C:1976:23, para 8, emphasis added.
[803] *Cinzano* (n 802); *Rewe-Zentrale* (n 716); *Miritz* (n 802).
[804] *Rewe-Zentrale* (n 716), para 26.
[805] ibid, para 27.
[806] *Cassis de Dijon* (n 612), para 7.
[807] *Peureux* (n 739) para 35 ; Case 119/78 *Grandes distilleries Peureux* [1979] EU:C:1979:66, para 28.

producers wishing to escape the French production monopoly on alcoholic beverages did not come under Article 37 TFEU since the subjection or not to the monopoly was not 'a factor which determines how the specific business of the monopoly is conducted.'[808] The Court applied Article 110 TFEU instead.

The *Cassis* formula ultimately prevailed.[809] In *Banchero*, applying the 'specific function of the monopoly – exclusive rights' test, the Court declared that a legislation reserving the exclusive right of retail sale of manufactured tobacco products to individuals to whom the monopoly had issued a concession or authorisation did not come under Article 37 TFEU but under Article 34 TFEU. The Court pointed especially at the fact that the monopoly did not exercise control over the procurement choices of the retailers.[810]

This narrow understanding of the scope of Article 37 TFEU was confirmed with *Franzen* and the following cases,[811] which mostly dealt with the question of licencing requirements for import. In *Franzen*, the Court upheld the *Cassis* line and brought further clarification to it. While Article 37 TFEU is 'specifically applicable to the exercise, by a domestic commercial monopoly, of its exclusive rights', provisions which 'are separable from the operation of the monopoly although they have a bearing upon it' are not covered by Article 37 TFEU and must be examined under Article 34 TFEU.[812] For the first time, the Court formalised the boundary between the two articles thereby excluding any possible overlap between them. This represented a significant evolution since Articles 34 TFEU and 37 TFEU had been applied simultaneously in some previous cases. In *Grande Distillerie Peureux* and *Commission v France*, the national measures at stake were for instance found to be, in their entirety, in breach of both articles.[813] Advocate General Elmer himself followed this approach in *Franzen*.[814]

In *Franzen*, the measures under scrutiny were part of the Swedish retail monopoly on alcoholic beverages. The Court considered that the national rules 'relating to the *existence and operation* of the monopoly', namely the product selection system, the monopoly's sale network and the rules governing the promotion of alcoholic beverages sold by the monopoly,[815] came under Article 37 TFEU. As in *Banchero*, the licencing system governing the production or the wholesale of alcoholic beverages, which also determined who could import alcoholic beverages into Sweden, came under Article 34 TFEU.[816]

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[808] *Peureux* (n 739), para 36.
[809] See *Hansen* (n 797) paras 9-10.
[810] *Banchero* (n 797), paras 29-31.
[811] Several Advocate Generals took the view that the Court in Franzen followed an approach closer to the one in *Grande Distillerie Peureux* and *Peureux*, see *Rosengren*, Opinion of Advocate General Tizzano (n 800), paras 40-42 and Case C-170/04 *Rosengren e.a.* [2006] EU:C:2006:213, Opinion of Advocate General Mengozzi, para 35 respectively; *Visnapuu*, Opinion of Advocate General Bot (n 799), para 124.
[812] *Franzen* (n 797), paras 35-36.
[813] *Grandes distilleries Peureux* (n 807) ; Case 90/82 *Commission v France* [1983] EU:C:1983:169, para 27.
[814] Case C-189/95 *Franzen* [1997] EU:C:1997:101, Opinion of Advocate General Elmer, paras 97 and 106.
[815] *Franzen* (n 797), paras 37-66.
[816] *Franzen* (n 797), paras 67-77.

The judgment in *Rosengren*, dealing with another aspect of the Swedish monopoly on alcohol, Systembolaget, confirmed the test devised in *Franzen*.[817] The measure at stake prohibited individuals to freely import alcohol in the country, requiring that they place an order through the retail monopoly in order to do so. As in *Franzen*, there was no monopoly on imports *stricto sensu* since companies holding a licence could also import alcoholic beverages. The Court considered that the specific function of the Swedish monopoly was 'the exclusive right of retail sale in Sweden of alcoholic beverages to consumers, with the exception of the catering industry'[818] and found that the rule prohibiting the direct import of alcoholic beverages by individuals did not govern, as such, the exercise of the monopoly's exclusive rights of retail sale.[819] The Court acknowledged that the rule had 'the effect of channelling consumers who wish to acquire such beverages towards the monopoly and, on that basis, is liable to affect the operation of that monopoly',[820] but yet considered that it did not 'truly' regulate the operation of the monopoly, in contrast with some of the rules dealt with in *Franzen*.[821] Article 34 TFEU was ultimately found applicable to this prohibition of imports by individuals.[822] The two Advocate Generals assigned to the case came to the opposite conclusion and applied Article 37 TFEU.[823] Advocate General Tizzano considered for instance that 'the rule governing liquor imports by Systembolaget (already held by the Court to be inherent in the operation of the monopoly) and the rule banning private imports (at issue here) are complementary and indivisible: both of them are designed to channel demand for alcohol on the part of Swedish consumers into the exclusive sales system controlled by Systembolaget.'[824]

Yet, the refusal by the Court to apply Article 37 TFEU to Member States' licensing rules restricting imports was later confirmed in the *ANETT* and *Visnapuu* judgments.[825] This solution constitutes an enduring disagreement with the Court's Advocate Generals. In *Visnapuu,* Advocate General Bot developed a rather convincing argumentation as to why the Finnish

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[817] Case C-170/04 *Rosengren* [2007] EU:C:2007:313. While the legal test used to determine the scope of Article 34 and 37 was the same in *Franzen* and *Rosengren*, the conclusion to which the Court came as to the applicability of Article 37 to the facts of the case was different in the two judgments. Some authors have therefore interpreted Rosengren as a quasi 'reversal' of *Franzen*. This conclusion appears somewhat exaggerated, not formally correct, to the very least. See Oliver (n 792) 413, Butler (n 790) 307.
[818] *Rosengren* (n 817), para 20.
[819] ibid, para 21.
[820] ibid, para 23.
[821] ibid, para 24.
[822] ibid, para 27. See also Case C-186/05 *Commission v Sweden* [2007] EU:C:2007:571, paras 22-23.
[823] *Rosengren*, Opinions of Advocate General Tizzano (n 800) and Mengozzi (n 811), para 48 and para 61 respectively. Due to the importance of the matter at stake, the case was reallocated from the Third to the Grand Chamber of the Court of Justice after the first hearing, which prompted the adoption of a second Advocate General opinion. See also Martin Johansson, 'Rosengren - A "Franzén Light"?' (2007) Europarättslig tidskrift 608.
[824] *Rosengren*, Opinion of Advocate General Tizzano (n 800), para 45. See also *Rosengren*, Opinion of Advocate General Mengozzi (n 811), para 47.
[825] *ANETT* (n 675), paras 25-31 ; *Visnapuu* (n 703), paras 89-91. In *Visnapuu*, only the rule reserving the import of certain alcoholic beverages to the Finnish retail monopoly came under Article 37 TFEU, see paras 92-93.

licensing scheme for imports was inseparable from the retail sale monopoly in place in the country and should come within the scope of Article 37 TFEU.[826]

Arguably, the Court's approach to Article 37 TFEU has become 'excessive[ly] formalistic and remarkably narrow'.[827] By construing Article 37 TFEU as only applicable to what constitutes the exclusive retail rights of the monopoly system in question, the Court has been able to make greater use of Article 34 TFEU and to apply a more stringent standard to national measures. In that regard, it is interesting to note that the measures at stake in *Rosengren* and *Visnapuu*, ultimately analysed by the Court as breaches of Article 34 TFEU, were found to be non-discriminatory by the Advocate Generals and therefore compatible with Article 37 TFEU.[828] In *ANETT*, where no Advocate General had been appointed to the case, the rule forcing retailers to purchase tobacco from authorised wholesalers could have also been considered as non-discriminatory.[829]

In place of this narrow approach, Article 37 TFEU could be construed as including 'all the provisions connected with the existence and operation of the retail monopoly on alcohol, on the basis of their intrinsic connection with the exercise of the specific function assigned to that monopoly, including those which do not, in strict terms, correspond to the scope of the right of exclusivity conferred on that monopoly'.[830] Such a balanced understanding of Article 37 TFEU would pay due respect to the specific nature of monopolies and gives a greater leeway to Member States in areas of core public interest, while keeping outside its scope rules which are not sufficiently connected to the monopolies. As the following development show, Article 37 TFEU does not provide a *carte blanche* to Member States.

4.1.1.2. Measures constituting a breach of Article 37 TFEU

Contrary to Article 34 TFEU, Article 37 TFEU is solely concerned with discrimination against imported products, be it direct or indirect.[831] According to the Court:

> Article 37 requires that the organization and operation of the monopoly be arranged so as to exclude any discrimination between nationals of Member States as regards conditions of supply and outlets, so that trade in goods from other Member States is not put at a disadvantage, *in law*

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[826] *Visnapuu*, Opinion of Advocate General Bot (n 799), paras 134-152.
[827] Lucio Di Cicco, 'The Visnapuu Case: The Narrow Interpretation of Article 37 TFEU and the Consequent Failure in the Application of the "Certain Selling Arrangements" Doctrine: European Court of Justice, Fifth Chamber, 12 November 2015, C-198/2014, Valev Visnapuu v. Kihlakunnansyyttäjä, Suomen Valtio – Tullihallitus' (2016) 43 Legal Issues of Economic Integration 309, 319.
[828] *Rosengren*, Opinion of Advocate General Mengozzi (n 811), para 64, 70-71; *Visnapuu*, Opinion of Advocate General Bot (n 799), paras 164-174. See however the contradictory Opinion of Advocate General Tizzano in *Rosengren*, (n 800).
[829] See *ANETT* (n 675), paras 6-8.
[830] *Rosengren*, Opinion of Advocate General Mengozzi (n 811), para 37.
[831] See for instance *Commission v Italy* (n 797), para 12: 'Since the rules at issue apply without distinction to domestic and imported products, it is appropriate to consider whether they are none the less liable to have a discriminatory effect or to distort competition by restricting imports of tobacco products, thereby impeding trade within the Community.'

or in fact, in relation to that in domestic goods and that competition between the economies of the Member States is not distorted.[832]

Throughout its case-law, the Court consistently opposed the suggestion made by some of its Advocate General to apply the broad understanding of what constitute measures having an equivalent effect to quantitative restrictions under Article 34 TFEU to Article 37 TFEU,[833] which would have striped the whole judicial debate on their respective scope of application of any relevance.

Article 37 precludes the existence of import monopolies. [834] The elimination of exclusive rights related to imports was one of the main objectives pursued by Article 37 TFEU and the main political priority in the early years of application of that provision,[835] leading to a number of adjustments being made to national monopolies. One could imagine a monopoly on imports which do not result in imported products being treated less favourably than domestic products, but the Court considers that the prohibition of exclusive rights for import is required so as 'to eliminate even the possibility of any discrimination being practised against […] exporters'.[836]

Retail monopolies, on the other hand, are permitted if they are devoid of any discriminatory feature. In *Franzen*, the Court analysed the product selection system, the monopoly's sale network and the promotion of alcoholic beverages operated by the Swedish monopoly. It concluded that no difference in treatment existed between foreign and imported products. The product selection system is the aspect of a retail monopoly that appears most problematic, due to the possibility of favouring domestic goods. In *Franzen*, the Court concluded that products were selected by Systembolaget on the basis of criteria independent of the origin of the products, 'their quality, lack of adverse effects on human health, consumer demand and business or ethical considerations',[837] and welcomed the existence of procedural guarantees allowing traders whose products are not selected to challenge the decision of the monopoly.[838]

Advocate General Elmer came in this case to a different conclusion. He considered that a centralised retail monopoly such as the one in place in Sweden, which decides on which products can be put on the market or not, had the same effect as an import monopoly and was therefore contrary to Article 37 TFEU.[839] Advocate General Elmer focused on the difficulties for foreign products to penetrate the Swedish market, which would undoubtedly be the approach followed had Article 34 TFEU applied, but is not the one followed under Article 37 TFEU. This provides another illustration of the importance of Article 37 TFEU for the

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[832] *Franzen* (n 797), para 40.
[833] Case 78/82 Commission v Italy [1983] EU:C:1983:109, Opinion of Advocate General Rozès ; Case C-438/02, *Criminal proceedings against Krister Hanner* [2004] EU:C:2004:317, Opinion of Advocate General Léger, para 86.
[834] *Manghera* (n 797), para 13
[835] See the various Commission recommendations of 22 December 1969 [1970] OJ L31; Council Resolution of 21 April 1970 on national monopolies of commercial character in manufactured tobacco [1970] OJ C50/2.
[836] *Manghera* (n 797), para 3.
[837] *Franzen* (n 797), para 44.
[838] ibid, paras 50-51.
[839] *Franzen*, Opinion of Advocate General Elmer (n 814), paras 93-96.

remaining national retail monopolies, as these would most likely be considered as restrictions to free movement under Article 34 TFEU.

In a series of early cases, Article 37 TFEU was found to be applicable to pecuniary measures linked to the existence of a State monopoly, a broad interpretation which would probably no longer be the one followed by the Court under the narrower approach to the scope of that article. In *Cinzano*, the Court considered that a duty levied on imports did not amount to an infringement of Article 37 TFEU if such charge was imposed similarly to imported and domestic products.[840] Logically, it is also permitted to impose internal taxation on domestic products superior to similar products imported from other Member States.[841] On the contrary, in *Miritz*, the Court ruled that Article 37 TFEU prevented 'a Member State from levying a charge imposed only on products imported from another member state for the purpose of compensating for the difference between the selling price of the product in the country from which it comes and the higher price paid by the state monopoly to domestic producers of the same product'.[842]

Monopolies often entail price measures. In *Commission v Italy*, the Italian measure fixed a uniform trading margin for tobacconists at 8% of the retail price. The Court considered that such a measure did not breach Article 37 TFEU. It could not lead to any discriminatory effect detrimental to imported products since producers could still freely fix the retail price of their products and therefore '[f]oreign producers of tobacco products [were] free either to take advantage of more competitive production costs or to pass on higher production costs in their entirety'.[843] The Court based its analysis on the one followed in its case-law on price measures under Article 34 TFEU.[844] Conversely, in *Commission v France* the Court considered that the setting of a uniform retail price for each tobacco product was contrary to Article 37 TFEU, as it was 'of such a nature as adversely to affect the marketing of imported tobacco under normal conditions of competition.'[845]

Finally, the Court has ruled on some other specific aspects of monopolies. In *Hansen*, a national practice consisting 'in marketing a product such as spirits with the aid of public funds at an abnormally low resale price compared to the price, before tax, of spirits of comparable quality imported from another Member State' was found to be incompatible with Article 37 TFEU of the Treaty.[846] In *Grandes Distilleries Peureux*, the Court found a breach of Article 37 TFEU with a national measure that prohibited the distillation of certain imported raw materials but allowed it if these materials were produced on the national territory.[847]

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[840] *Cinzano* (n 802), para 12; see also *Rewe-Zentrale* (n 716), para 27.
[841] *Peureux* (n 739), para 38.
[842] *Miritz* (n 802), para 12.
[843] *Commission v Italy* (n 797), para 17.
[844] ibid. para 16.
[845] *Commission v France* (n 813), para 27.
[846] *Hansen* (n 797), para 14.
[847] *Grandes Distilleries Peureux* (n 807), para 30.

4.1.1.3. Justification

Contrary to what is the case with Articles 34 and 35 TFEU, no possibility of justifying a breach of Article 37 TFEU is provided for in the Treaty. After some uncertainty,[848] the Court formally ruled out in a series of electricity cases any application of Article 36 TFEU to breaches of Article 37 TFEU.[849] In agreement with the Court regarding the use of Article 36 TFEU, Advocate General Rozès argued for mandatory requirements to be recognised under Article 37 TFEU,[850] a recommendation which has never been followed by the Court in later judgments.

According to some authors,[851] the Court's statement in *Franzen*, that Article 37 TFEU 'aims at the elimination of obstacles to the free movement of goods, *save, however, for restrictions on trade which are inherent in the existence of the monopolies in question*',[852] could have been construed as the recognition of public interest justifications under that article. Yet, this interpretation has not only been rejected by subsequent case-law, where no such justification has ever been applied, but it sits awkwardly with the rest of the Franzen judgment itself. Indeed, the Court started its analysis of the monopoly's compatibility by stating that 'in aiming to protect public health against the harm caused by alcohol, a domestic monopoly on the retail of alcoholic beverages, such as that conferred on Systembolaget, pursues a public interest aim',[853] only to examine its non-discriminatory character afterwards. Rather than recognising a public interest defence that could be used by Sweden to justify a breach of Article 37 TFEU, the Court seemed to make of the public interest character of the Swedish alcohol retail monopoly a prerequisite for its lawfulness under Article 37 TFEU.[854] This is actually the opposite of a system of justifications, since it subjects Member States monopolies to a condition, the presence of a public interest aim, which is not contained in the wording of Article 37 TFEU.[855] In this way, the Court's statement in *Franzen* recalls the Court's approach under Article 110 TFEU regarding the presence of objective criteria underlying Member States tax measures, and is open to similar criticisms.

As exemplified by Advocate General Bot's opinion in *Visnapuu*,[856] the formal recognition of justification grounds under Article 37 TFEU, in the form of mandatory requirements, would

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[848] See Case C-347/88 *Commission v Greece* [1990] EU:C:1990:470, paras 56–58, where the Court applied article 36 to a measure found in breach both of articles 34 and 37.
[849] Case C-157/94 *Commission v Netherlands* [1997] EU:C:1997:499, para 24 ; Case C-158/94 *Commission v Italy* [1997] EU:C:1997:500, para 33 ; Case C-159/94 *Commission v France* [1997] EU:C:1997:501, para 41.
[850] *Commission v Italy*, Opinion of Advocate General Rozès (n 833).
[851] Butler (n 790) 299-300. See also Oliver (n 792) 420.
[852] *Franzen* (n 797), para 37, emphasis added.
[853] ibid, para 41.
[854] This appears even more clearly from Advocate General Bot's opinion in *Visnapuu* (n 799), paras 157-160.
[855] See in that regard the *Hanner*, Opinion of Advocate General Léger (n 833), para 78: 'Article [37] does not require a Member State which wishes to maintain a national monopoly to demonstrate that that monopoly pursues a public interest aim. According to its wording, that provision only requires Member States to adjust their State monopolies so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States. Consequently, once the Member States have made such an adjustment, Article [37] allows them to maintain their monopolies without imposing any further conditions.'
[856] *Visnapuu,* Opinion of Advocate General Bot (n 799), paras 170-173.

allow an open and transparent discussion of Member States measures and give the requirement of health the space it deserves.

4.1.1.4. Interim conclusion

Commercial monopolies on tobacco products and alcoholic beverages have nearly all been eliminated from the regulatory landscape in the European Union. This, combined with the narrow approach adopted by the Court regarding the scope of Article 37 TFEU, in relation to Article 34 TFEU, makes the former largely irrelevant today.[857] This has prompted some authors to call for a repeal of that provision, arguing that 'state monopolies [were] no longer deserving of such sensitive treatment'.[858] However, current discussions in some EU Member States regarding the possible legalisation of cannabis production, sale and consumption, operated under a State monopoly, could for instance render that article relevant again, provided as mentioned above, that such legalisation is lawful under EU law.

Whether monopolies deserve a special treatment is indeed an open question. A retail sale monopoly, such as those still in place in Sweden or Finland, could also be analysed under the general rule of Article 34 TFEU. They would constitute a measure having equivalent effect but, provided that they function in a non-discriminatory way, could probably be justified under Article 36 TFEU. This would yet depend on the application of the proportionality principle, always a risky exercise for Member States. From a public health standpoint, there is thus a benefit in subjecting commercial monopolies to a separate provision that offers greater leeway to Member States to set up monopolies for controlling the sales of harmful products to the population. At the same time, for this benefit to fully be accessible, justifications should also be recognised under Article 37 TFEU.

4.1.2. Gambling: Article 56 TFEU

Gambling monopolies are considered restrictions to the free movement of services and free movement of establishment. Monopolies can be put in place in relation to all gambling operations in the territory of a Member State or in relation only to one type of game of chance. The Court's judgments sometimes use the term 'licence' to refer to an exclusive right granted to a single operator, which amounts to the same thing as a monopoly.

In *Läära*, a national legislation prohibiting any person other than the licenced public body from running the operation of slot machines was considered, even if not leading to any discrimination on grounds of nationality, to be an impediment to the freedom to provide services.[859] In *Liga Portuguesa*, the Court ruled that the Portuguese gambling system whereby the operation of all games of chance authorised on the territory, such as lotteries and sports betting, including those offered by electronic means, was entrusted to a charitable body, Santa

[857] See also Oliver (n 792) 413.
[858] Butler (n 790) 305.
[859] *Läära* (n 645), paras 28-29.

Casa, prevented any foreign operator from offering internet betting in Portugal, thus constituting a restriction to the freedom to provide services.[860] Similarly in *Betfair* and *Ladbroke*s, Netherlands reserved the organisation of games of chance to holders of a licence which was specific to each of the authorised games.[861] This resulted in internet gambling being prohibited[862] and in a restriction to the freedom to provide services.[863]

4.2. Licences and authorisation

Aspects of commercial monopolies that do not fall under the scope of Article 37 TFEU, such as those related to licences for import or retail sales, may constitutes measures having equivalent effect to quantitative restrictions prohibited by Article 34 TFEU. Systems of licences and authorisations may also fall foul of Article 56 TFEU.

In *Banchero*, regarding a system of licences for the retail sale of tobacco, the Court applied *Keck* and, since the system did not lead to any discrimination in law or in fact between domestic and imported products, concluded that Article 34 TFEU was not breached.[864]

The situation is different for licences that concern the import of products, where the restrictive impact on the free movement of goods is much clearer.

In *Franzen*, the Court reviewed the legality of the Swedish licences for the wholesale or production of alcohol, that were required for anyone to import alcoholic beverages in the country. The conditions for obtaining the licences gave rise to a number of costs which constituted an obstacle to the importation of alcoholic beverages from other Member States contrary to Article 34 TFEU.[865]

In *Visnapuu*, the Court ruled that the obligation to hold a retail sale licence in order to import alcoholic beverages prevented traders established in other Member States from freely importing alcoholic beverages in order to sell them on the Finnish market.[866] Surprisingly, since the measure at stake did not only deal with a selling arrangement – the restriction of retail sales – but also the very possibility of importing, the Court also applied the *Keck*. It found that the first condition – the applicability to all relevant traders operating on the national territory – was not met since the retail monopoly, which was the only operator able to sell beverages above a certain alcoholic content, did not need any licence to operate and since licences were not available to manufacturers established in other Member States.[867] Applying *Keck* to a system where licence holders operate alongside a monopoly appears largely unsuited since, by essence,

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[860] *Liga Portuguesa* (n 643), para 5.
[861] Case C-203/08 *Sporting Exchange (Betfair)* [2010] EU:C:2010:307, para 10; Case C-258/08 *Ladbrokes Betting & Gaming et Ladbrokes International* [2010] EU:C:2010:308, para 6.
[862] *Betfair* (n 861), para 11; *Ladbrokes* (n 861), para 7.
[863] *Betfair* (n 861), para 24; *Ladbrokes* (n 861), para 16. See also Joined cases C-316/07, C-358/07, C-359/07, C-360/07, C-409/07 and C-410/07 *Stoß* [2010] EU:C:2010:504, para 68.
[864] *Banchero* (n 797), paras 34-44.
[865] *Franzen* (n 797), paras 70-73.
[866] *Visnapuu* (n 703), paras 99-102.
[867] *Visnapuu* (n 703), paras 103-107.

the requirement to hold a licence cannot apply to all traders.[868] It is thus hard to see how such a measure could comply with the conditions set in Keck and escape the qualification of a measure having equivalent effect to a quantitative restriction.

Authorisations for the import or marketing of a product are also restrictive of cross-border trade and constitute measures having equivalent effect to quantitative restrictions on imports. In *Ahokainen*, the Court declared, regarding the Finnish requirement to hold a licence to import ethyl alcohol of a higher of 80% vol. content, that imposing formalities for import was capable of hindering intra-Union trade by impeding access to the market for goods which are lawfully produced and marketed in other Member States.[869] It added, referring to its judgment in *Franzen*, that the restriction was even greater if the system added to the costs of those goods, in which case 'there is more than a 'mere' restriction or prohibition of certain selling arrangements'.[870]

In *Sandoz*, the national measure prohibited the marketing of food to which vitamins had been added without prior administrative authorisation. The Court found that rules of this kind were 'likely to impede trade between Member States' and therefore constituted measures having equivalent effect to quantitative restrictions.[871] Similarly, a legislation 'which requires for the marketing of foodstuffs fortified with vitamins and minerals prior inclusion of those nutrients on an 'authorised list', makes the marketing of such foodstuffs more difficult and more expensive, and consequently hinders trade between the Member States'.[872]

The Court also ruled in several cases that licences or authorisations requirements necessary for the operation of gambling activities constituted a restriction to the freedom to provide services and freedom of establishment. In *Zenatti*, the Court declared for instance regarding the Italian licensing system that

> […] the Italian legislation, inasmuch as it prohibits the taking of bets by any person or body other than those which may be licensed to do so, applies without distinction to all operators who might be interested in such an activity, whether established in Italy or in another Member State.
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> However, such legislation, preventing as it does operators in other Member States from taking bets, directly or indirectly, in Italian territory, constitutes an obstacle to the freedom to provide services.[873]

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[868] See also Di Cicco (n 827) 321.
[869] Case C-434/04 *Ahokainen and Leppik* [2006] EU:C:2006:609.
[870] ibid, para 21.
[871] Case 174/82 *Sandoz* [1983] EU:C:1983:213.
[872] Case C-24/00 *Commission v France* [2004] EU:C:2004:70, para 23. See also Case C-192/01 *Commission v Denmark* [2003] EU:C:2003:492, para 41; Case C-41/02 *Commission v Netherlands* [2004] EU:C:2004:762, para 41.
[873] *Zenatti* (n 635), paras 26-27. See also *Gambelli* (n 640), para 59; *Placanica* (n 644), para 42; *Costa and Cifone* (n 644), para 70; *Stanley International Betting* [2015] (n 644), para 46; *Stanley International Betting* [2018] (n 644), para 38. For authorisations, see *Gambelli* (n 640), para 59; *Placanica* (n 644), para 42; Case C-390/12 *Pfleger e.a.* [2014] EU:C:2014:281, para 39.

These examples show that national rules granting specific rights to operators through licences or authorisations are liable, in a variety of situations, to constitute restrictions to the free movement of goods or the freedom to provide services.

5. Rules on advertising

Advertising and promotion occupy a central role in today's economy. National rules restricting the advertising and promotion of hazardous products or activities may affect the functioning of markets powerfully. Such rules pose a particular challenge to the internal market since, as argued by Advocate General Jacobs in *Leclerc-Siplec*, '[a]dvertising plays a particularly important part in the launching of new products [and] it is by means of advertising that consumers can be induced to abandon their existing brand loyalties and make a sample purchase of a different manufacturer's goods'.[874] Hence, '[w]ithout advertising it would be extremely difficult for a manufacturer located in one Member State to penetrate the market in another Member State where his products have not previously been sold and so enjoy no reputation among consumers', meaning that measures that prohibit or severely restrict advertising 'prevent the interpenetration of markets and are inimical to the very concept of a single market'.[875]

National rules on advertising form a complex canvas of possible restrictions to both the free movement of goods and services.[876] A prohibition of certain types of advertising in magazines or on television may, for instance, constitute an impediment to the free circulation of foreign magazines containing this type of advertisements,[877] goods, or to the free of movement of television programmes,[878] services. It may also restrict the free movement of the product or service advertised, where such product or service have more difficulties penetrating a foreign market without resorting to promotional means.[879] Finally, such prohibition may also represent a restriction from the perspective of the providers of advertising services themselves.[880] The fate of national rules on advertising and promotion with regard to the prohibitions contained in Articles 34 and 56 TFEU is also dependent on the magnitude of the restriction: a total prohibition of the advertising of a certain product, a partial prohibition in certain channels or a

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[874] Case C-412/93 *Leclerc-Siplec* [1995] EU:C:1995:26, Opinion of Advocate General Jacobs, para 20.
[875] ibid, para 21.
[876] See in that regard *Tobacco Advertising II* (n 26), para 56-58. See also Rosa Greaves, 'Advertising Restrictions and the Free Movement of Goods and Services' (1998) 23 European Law Review 305.
[877] See *Familiapress* (n 634), para 11 : 'The Court finds that, even though the relevant national legislation is directed against a method of sales promotion, in this case it bears on the actual content of the products, in so far as the competitions in question form an integral part of the magazine in which they appear. As a result, the national legislation in question as applied to the facts of the case is not concerned with a selling arrangement within the meaning of the judgment in Keck and Mithouard.'. See also *Tobacco Advertising II* (n 26), para 58.
[878] See *Bond* (n 617).
[879] Joined Cases C-34/95, C-35/95 and C-36/95 *Konsumentombudsmannen v De Agostini and TV-Shop* [1997] EU:C:1997:344 ; Case C-405/98 *Gourmet International Products* [2001] EU:C:2001:135; *Tobacco Advertising II* (n 26), para 56.
[880] *Tobacco Advertising II* (n 26), para 57.

mere restriction on the form and content of the advertisement do not affect free movement in the same manner.

5.1. Advertising rules under Article 34 TFEU

National rules which specifically target the advertising of tobacco products, alcoholic beverages and other foodstuffs tend to be analysed with regard to Article 34 TFEU.

Advertising rules adopted by Member States with a view to limit the appeal of unhealthy products usually apply equally to domestic and imported products, for the opposite would defeat the very purpose of such restrictions. An exception to this can be seen in an early case, *Commission v France*, where the French rule establishing a different advertising regime for five different categories of beverages, one category being entirely prohibited from resorting to advertising, was found to be in breach of Article 34 TFEU.[881] The Court found the measure to be discriminatory, both directly, because national natural sweet wines enjoyed unrestricted advertising whilst imported natural sweet wines and liqueur wines were subjected to a system of restricted advertising, and indirectly, because the category of beverages for which advertising was totally prohibited mostly contained imported products.[882]

For the most part, however, restrictions on advertising treat all products in the same way and, save for disguised protectionist purposes or mere coincidences, usually affect a comparable proportion of domestic and imported products.

At first, the Court made an unfettered application of the *Dassonville* formula, focusing on the restrictive effect that advertising rules can have on trade without comparing their respective effect on domestic and imported products.[883] This can be seen in *Aragonesa*. In this case, the rule adopted by the Autonomous Community of Catalonia prohibited the advertising of beverages having an alcoholic strength of more than 23% vol. in the media, on streets and highways, in cinemas and on public transport. The Court ruled that a measure 'which restricts or prohibits certain forms of advertising and certain means of sales promotion may, although it does not directly affect trade, [is] such as to restrict the volume of trade because it affects marketing opportunities'[884] and must therefore 'in principle be regarded as a measure having equivalent effect within the meaning of Article [34]'.[885]

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[881] Case 152/78 *Commission v France* [1980] EU:C:1980:187, paras 13-14.
[882] ibid, para 13.
[883] Case 286/81 *Oosthoek* [1982] EU:C:1982:438, para 15; Case C-362/88 *GB-INNO-BM v Confédération du Commerce Luxembourgeois* [1990] EU:C:1990:102, para 7.
[884] Joined cases C-l/90 and C-176/90, *Aragonesa de Publicidad Exterior and Publivia v Departamento de Sanidad y Seguridad Social de Cataluña* [1991] EU:C:1991:327, para 10.
[885] ibid, para 11.

This changed with the *Keck* judgment, after which advertising rules were considered selling arrangements. They would hence only constitute measures having equivalent effect to quantitative restrictions if treating domestic and imported products differently, in law or in fact. In a first series of advertising cases, the Court refrained from analysing in detail the effect of the national measures at stake and concluded that they did not lead to any form of discrimination against imported products.[886] The Court's position evolved in subsequent cases, where it decided to scrutinise advertising rules more closely, to ensure that these did not have a greater impact on foreign products,[887] thereby following the lead of Advocate General Jacobs in *Leclerc-Siplec*.

This led to the decision in *Gourmet*, where the Swedish ban on alcohol advertising and promotion, save for some 'insignificant exceptions',[888] came before the Court of Justice. The Court ruled that:

> [I]n the case of products like alcoholic beverages, *the consumption of which is linked to traditional social practices and to local habits and customs*, a prohibition of all advertising directed at consumers in the form of advertisements in the press, on the radio and on television, the direct mailing of unsolicited material or the placing of posters on the public highway *is liable to impede access to the market by products from other Member States more than it impedes access by domestic products*, with which consumers are instantly more familiar.[889]

Advertising bans are generally liable to have a greater effect on foreign products than domestic ones, since locals are usually more familiar with the latter, in which case they fail to respect the second proviso of the Keck judgment and constitute a measure having equivalent effect to quantitative restrictions on imports.[890] This is especially true, according to the Court, for products 'the consumption of which is linked to traditional social practices and to local habits and customs'. This argument, applied to alcoholic beverages in *Gourmet*, can be extended to other products with an important cultural aspect, like foodstuffs or tobacco products.

The solution adopted in *Gourmet* is complementary to the one reached in *Franzen*, where the Swedish rules on the promotion of alcoholic beverages were analysed under Article 37 TFEU, as part of the body of rules governing the operation of the retail monopoly. The general prohibition on alcohol advertising was not part of the question referred to the Court, which

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[886] Case C-292/92 *Hünermund e.a. v Landesapothekerkammer Baden-Württemberg* [1993] EU:C:1993:932, para 23; Case C-412/93 *Leclerc-Siplec / TF1 et M6* [1995] EU:C:1995:26, para 23.
[887] *De Agostini* (n 879), paras 42-45.
[888] *Gourmet* (n 879), para 20.
[889] ibid, para 21, emphasis added. The Court made an additional argument and considered the fact that 'the Swedish legislation [did] not prohibit 'editorial advertising', that is to say, the promotion, in articles forming part of the editorial content of the publication, of products in relation to which the insertion of direct advertisements is prohibited', was 'liable to increase the imbalance inherent in the absolute prohibition on direct advertising', since 'for various, principally cultural, reasons, domestic producers have easier access to that means of advertising than their competitors established in other Member States', ibid, para 24.
[890] ibid. para 25. See also the Opinion of Advocate General Jacobs in *Gourmet* [2000] EU:C:2000:690, para 34: 'It might be argued that these are matters of fact for the national court to decide, but it seems to me inherent in any rule which prevents producers from advertising directly to the public that it will disproportionately affect imported products - and will at any rate "prevent their access to the market or ... impede access ... more than it impedes the access of domestic products".'

only evaluated the promotion done by the monopoly itself, in the form of written material available at sales outlets and mentions in press articles. The Court considered that this method of promotion 'applie[d] independently of products' origin and [was] not in itself apt to put at a disadvantage, in fact or in law, beverages imported from other Member States in relation to those produced on national territory.'[891]

What the judgment in *Franzen* shows is that the effect of advertising rules on imported products, if compared to domestic products, is likely to be different whether we are dealing with a very wide advertising ban covering the mass media and public spaces, like in *Aragonesa* and *Gourmet*,[892] or whether we are dealing with a rule restricting the use of a single advertising channel or simply prescribing the form or content of advertisements.[893] Example of the latter would be a national rule allowing all forms of advertising for alcoholic beverages but preventing advertisements to depict minors or restricting the frequency at which such ads can be broadcasted on television. In comparable situations, the Court found that such advertising rules did not impact imported products more than domestic product and hence did not constitute measures having equivalent effect within the meaning of Article 34 TFEU.[894]

The wider and more intense the advertising restriction is, the greater is the likeliness that it will affect foreign products more than domestic product and constitute a measure having equivalent effect.[895] This appraisal would change were the Court to definitively abandon its *Keck* ruling and to subject all national measures to a market access test. Some measures deprived of any discriminatory effect could nonetheless hinder the access of imported products to the market where the rule is enacted.

5.2. Advertising rules under Article 56 TFEU

The situation is easier to apprehend under Article 56 TFEU, which covers all rules which prohibit, impede or render less attractive the exercise of the freedom to provide services. As such, any rule that restrict advertising is susceptible to render the exercise of that activity less attractive for foreign providers of advertising services.

The variety of ways in which advertising rules can restrict the freedom to provide services appears clearly from the judgments in *Commission v France* and *Bacardi France*,[896] where the Court analysed the compatibility of the French Loi Evin, which prohibits all television advertising for alcoholic beverages, whether direct or indirect, with Article 56 TFEU. The

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[891] *Franzen* (n 797), para 64.
[892] See also *De Agostini* (n 879), para 43; *De Agostini* [1996] EU:C:1996:333, Opinion of Advocate General Jacobs, para 99.
[893] For a recent expression by the Court of the difference under Article 34 TFEU of 'national provisions prohibiting certain types of advertisements in specific sectors' and 'an outright prohibition' of a type of promotion for a product, see *DocMorris* (n 643), paras 40-41.
[894] See *Karner* (n 671) para 42; Case C-6/98 *ARD* [1999] EU:C:1999:532, para 48. See also Case C-649/18 *A (Advertising and sale of medicinal products online)*, Opinion of Advocate General Saugmandsgaard Øe [2020] EU:C:2020:134, para 77.
[895] See Barnard (n 664) 131.
[896] Case C-492/02 *Bacardi France* [2004] EU:C:2004:432; Case C-262/02 *Commission v France* [2004] EU:C:2004:431.

Court was asked, in particular, to rule on the existence of a restriction in the case of indirect television advertising resulting from the appearance on screen of hoardings visible during the retransmission of sporting events taking place in other Member States. The Court concluded that:

> [R]ules on television advertising such as those at issue in the main proceedings constitute a restriction on freedom to provide services within the meaning of Article [56] of the Treaty. They entail a restriction on freedom to provide advertising services in so far as *the owners of the advertising hoardings* must refuse, as a preventive measure, any advertising for alcoholic beverages if the sporting event is likely to be retransmitted in France. They also impede *the provision of broadcasting services* for television programmes. French broadcasters must refuse all retransmission of sporting events in which hoardings bearing advertising for alcoholic beverages marketed in France may be visible. Furthermore, *the organisers of sporting events* taking place outside France cannot sell the retransmission rights to French broadcasters if the transmission of the television programmes of such events is likely to contain indirect television advertising for those alcoholic beverages.[897]

Here, three operators are concerned by the restriction to the free provision of services: those who own the advertising hoardings in stadiums, those who organise sports events and those who would wish to broadcast sports events.

In *Gourmet*, where the Swedish ban on alcohol advertising was also analysed under Article 56 TFEU, the Court considered that the measure restricted the right of press undertakings established in Sweden to offer advertising space in their publications to potential advertisers established in other Member States.[898] This had 'a particular effect on the cross-border supply of advertising space, given the international nature of the advertising market in the category of products to which the prohibition relates' and therefore constituted a restriction on the freedom to provide services.[899] What this judgment also shows is that Article 56 TFEU not only covers situations where neither the service provider nor the recipient are engaged in a cross-border movement, but also extends to situations where the provision of services remains potential, where no receiver is clearly identified and has entered into an economic relationship with the provider.[900]

An important question arises from a case like *Gourmet*,[901] that of the relationship between Articles 34 and 56 TFEU with regards to advertising restrictions. Could both articles be applied simultaneously in all cases? If yes, this would mean that a rule that does not constitute a quantitative restriction within the meaning of Article 34 TFEU could still constitute a restriction to the freedom to provide services, a likely prospect if considering the particularly

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[897] *Bacardi France* (n 896), para 35. See also *Commission v France* (n 896), para 26.
[898] *Gourmet* (n 879), para 38.
[899] *Gourmet* (n 879), para 39.
[900] See also Case C-384/93 *Alpine Investments* [1995] EU:C:1995:126, para 38.
[901] For a simultaneous application of Articles 34 and 56 TFEU, see also *De Agostini* (n 879) and *ARD* (n 894).

wide scope of Article 56 TFEU.[902] This would render the debate over the qualification of advertising rules and Article 34 TFEU largely superfluous.[903]

As it is the rule in free movement cases, '[w]here a national measure relates both to the free movement of goods and to the freedom to provide services, the Court will in principle examine it in relation to one only of those two fundamental freedoms where it is shown that one of them is entirely secondary in relation to the other and may be considered together with it'.[904] This depends of the circumstances of the case in the main proceedings,[905] and, when it comes to advertising, whether the 'dissemination of advertising is […] an end in itself' or 'a secondary element in relation to the sale of the goods in question'.[906] This, it seems, will very much depend of the perspective taken in the main proceedings at the national level and whether it involves the provision of 'advertising services provided by a service provider established in one Member State to a recipient (advertiser) established in another Member State'.[907]

No such discussion arises in relation to gambling, where only the provision of services is involved. In *Sjöberg and Gerdin*, the Court ruled, regarding the Swedish rule prohibiting the advertising to residents of that State of gambling organised by private operators in other Member States, that such a measure constituted 'a restriction on the freedom of Swedish residents to receive, on the internet, services offered in other Member States [and] impose[d], so far as providers of gambling services established in Member States other than […] Sweden are concerned, a restriction on their freedom to provide services'.[908]

In *HIT*, the Court dealt with an Austrian rule making the promotion in Austria of services offered in casinos located in another Member State subject to an authorisation scheme which required, in particular, that the operator of the casino concerned proved that the legal provisions for the protection of gamblers adopted in the Member State where that casino was operating provided a degree of protection corresponding at least to the one in place in Austria. This, according to the Court, impeded the access of consumers resident in Austria to casino services

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[902] See for instance in *Karner* (n 671), where the national advertising restriction did not constitute a restriction within the meaning of Article 34 TFEU and the Court moved to consider if Article 56 TFEU was applicable.
[903] This would also be the case where the Services Directive and Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market [2000] OJ L178/1, as regards online advertising, apply.
[904] *Doc Morris* (n 643), para 30. See also Karner (n 671), para 46; Case C-222/18 *VIPA* [2019] EU:C:2019:751, para 58.
[905] *Doc Morris* (n 643), para 31; *Karner* (n 671), para 47; *VIPA* (n 905), para 59.
[906] *Karner* (n 671), para 47.
[907] In that regard, see *A (Advertising and sale of medicinal products online)*, Opinion of Advocate General Saugmandsgaard Øe (n 894), para 67. As Advocate General Saugmandsgaard Øe observes in footnote 36 contained in this paragraph, the judgments in *De Agostini* and *ARD* 'concerned the provision of services relating to the broadcasting of television advertising by bodies established in one Member State for the benefit of advertisers established in another Member State' and the judgment in *Gourmet* 'concerned the right of press undertakings established in the territory of one Member State to offer advertising space in their publications to potential advertisers established in other Member States'. Something similar can be said of the judgments in *Bacardi France* (n 896) and *Commission v France* (n 896).
[908] Joined Cases C-447/08 and C-448/08 *Sjöberg and Gerdin* [2010] EU:C:2010:415, para 34.

offered in other Member States and constituted a restriction to the freedom to provide services.[909]

5.3. Interim conclusion

It is hard to think of a national rule seeking to limit advertising or promotional opportunities for unhealthy products or gambling that would not constitute a restriction to free movement, especially if considering that a service provider is almost always involved in an advertising process, to convey the advertising material or to create it. In some very specific situations, where the company that manufactures the good is also the only one involved in its promotion, where no potential service provider can be identified, and where the restriction is unlikely to have a significant effect on trade patterns, it could however be possible to conclude in the absence of a breach of Articles 34 and 56 TFEU.

6. Other lifestyle risks measures restricting free movement

6.1. Bans on certain products or services

From the perspective of free movement, a ban on the import or marketing of a specific product or service is surely 'the most restrictive measure' that a Member State can adopt.[910]

Under Article 34 TFEU, such bans, depending on the perspective taken, constitute quantitative restrictions to imports or measures equivalent to quantitative restrictions. In *Commission v France (Milk substitutes)*,[911] the Court declared the French rule prohibiting the import and sale of substitutes for milk powder and concentrated milk to be in breach of Article 34 TFEU without specifying whether it constituted a quantitative restriction or a measure having equivalent effect.

Insofar as it prohibits imports, a ban can be construed as a quantitative restriction, equivalent to zero. This can be seen in *Rosengren*, where the Swedish rule preventing individual purchases of alcohol was considered a quantitative restriction on imports.[912] The rule actually required the retail sale public monopoly to import alcoholic beverages upon request from individuals, meaning that imports were not entirely prohibited. This, however, did not alter the Court's finding since the monopoly could refuse to place the order[913] and the rule entailed a number of inconveniences for individuals 'with which they would not be faced were they to import the beverages themselves'.[914] In *ANETT*, however, the Court considered that the Spanish rule

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[909] Case C-176/11 *HIT and HIT LARIX* [2012] EU:C:2012:454, para 18.
[910] European Commission, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (n 680), 52. See also Case 34/79 *Henn et Darby* [1979] EU:C:1979:295, in which the Court speaks of a prohibition on imports as the 'most extreme form of restriction'.
[911] Case 216/84 *Commission v France (Milk substitutes)* [1988] EU:C:1988 :81.
[912] *Rosengren* (n 817), para 36. See also *Commission v Sweden* (n 822).
[913] *Rosengren* (n 817), para 33.
[914] ibid, paras 34-35.

requiring tobacco retailers to procure from authorised wholesalers and preventing them to directly import tobacco products, constituted a measure having equivalent effect to a quantitative restriction.[915] Although the import of tobacco products to Spain was not as such prohibited, the Court considered that this measure implied a series of inconveniences for retailers which were 'capable of having a negative effect on the choice of products that the tobacco retailers include in their range of products and, ultimately, on the access of various products coming from other Member States to the Spanish market'.[916]

From the perspective of sales, bans are without doubt measures having equivalent effect.[917] A number of cases have dealt with national rules prohibiting the use of additives in food, including vitamins and minerals,[918] or beer.[919] More recently, the Court ruled in the *CBD* case that 'the prohibition on marketing CBD lawfully produced in another Member State […] constitutes a measure having equivalent effect to quantitative restrictions within the meaning of Article 34 TFEU'.[920]

Equally, bans on certain forms of gambling, or gambling in general, constitute restriction to the freedom of establishment or the freedom to provide services prohibited by Articles 49 and 56 TFEU. This can be seen in *Schindler*, where a national legislation wholly precluding lottery operators from other Member States from promoting their lotteries and selling their tickets, whether directly or through independent agents, was found to be restrictive of the freedom to provide services.[921]

6.2. Product requirements

Since the ruling in *Cassis de Dijon*, it is established that rules on product requirements, 'such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging',[922] constitute measures having equivalent effect to quantitative restrictions on imports.[923] A large body of case-law exists regarding the composition, designation, packaging, labelling and presentation of products under Article 34 TFEU, for food especially.[924] In *Rau*,

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[915] ibid, paras 37-44.
[916] ibid, para 42.
[917] For a discussion on the precise nature of such measures, see Barnard (n 664) 134-135.
[918] Some cases dealing with authorisation requirements could also be construed as cases involving a prohibition, see *Commission v Denmark* (n 872); *Commission v Netherlands* (n 872); *Commission v France* (n 872).
[919] *Beer purity* (n 612); Case 176/84 *Commission v Greece* [1987] EU:C:1987:125; Joined Cases C-13/91 and C-113/91 *Criminal proceedings against Michel Debus* [1992] EU:C:1992:247.
[920] *CBD* (n 650), para 82.
[921] *Schindler (*n 632) para 44.
[922] *Keck* (n 669), para 15.
[923] Regarding designation, see e.g Case 27/80 *Criminal proceedings against Anton Adriaan Fietje* [1980] EU:C:1980:293; *Pistre* (n 620); Case 182/84 *Miro* [1985] EU:C:1985:470; Case C-448/98 *Guimont* [2000] EU:C:2000:663.
[924] These different categories of rules are not always easy to distinguish in practice, as a measure will often combine different elements thereof. Composition rules, for instance, often imply an obligation for a specific designation, which may also be supplemented by a labelling obligation. See Onno Brouwer, 'Free Movement of

the Belgian rule prescribing that margarine should be sold in cube-shaped blocks was for instance found to be a measure having equivalent effect.[925] So was the German measure, at stake in *Mars*, which opposed the marketing of a product whose packaging was marked with a '+10%' message that covered more than 10% of the packaging surface, on the grounds that such a message could be misleading to consumers.[926]

Two types of these requirements are particularly, and widely, used for the purpose of regulating products or substances that are harmful to health: rules that regulate the presence of information on the packaging or labelling of products and requirements pertaining to the composition of products.

Regarding information requirements, there has not been any case involving a national measure dealing with lifestyle related health-risks specifically. For food and tobacco, this can be explained by the broad harmonisation measures adopted at the EU level, which restrain Member States in their ability to adopt diverging national rules restricting the free movement of products. For alcohol, this may signal an unwillingness on the part of Member States to act to regulate the use of information on the packing, labelling and presentation of alcoholic beverages.

Regarding the composition of products, national measures purporting to promote healthy diets have been found to constitute measures having equivalent effect in a number of cases:[927] rules prohibiting the sale of bread and other bakery products with a salt content higher than 2% in *Van der Veldt* and *Bellamy*,[928] rule prohibiting the marketing of meat products containing ingredients other than meat, so as to ensure an adequate intake of 'certain essential nutrients contained in meat, especially proteins', in *Commission v Germany (Meat products)*,[929] rule prohibiting the marketing of energy drinks containing caffeine in excess of a certain limit, finally, in *Commission v Italy (Energy drinks)*.[930]

The *Cassis de Dijon* case is interesting in that regard. The German measure at stake prevented the marketing of the French blackcurrant liqueur 'Cassis de Dijon' because its alcoholic content was too low, between 15 and 20% vol., while the lower limit set in German law was of 25% vol. for fruit liqueurs.[931] That rule, Germany claimed, was necessary 'to avoid the proliferation

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Foodstuffs and Quality Requirements: Has the Commission Got It Wrong?' (1988) 25 Common Market Law Review 26, 239–240. This, however, does not in any way affect the test applied to the measure.

[925] Case 261/81 *Rau v de Smedt* [1982] EU:C:1982:382.

[926] Case C-470/93 *Mars* [1995] EU:C:1995:224.

[927] Many cases have involved composition requirements linked to the protection of traditional recipes rather than nutritional purposes, see e.g Case 90/86 *Criminal proceedings against Zoni* [1988] EU:C:1988:403; Case 407/85 *3 Glocken and Others v USL Centro-Sud and Others* [1988] EU:C:1988:401; Case 94/82 *Kikvorsch* [1983] EU:C:1983:85; *Beer purity* (n 612).

[928] Case C-17/93 *Van der Veldt* [1994] EU:C:1994:299; Case C-123/00 *Bellamy and English Shop Wholesale* [2001] EU:C:2001:214.

[929] Case 274/87 *Commission v Germany (Meat products)* [1989] EU:C:1989:51, para 7.

[930] Case C-420/01 *Commission v Italy* [2003] EU:C:2003:363.

[931] For another rule governing the alcoholic content of alcoholic beverages, see Case 59/82 *Weinvertriebs-GmbH* [1983] EU:C:1983:101.

of alcoholic beverages on the national market, in particular alcoholic beverages with a low alcohol content, since, in its view, such products may more easily induce a tolerance towards alcohol than more highly alcoholic beverages'.[932] The measure was found to be a measure having equivalent effect and Germany's somewhat surprising health related justification was ultimately rebuffed by the Court.

6.3. Rules applicable to the selling environment

In order to limit the sales of harmful products or services, Member States may adopt rules that regulate the environment in which these are sold. These can be referred to as 'market circumstances rules', which concern '[w]ho […] sells […], and when […], where […] and how […] he goes about it'.[933] These rules, where part of a retail monopoly system, are analysed under Article 37 TFEU. This can be seen in *Franzen*, where the Court analysed the rules governing the Swedish monopoly's sales network, which restricted the number and the location of shops on the territory. In other occasions, these rules may come within the scope of Article 34 TFEU and are likely to constitute selling arrangements, meaning that, if complying with the two conditions of *Keck*, they do not constitute measures having equivalent effect to quantitative restrictions on imports. Since the activity of retail sales is considered a service within the meaning of Article 56 TFEU, these rules may also constitute restrictions to the freedom to provide services. The 'who' question having already been addressed in the section devoted to monopolies, licences and authorisations, this section focuses on the 'when', 'where' and 'how'.

6.3.1. When?

A number of rules regulate the opening hours of shops or restrict the time when specific products can be sold and purchased or when shops can open their premises. This is often the case for alcoholic beverages, whose sales may for instance not be allowed after a certain hour in the evening to prevent excessive drinking or be forbidden on Sundays, like it is the case in Sweden or Finland.

The fate of national rules governing the opening hours of shop under Article 34 TFEU has proved to be a thorny issue for the Court of Justice. In *Torfaen*, the Court had to rule on the legality of the UK Shops Act of 1950, which required that most shops be closed on Sunday, and was visibly not at ease. Whilst recognising that such a rule was non-discriminatory, formally and materially,[934] that it reflected 'certain political and economic choices' that were a matter for the Member States and was 'not designed to govern the patterns of trade between Member States',[935] the Court could not dismiss the fact that it restricted trading opportunities and could have an effect on cross-border trade. The Court, rather cryptically, decided to leave

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[932] *Cassis de Dijon* (n 612), para 10.
[933] Kamiel Mortelmans, 'Article 30 of the EEC Treaty and Legislation Relating to Market Circumstances: Time to Consider a New Definition?' (1991) 28 Common Market Law Review 115, 116.
[934] Case C-145/88 *Torfaen Borough Council v B & Q PLC* [1989] EU:C:1989:593, para 11.
[935] ibid, para 14

it to the national court to decide whether 'the restrictive effects on Community trade which may result therefrom do not exceed the effects intrinsic to rules of that kind',[936] in which case it would not constitute a measure having equivalent effect. It would only with *Stoke-on-Trent* that the Court ruled that Article 34 TFEU did not apply to national legislation prohibiting retailers from opening their premises on Sundays.[937] Ironically, from the present point of view, the UK rule preventing shops from opening on Sundays did not pursue any public health purpose since, by way of exception, it authorised the sales of items including 'intoxicating liquors, certain foodstuffs, tobacco, newspapers and other products of everyday consumption' on that day.[938]

After the *Keck* ruling, it became clear that rules governing the opening hours of shops,[939] including those applicable to Sunday trading,[940] when applying to all relevant traders on the territory, do not breach Article 34 TFEU. Even if considering, post-*Trailers*, that all national rules were now subject to a general market access test, it is unlikely that rules governing the opening hours of shops or the time when a specific product can be sold would be deemed influential enough to restrict the access of foreign products to the domestic market (the quantitative nature of the market access test is explored below in Section 6.4).[941]

Yet, a question regarding the application of Article 56 TFEU to this type of rules arises, similar to the one addressed for advertising restrictions. Indeed, the activity of retail trade in goods also constitutes a service within the meaning of Article 56 TFEU,[942] so it would need to be seen whether such rules could be considered as restricting the provision of retail services in the Member State where they are enacted. In some circumstances, for instance for rules targeting the sales of a specific products rather than the opening hours of shops in general, it could be argued that the freedom to provide services is entirely secondary to the free movement of goods and that only Article 34 TFEU should be applied.[943]

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[936] ibid, para 17.
[937] Case C-169/91 *Stoke-on-Trent and Norwich City Council v B & Q PLC* [1992], EU:C:1992:519, para 17, see also Case C-312/89 *Union départementale des syndicats CGT de l'Aisne v Conforama and Others* [1991] EU:C:1991:93, para 13.
[938] *Torfaen* (n 934), para 4 ; *Stoke-on-Trent* (n 937), para 4.
[939] See Joined Cases C-401/92 and 402/92 *Tankstation 't Heukske and Boermans* [1994] EU:C:1994:220, para 14.
[940] See Joined Cases C-69/93 and 258/93 *Punto Casa and PPV* [1994] EU:C:1994:226, para 14 ; Case 418/93 *Semeraro Casa Uno and Others v Sindaco del Comune di Erbusco and Others* [1996] EU:C:1996:242, para 28; Case C-483/12, *Pelckmans Turnhout* [2014] EU:C:2014:304, para 24.
[941] As pointed out by Catherine Barnard, 'a more extreme version of the rule' requiring 'shops to be closed six days a week (e.g. Sunday to Friday) instead of just one day (Sunday)' could be construed as a substantial hindrance to market access. The adoption of such a rule by a Member State remains yet quite a hypothetical prospect. See Barnard (n 664) 136.
[942] See, by analogy, *Visser* (n 620), para 97, regarding the application of the Services Directive to the activity of retail services.
[943] In *Visser* (n 620), paras 92-96, the Court made clear that, where the Services Directive applies, no such balance between the free movement of goods and the freedom to provide services can be made. This means that all rules applicable to the retail sale of goods and falling under the Services Directive may constitute a prohibited restriction under that legal act. The same can also be said for retail licences.

Other situations undoubtfully trigger the application of Article 56 TFEU and would surely constitute a restriction to the free provision of services. This would be the case of rules restricting the opening hours or the time of sales in the catering sector,[944] or for gambling venues.

6.3.2. Where?

Some rules restrict the place where a specific product can be sold, prohibiting for instance the sales of alcoholic beverages in gas stations or near schools or restricting the density of tobacco outlets in a city to limit the availability of tobacco products, so as to prevent smoking initiation and facilitate smoking cessation.[945] These rules constitute selling arrangement and, provided they apply to all relevant traders on the territory, are unlikely to lead to any sort of discrimination against foreign products and hence to constitute a breach of Article 34 TFEU. Likewise, unless their magnitude is susceptible to lead to a severe effect on trade, they are unlikely to be considered as substantially hindering access to the market. From the perspective of the retail service, such rules could, depending on the circumstances, constitute restrictions to the freedom to provide services within the meaning of Article 56 TFEU, as has just been discussed.

Several judgments from the Court of Justice have dealt with national rules restricting the operation of certain games of chance to specific venues, generally casinos, or specific areas. These rules are liable to prohibit or otherwise impede the activities of providers of gambling services established in another Member State where they lawfully provide similar services, which means that they constitute restrictions within the meaning of Article 56 TFEU.[946] Such rules, provided that providers of gambling services established in the Member States where they are enacted can prove that some of their customers originate from another Member States, may also constitute a restriction to the reception of the gambling services by such customers.[947]

6.3.3. How?

Regarding the way products are sold, and leaving aside the question of advertising, already addressed, two types of rules come to mind in relation to lifestyle risks: those preventing the retail display ban of products – most often tobacco products, but also alcoholic beverages – and those restricting the use of vending machines.

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[944] See in that regard *Josemans*, Opinion of Advocate General Bot (n 659), para 76.
[945] For evidence that tobacco outlet density influences smoking cessation and initiation, see Jaana I Halonen and others, 'Proximity to a Tobacco Store and Smoking Cessation: A Cohort Study' (2014) 23 Tobacco Control 146; Jennifer Cantrell and others, 'Tobacco Retail Outlet Density and Young Adult Tobacco Initiation' (2016) 18 Nicotine & Tobacco Research 130; Nina C Schleicher and others, 'Tobacco Outlet Density near Home and School: Associations with Smoking and Norms among US Teens' (2016) 91 Preventive medicine 287; Michael O Chaiton, Graham Mecredy and Joanna Cohen, 'Tobacco Retail Availability and Risk of Relapse among Smokers Who Make a Quit Attempt: A Population-Based Cohort Study' (2018) 27 Tobacco Control 163.
[946] *Anomar* (n 649), paras 65-66; *Commission v Greece* (n 633), para 53.
[947] *Bonver Win* (n 622), para 35.

A retail display ban is a rule that prohibits stores to display a given product inside their premises, keeping it for instance hidden under the counter or behind a screen, so as not to attract consumers' attention. Such a measure would surely qualify as a selling arrangement and hence escape the prohibition contained in Article 34 TFEU if complying with the two conditions laid down in *Keck*. Considering that the display of tobacco products or alcoholic beverages could be assimilated to an advertising practice, the argument could be made, like in *Gourmet* and other similar cases, that a retail display ban has more of an adverse effect on imported products if compared to domestic products. The EFTA Court pointed in that direction in a judgment regarding the Norwegian retail display ban for tobacco products.[948] The Court classified the rule as a selling arrangement and left it to the national Court to decide, on the basis of an analysis of the characteristics of the relevant market, whether the effects of the display ban put products which are new on the market at a disadvantage compared to products bearing an established trademark. The Court noted that 'depending on the level of brand fidelity of tobacco consumers, the penetration of the market may be more difficult for new products due to the display ban which applies in addition to a total advertising ban'.[949]

The use of vending machines is often restricted or prohibited to prevent an easy and uncontrolled access to harmful products.[950] This is the case for tobacco products in many EU countries. If considering the products sold, the use of vending machines must be considered as a selling arrangement, and it is hard to see how a rule restricting their operation, provided it applies to all relevant traders on the territory, would materially discriminate between foreign and domestic products and hence constitute a breach of Article 34 TFEU. If considering the vending machine itself, however, insofar as this machine is specifically designed for the sale of a given product, a ban on the use of the machine would surely constitute an obstacle to the free movement of goods prohibited by Article 34 TFEU.[951] The 2010 English ban of tobacco vending machines was for instance found by a national court to constitute a measure having equivalent effect.[952]

6.4. Rules on the use of products

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[948] Case E-16/10 *Philip Morris Norway AS v the Norwegian State* [2011]. See Alberto Alemanno, 'The legality, rationale and science of tobacco display bans after the Philip Morris judgment' (2011) 2 European Journal of Risk Regulation 591; Alemanno, 'Out of Sight, Out of Mind. Towards a New EU Tobacco Products Directive' (n 33) 213-214.

[949] *Philip Morris Norway* (n 948), para 49.

[950] These bans can be effective but may also lead to compensation effects. Regarding the 2005 I ban on vending machines in secondary schools, an evaluation study showed that the ban led to a reduction in both the sugar intake during morning breaks at school, as well as the frequency of these morning snacks, but that its effect on the overall diet had been limited, due to possible compensation behaviours outside of school: Sara Capacci, Mario Mazzocchi and Bhavani Shankar, 'Breaking Habits: The Effect of the I Vending Machine Ban on School Snacking and Sugar Intakes' (2018) 37 Journal of Policy Analysis and Management 88.

[951] See Frederic Geber, 'Between a rock and a hard place', in Alemanno and Garde (n 31), 166-167.

[952] Joined Cases C1/2011/0123 and C1/2010/2978 *R (Sinclair Collis Ltd) v The Secretary of State for health* [2011] EWCA Civ 437, para 19. See Geber (n 951), 166-167.

As part of their lifestyle risks regulation toolbox, Member States have put in place a number of rules restricting the place where harmful products can be used, tobacco and alcohol especially. This is usually done so as to limit the harmful consequences that these consumptions can have on others. Smoke-free environments aim at protecting people from second-hand smoke. Rules prohibiting the consumption of alcohol in certain public places or after a certain hour of the day seek to limit the disturbances to public order.

There has been only one case dealing with this sort of rules applicable to lifestyle risks. In *Blesgen*, Belgium prohibited the consumption, the sale and the stocking of alcoholic beverages containing more than 22° alcohol in public places. The Court considered that the measure did not constitute a measure having equivalent effect to a quantitative restriction because it had 'no connection with the importation of the products and for that reason [was] not of such a nature as to impede trade between Member States'.[953] Although, it is true that the connection of a restriction on use on the free movement of products appears prima facie slight, like it does for selling arrangement, it is not hard to see that it could, in certain circumstances, hinder directly or indirectly, actually or potentially, intra-Union trade. In *Blesgen*, Advocate General Reischl noted himself that the Belgian rule had led to a reduction in the Belgian production of spirits,[954] meaning that it could perfectly have led to a reduction on the imports of spirit too.

The restrictive effect that rules on use can have on the free movement of goods would appear from a later series of cases.[955] After *Trailers* and *Mickelsson*,[956] the Court would now analyse whether such rules, which are not product requirement or selling arrangements, have the effect of hindering the access to the domestic market of foreign goods to which the restriction on use applies. Such an effect occurs if the rule is liable to have 'a considerable influence on the behaviour of consumers',[957] implying that 'consumers, knowing that the use permitted by such regulations is very limited, ha[ve] only a limited interest in buying that product'.[958] This suggests the existence of some sort of threshold in the Court's appraisal,[959] meaning that not restrictions on use that only marginally influence consumers' purchasing behaviour would not constitute measures having equivalent effect to quantitative restrictions on imports.

In these two cases, the effect of the national measures was likely to be considerable since the use of the products in question was almost entirely prevented. In *Trailers*, the Italian rule prohibited motorcycles from towing trailers on the roads, meaning that Italian consumers had virtually no interest in buying trailers specifically designed for motorcycles.[960] In *Mickelsson*, the Swedish rule prohibited the use of personal watercraft on waters other than general

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[953] Case 75/81 *Blesgen* [1982] EU:C:1982:117, para 9.
[954] Case 75/81 *Blesgen* [1982] EU:C:1982:45, Opinion of Adovate General Reischl.
[955] Case C-265/06 *Commission v Portugal* [2008] EU:C:2008:210; *Trailers* (n 668); Case C-142/05, *Åklagaren v Percy Mickelsson and Joakim Roos* [2009] EU:C:2009:336.
[956] *Trailers* (n 668); *Mickelsson* (n 955).
[957] *Mickelsson* (n 955), para 26; *Trailers* (n 668), para 56.
[958] *Mickelsson* (n 955), para 27. See also *Trailers* (n 668), para 57
[959] Kalimo and Jansson (n 625) 537; Barnard (n 664) 102-103.
[960] *Trailers* (n 668), para 57.

navigable waterways, which resulted in the actual possibilities for the use of personal watercraft in Sweden being 'merely marginal'.[961]

Regarding rules adopted in the field of lifestyles, which typically only involve a restriction on use in certain specific places, it does not seem that these would lead to a market foreclosure comparable to the one it *Trailers* and *Mickelsson*. Extensive smoke-free environments may have led some consumers to abandon smoking, but not to a 'considerable' extent. In the event of a very comprehensive smoking ban, whereby the use of cigarettes would for instance only be allowed in private homes, one could potentially argue that such a rule has a considerable influence on consumer behaviour, although it would remain to be seen if opportunities for the use of cigarettes are so limited that access to the market is effectively hindered.

6.5. Other measures

The present chapter does not seek exhaustivity. There has been and will be other types of national measures not described here that may constitute restrictions to free movement. Two other types of rules nonetheless appear worth mentioning.

The first type is the residency requirement analysed in *Josemans*, which limited access to the city of Maastricht's coffee-shops to persons residing in the Netherlands only, so as to prevent drug tourism. Although *Josemans* is the only existing judgment involving a residency rule adopted in relation to the consumption of harmful products, it is not impossible to imagine another such case arising in the future. Indeed, the wide variations existing between national policies on lifestyles, regarding in particular the taxation of tobacco products and alcoholic beverages, lead to significant cross-border movements of persons in certain border regions of the EU, which may give rise to disturbances similar as those seen in *Josemans* (see Chapter 5, Section 4.2). This could prompt Member States to adopt similar residency rules to limit the nuisance.[962]

Another important aspect of national lifestyle policies are the penalties which can be incurred when violating the various national rules that restrict free movement. These penalties themselves constitute restrictions to free movement and must be assessed separately from the main restrictive measure to which they are attached.[963] In relation to gambling, the Court ruled for instance that 'a national court, hearing an assessment of the lawfulness of a penalty imposed for infringement of a monopoly in the sector of games of chance, *must specifically assess whether that restriction complies with Article 56 TFEU*, even if the other restrictions surrounding the establishment of that monopoly have already been held to be compatible with that provision'.[964] In *Sjöberg and Gerdin*, the Swedish restriction on gambling advertising also prohibited such advertising when organised in Sweden without a licence. It appeared however

[961] *Mickelsson* (n 955), para 25.
[962] For examples of such nuisance, see *Heinonen* (n 501).
[963] In relation to the freedom to provide services, see Case C-231/20 *Landespolizeidirektion Steiermark and Others* [2021] EU:C:2021:845, para 27.
[964] ibid, para 28, emphasis added.

that the penalties incurred in case of violation of this precise prohibition were less strict than in the case of unlawful advertising for gambling operations organised in other Member States, although this precise point was in discussion before the national court. Such arrangement, the Court concluded, would be discriminatory and in breach of Article 56 TFEU.[965]

7. Conclusion

Trading unhealthy commodities and providing gambling services constitute economic activities to which free movement provisions apply. In most cases, when adopting lifestyle risks control measures, Member States create restrictions to free movement. This is certainly true, regardless of which provision of the TFEU applies, where a measure directly or indirectly discriminates against imported products or foreign service providers, and more generally, where a measure hinders access to the market for imported products or impedes the free movement of services and the freedom of establishment. Only rules whose effects on cross-border trade appear most remote, such as those applicable to retail sales or to the use of products, do not qualify as restrictions, although some uncertainty remains on the matter.

Interestingly enough, measures that are most restrictive of individual autonomy, as per the 'intervention ladder' introduced in Chapter 1, are not necessarily those which straightforwardly qualify as restrictions to free movement, free movement of goods in particular. Price and tax measures, on the one hand, are situated at the top of the intervention ladder and are recognised as powerful incentives to guide individual choice. Where no discriminatory effect is present, however, they are likely not to constitute unlawful restrictions under Articles 34 and 110 TFEU. Labelling requirements, on the other hand, although they have a limited impact on consumer autonomy and consumer choice, always constitute measures having equivalent effect to quantitative restrictions under Article 34 TFEU.

National measures that restrict free movement may be justified on various grounds relating to the public interest, among which the protection of public health features prominently. However, the requirements applicable so that these measures may be defended create constraints for the national regulatory process, as will be shown in the next chapter. This matters a great deal from the perspective of national regulatory autonomy.

Two exceptions apply to this narrative. First, trade in illicit drugs is not considered as an economic activity to which free movement applies. Hence, Member State measures applicable to illicit drugs escape free movement altogether. National authorities have a considerably greater leeway to adopt the measures that they deem necessary, keeping in mind that the measures surveyed in this chapter apply by nature only to licit products. There cannot be any advertising made on television or printed media for illicit drugs, nor can there be any labelling or packaging requirement applicable to these products.

Second, for two categories of national measures, internal taxation regulated by Article 110 TFEU and commercial monopolies regulated by Article 37 TFEU, no formal justification exist.

[965] ibid, para 56.

This means that national measures prohibited under these provisions cannot be saved under public health grounds and that Member States may therefore be deprived of some useful policy tools when regulating lifestyles. This is especially true of tax measures. The Court of Justice has tried to remedy this problem by integrating public interest requirements in its reasoning, yet it has done so in a way that lacks predictability and does not offer adequate protection to Member State interests.

Chapter 4

Defending Member State measures: shaping the national risk regulation process

1. Introduction

The application of free movement provisions to national lifestyle risks control measures pits the establishment of the internal market against the protection of human health, two fundamental objectives of the European Union which are at the core of the lifestyle risks regulatory model developed under EU law. When restricting the free movement of goods, services or the freedom of establishment, Member State measures put the internal market in jeopardy while at the same time contributing to the achievement of the EU commitment, expressed inter alia at Article 168(1) TFEU and Article 35 of the Charter, that a high level of protection for human health is ensured in the definition and implementation of all its policies and activities.[966]

Through a careful examination of the grounds of justification put forward by national authorities and the application of the principle of proportionality, the Court of Justice has a degree of oversight over Member State choices and shapes the national regulatory process, at both stages of risk assessment and risk management. National authorities are constrained in their assessment of the risk to human health incurred, which justifies the adoption of measures restricting free movement, and in their analysis and choice of possible control measures. Proportionality, in particular, is the main instrument used by the Court to police national measures. Although not conceived as such originally, proportionality has become 'a main tenet of the risk management phase by providing a detailed and useful set of guidelines that risk managers must abide by when regulating risk'.[967] It has acquired its own specificity in the field of risk regulation,[968] if compared to other areas subject to free movement rules.

This chapter analyses first the types of risks to health, and related threats to other protected public interests, recognised by the Court as constituting legitimate reasons to restrict free movement. Second, it addresses the type of control measures which may pass the proportionality assessment and therefore be upheld in spite of their restrictive effect on free movement. For both risk assessment and risk management, the question of evidence is investigated in particular detail. When discussing the role of evidence in the context of lifestyle risks regulation, it is crucial 'to distinguish between evidence on causes (in other words, the causal link between a suggested risk factor and an illness or otherwise undesirable health outcome) and evidence on policy interventions (in other words, the potential of different paths

[966] See Joined Cases C-570/07 and 571/07 *Blanco Pérez et Chao Gómez* [2010] EU:C:2010:300, para 65; Joined Cases C-159/12 and 161/12 *Venturin*i [2013] EU:C:2013:791, para 41.
[967] Alemanno, 'The Shaping of European Risk Regulation by Community Courts' (n 495) 52.
[968] ibid 56.

of action to promote health or reduce harm)'.[969] We therefore look at these two types of evidence separately, at the risk assessment – justification – stage and the risk assessment – proportionality – stage. The use of evidence becomes even more important in a field where scientific data play such a crucial role.

Thus doing, the present chapter examines three inter-related questions. It seeks first to analyse how the Court strikes the balance between the requirements of the internal market and health protection in the area of lifestyle risks, and whether legitimate national measures do escape the prohibitions contained in Articles 34, 49 and 56 TFEU. Second, it aims to understand how proportionality influences risk management at the national level, in particular the ability for risk managers to integrate concerns other than those related to risk in the design and application of their measures. Finally, it seeks to determine whether the Court conducts a coherent assessment across the various lifestyle risk factors concerned, potentially different from other areas of national regulatory activity, and whether it is hence possible to talk about a particular 'lifestyle risks model' as regards the Court's assessment of national measures.

2. Existence of a legitimate interest – *risk assessment*

Under the formal derogation grounds contained in the Treaty or the additional grounds recognised by the Court in its case-law, Member States may defend their lifestyle risks control measures. Overall, the Court has accepted that the trade in unhealthy commodities and the provision of gambling services involve risks, to health mostly. In a number of cases, the existence of such risks must however be proven by national authorities. This requirement, and the Court's review of the evidence adduced, shape the way in which the risk assessment is conducted at the national level.

2.1. Legitimate objectives

2.1.1. Alcohol and tobacco

The Court of Justice has recognised without any difficulty alcohol and tobacco control as legitimate objectives justifying a restriction to free movement. The main and sizeable difference between the two risk factors, as we shall see, is the far smaller number of judgements that have been handed down by the Court in the field of tobacco if compared to that related to alcohol.

National measures aimed at curbing the consumption of alcohol have yielded a significant number of cases, where the Court has been able to discuss these measures' justification and proportionality in depth. In the early *Commission v France* case, the Court recognised, with a somewhat tortuous formulation, that 'the connexion made by the French Government between the control of advertising in respect of alcoholic drinks and the campaign against alcoholism'

[969] Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 153–154.

did exist since 'advertising acts as an encouragement to consumption', and therefore that the disputed measure were not 'a matter of indifference from the point of view of the requirements of public health recognized by Article 36 of the Treaty'.[970] In subsequent cases, the Court would simply accept that 'legislation which has as its objective the control of the consumption of alcohol so as to prevent the harmful effects caused to health of humans and society by alcoholic substances, and which thus seeks to combat alcohol abuse, reflects health and public policy concerns recognised by Article 36 TFEU',[971] the same holding true for Article 52(1) TFEU.[972] In *Heinonen*, in addition to a public health argument, the Court also accepted Finland's reliance on a broad definition of public order, encompassing elements of public policy, public security and public morality, including for instance the need to limit alcohol-induced violence or drink-driving.[973]

Tobacco control has only given rise to a handful of judgments under Article 34 TFEU and none, to the knowledge of the author, under Article 49 or 56 TFEU. In only two judgments involving restrictions to the free movement of goods has the justification for the adoption of national tobacco control measures been discussed, without however any developments on proportionality.[974] If compared to alcohol, this situation may be explained in part by the adoption of early EU harmonisation measures in the field of tobacco, which have restrained Member States' capacity to act unilaterally. Although the Court has never formally recognised the fight against tobacco consumption as a legitimate public health objective, contrary to what it has done for alcohol, it has nonetheless shown its readiness to accept it.[975] Were more cases relating to tobacco control to arise in the future, there is little doubt that the Court would accept Member State's public health arguments in this regard.

2.1.2. Food and nutrition

The judicial landscape appears more complex and more nuanced regarding food and nutrition. The Court is ready to accept Member State arguments based on the hazardous effect of specific nutrients or other substances present in food on human health but has been more reluctant towards arguments based on the necessity to maintain the overall quality of people's diets.

The Court of Justice has clearly recognised that the consumption of certain nutrients in excess could be harmful to health and that limiting the intake of such nutrients could constitute a legitimate public health objective. This can be seen from an early series of cases dealing with

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[970] *Commission* v *France* (n 881), para 17.
[971] *Visnapuu* (n 703), para 115. See also *Aragonesa* (n 884), para 15; *Franzen* (n 797), para 76; *Ahokainen* (n 869), para 28, *Rosengren* (n 817), para 40.
[972] Case *Commission v France* (n 896), para 30; *Bacardi France* (n 896), para 37.
[973] *Heinonen* (n 501), paras 18, 30-35.
[974] *Commission v France* (n 813); *ANETT* (n 675).
[975] *Commission v France* (n 813), para 29; *ANETT* (n 675), para 51. In cases involving EU measures, see also Case C-434/02 *Arnold André* [2004] EU:C:2004:800, para 59; Case C-210/03 *Swedish Match* [2004] EU:C:2004:802, para 61. The lack of a formal recognition of tobacco control as a legitimate public health objective could be explained by the 'obvious' nature of the health risks linked to tobacco, regarding which the Court may have felt that a clarification was not necessary.

Member State rules restricting the use of certain additives in food and beverages, including vitamins and minerals. In *Sandoz*,[976] the Court examined a Dutch rule prohibiting the sale of food and beverages fortified in vitamins without prior authorisation. The Dutch government considered that such rule was necessary 'owing to the very nature of the substances added since the absorption of any vitamins in high doses or for a prolonged period may entail risks to health or at least undesirable side-effects such as *malnutrition*'.[977] The Court accepted the argument. It recognised that even if vitamins were necessary for the human organism and were not 'in themselves' harmful substances, 'excessive consumption of them over a prolonged period may have harmful effects',[978] taking also into account 'the general nutrition, the composition of which is unforeseeable and cannot be monitored'.[979] Hence, national rules prohibiting the marketing of vitamin-fortified foodstuffs without prior authorisation are in principle justified on public health grounds.[980] The Court would be even clearer in *Commission v Germany (Beer purity)*, stating that such rules '*meet a genuine need of health policy*, namely that of restricting the uncontrolled consumption of food additives'.[981]

This shows, and the use of the term 'malnutrition' is important in this regard, that the Court is ready to accept defences based on not only an immediate risk to health but also on the long-term effects of a food or a substance contained therein. To establish the existence of a risk, the Court requires a global assessment to be carried out, taking into consideration the place occupied by the food in the general diet of the population. This was confirmed in subsequent cases[982] and clearly expressed in *Commission v Netherlands*, where the Court ruled that:

> [T]he mere fact that a foodstuff fortified with a given nutrient is not per se harmful to public health […] does not necessarily mean that it is free of risk […], it is still necessary to determine whether it entails a risk for public health *having regard to other sources of that nutrient in overall food intake*.[983]

Something similar can be seen in *Commission v France*, where one of the contested rules prohibited the marking of the (in)famous energy drink Red Bull. France's position was avowedly not 'based on mainstream toxicology' but grounded on 'the risk of excessive caffeine consumption, in particular among pregnant women'.[984] The Court accepted it as a valid public health justification.[985]

The Court is therefore, on principle, open to Member State defences based on the presence of nutritional risks, provided that the existence of these risks be proven by appropriate evidence

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[976] *Sandoz* (n 871).
[977] ibid, para 10, emphasis added.
[978] ibid, para 11.
[979] ibid, para 17.
[980] ibid, para 16.
[981] *Commission v Germany (Beer purity)* (n 612), para 42, emphasis added.
[982] See *Commission v Denmark* (n 872); *Commission v France* (n 872).
[983] *Commission v Netherlands* (n 872), para 30, emphasis added.
[984] *Commission v France* (n 872), para 67.
[985] ibid, para 69. See contra *Commission v Italy* (n 930), paras 32, where Italy produced no proper evidence to substantiate its claim, which led the Court to reject the prohibition of certain energy drinks.

(see section 2.3). Regarding food, it is established case-law that it is for the competent national authorities who wish to restrict the marketing of a product to show that this product poses 'a real risk to public health'.[986] If the risk to health of a nutrient cannot be established with regard to its long-term consumption and the overall diet, the absence of a need for this nutrient in the population cannot itself suffice to justify the prohibition of foods that contain it.[987] A detailed, case-by-case assessment of the effects of such nutrient on human health must be performed.[988]

The focus on the existence of a 'real threat to human health'[989] has yet led to some unfortunate outcomes, where the Court has seemingly neglected the importance of a balanced and healthy diet for human health, beyond the existence of specific risks linked to the consumption of specific nutrients or foods. This appears from two judgments, adopted within a short timespan, *Commission v France (Milk substitutes)* and *Commission v Germany (Meat Products)*.[990]

In *Commission v France*, where France prohibited the importation and sale of substitutes for milk powder and concentrated milk, the Court considered that:

> [A] Member State *may not invoke public health grounds* in order to prohibit the importation of a product by *arguing that its nutritional value is lower* or its fat content higher than another product already available on the market in question. It is plain that *the choice of foodstuffs available to consumers* in the Community is such that the mere fact that an imported product has a lower nutritional value does not pose *a real threat to human health*.[991]

Such a statement is problematic for several reasons. One could have expected the Court to declare the prohibition of a product with a lower nutritional value to be disproportionate to the objective of safeguarding public health or to consider that no proper evidence had been adduced in this case. An outright rejection of any public health argument based on the poor nutritional value of food appears however misguided. Certain nutrients are essential to good health and the consumption of any substitute product that does not match the nutritional composition of the product that it is supposed to replace is thus liable to have an effect on health. Thus doing, the Court 'simply refuses to accept that placing restrictions on the marketing of nutritionally inferior substitutes is ever justifiable on health protection grounds'.[992] Furthermore, the Court's mention of 'the choice of foodstuffs available to consumers' shows that the Court's rejection of France's argument is also grounded in the belief that consumers can simply decide to prioritise products with a higher nutritional value over those with a lower one. This belief in the capacity of the consumer to make enlightened food choices is a recurrent feature of the Court's case-law that has pervaded EU policy and legislation, as will be discussed further in

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[986] *Commission v Denmark* (n 872), para 46. See also *Sandoz* (n 871), para 22; *Commission v Germany (Beer purity)* (n 612), para 46.
[987] *Commission v Denmark* (n 872), para 54 ; *Commission v Netherlands* (n 872), para 59 ; Case *Commission v France* (n 872), paras 59-60.
[988] *Commission v Denmark* (n 872), para 56; *Commission v Netherlands* (n 872), para 63; Case *Commission v France* (n 872), para 62.
[989] Iris Goldner Lang, 'Public Health in European Union Food Law', in Hervey, Alasdair Young and Bishop (n 37) 424.
[990] *Commission v France (Milk substitutes)* (n 911) ; *Commission v Germany (Meat products)* (n 929).
[991] *Commission v France (Milk substitutes)* (n 911), para 15, emphasis added.
[992] MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 92.

the part devoted to labelling and the information paradigm (see section 3.1.2), as well as in Chapter 6.

The Court followed a similar reasoning in *Commission v Germany*, where the German measure prohibited the marketing of meat products containing ingredients other than meat, subject to certain exceptions. One of Germany's arguments was that vegetable proteins had a lower nutritional value than animal proteins – a dubious claim in light of current scientific knowledge – to which the Court answered, as in *Commission v France*, that a Member State may not rely on public health grounds to justify the prohibition of a product whose nutritional value is lower than another product available on the market, 'since it is plain that the choice of foodstuffs available to consumers in the Community is such that the mere fact that an imported product has a lower nutritional value *does not pose a real threat to human health'*.[993]

This came after Germany's first argument had been, understandably, dismissed by the Court. Indeed, the German government argued that its rule was necessary, on grounds of public health, to ensure an adequate intake in the population of 'certain essential nutrients contained in meat, especially proteins'.[994] At the same time, Germany had published a report indicating that protein intake levels in Germany were generally sufficient and, where these levels were lower than recommended, were in any way not situated at a level so low so as to pose a threat to human health.[995] The report further added that 'some meat ingredients contain[ed] harmful substances such as purine, cholesterol and saturated fatty acids' and therefore expressed 'some concern about any future increase in the consumption of meat and meat products'.[996] There was hence little case to be made for promoting the consumption of 'pure' meat products. This judgment from 1989 appears interestingly precursory to the current discussions surrounding meat consumption, red meat in particular.

The general picture that emerges from these various judgments, as rightly expressed by the European Commission, is that the Court 'whilst fully recognising the necessity for the Member States to establish a food policy intended to improve the state of the population's general health', considers that 'general preoccupations relating to the desired composition of the nutritional regime of the population of those States cannot constitute a lawful justification for obstacles to trade between them'.[997] The Court is ready to accept claims based on the risk to health arising from the consumption of a specific nutrient or substance, taking the overall diet into consideration if necessary, but rejects arguments grounded on the comparative nutritional composition of products, hence limiting the possibilities to adopt measures promoting healthier and more balanced diets.

That being said, it seems exaggerated to consider, like MacMaoláin does, that cases such as *Commission v Germany* and *Commission v France* 'effectively prohibit[…] the adoption of

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[993] *Commission v Germany (Meat products)* (n 929), para 10, emphasis added.
[994] ibid, para 7.
[995] ibid, para 8.
[996] ibid, para 9.
[997] *Commission v Denmark* (n 872), para 21.

measures at national level which are designed to promote good health' and that 'this position, combined with the other jurisprudence of the Court on measures equivalent to quantitative restrictions on trade, bars Member States from taking meaningful interventionist action to deal with a public health crisis like obesity'.[998] First, one should keep in mind that these two judgments were rendered in 1989, at a time where obesity and diets were not a public health priority and scientific knowledge on nutrition was less developed. One can wonder whether a similar stance would be adopted by the Court today, in light especially of the developments of EU policy on the matter. Second, and most importantly, it should be possible for Member States, on the basis of judgments such as *Sandoz* and following, to adopt meaningful policies aimed at tackling obesity and other public health scourges. It could perfectly be argued that fat or sugar, while not being harmful 'in themselves', have 'harmful effects' when consumed 'over a prolonged period',[999] considering also 'the general nutrition, the composition of which is unforeseeable and cannot be monitored'.[1000] The Court is not in principle hostile to the adoption of national measures designed to promote healthier diets.

2.1.3. Illicit drugs

Member State measures restricting the use of and trade in illicit drugs are not subject to free movement provisions, which means that national governments should not have to defend any of these measures based on the need to prevent harm arising from their consumption. It is therefore logical that this ground of justification is nearly absent from the Court's free movement case-law. The only exception can be found in *Josemans*, where the Court had ruled that the residency requirement enacted by the city of Maastricht for accessing coffee-shops constituted a restriction on the freedom to provide services, insofar as foreign residents could access these establishments to consume food or non-alcoholic beverages. The Court considered that combatting drug tourism and the accompanying public nuisance constituted a legitimate interest capable of justifying restrictions to the free movement of services, since these were concerned with both the maintenance of public order and the protection of public health, 'at the level of the Member States and also of the European Union'.[1001] In that regard, the Court mentioned 'the danger to the health and well-being of individuals constituted, in particular, by demand for and the illicit traffic in narcotic drugs and psychotropic substances, as well as their harmful effects on the economic, cultural and political bases of society'.[1002] Here again, echoing Advocate General Bot's analysis (see Chapter 3, Section 2.2.2), the Court identifies risks that go beyond health and expresses a moral reprobation towards illicit drugs and their negative effect on the fabric of society. It is however clear from the *CBD* judgment that no such defence is available where a given substance 'does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data'.[1003]

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[998] MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 90–91.
[999] *Sandoz* (n 871), para 11.
[1000] ibid, para 17.
[1001] *Josemans* (n 650), paras 65-66.
[1002] ibid, para 67.
[1003] *CBD* (n 650), paras 72 and 95.

2.1.4. Gambling

Aside from the express grounds of justification contained in Article 52(1) TFEU on freedom of establishment – public policy, public security, or public health – also applicable in the area of freedom to provide services by virtue of Article 62 TFEU, the Court has recognised in the field of gambling the existence of a number of overriding requirements relating to the general interest capable of justifying national restrictive measures. In most cases, the Court relies on these overriding requirements rather than on the Treaty-based justifications.[1004] These various grounds form two main categories of protected interests: those, on the one hand, relating to the protection of consumers and those, on the other, relating to the protection of public order.[1005] Regarding the latter, the Court considers that gambling involves 'a high risk of crime and fraud, given the scale of the earnings and the potential winnings on offer to gamblers',[1006] which may justify the need to limit its expansion. It is not always easy to distinguish between the various grounds of justification put forward by Member States, whose gambling policies tend to pursue different objectives at the same time. The Court tends to assess these various considerations taken in bulk. [1007]

As regards consumer protection, the most relevant concern for our purpose, the Court, rather than adopting a genuine public health perspective recognising the harmfulness of this activity for consumers' health, seemed for a long time to adopt a more moral standpoint, focused on the inherently *wrong* nature of this activity and the threat it poses to society. This ambiguity appears from early cases, where the Court uses expressions such as limiting 'exploitation of the human passion for gambling',[1008] 'confining the desire to gamble and the exploitation of gambling',[1009] or preventing 'incitement to *squander* on gambling'.[1010] All of these expressed a disapproval of gambling without a clear recognition of its addictive potential and its harmful effects on players. In *Commission v Spain* and *Lindman*, the Court even seemed to doubt the reality of gambling addiction. In *Commission v Spain*, it declared, regarding the need to fight addiction to gambling, that 'although it *cannot be excluded* that that objective could be regarded as falling within the definition of protection of public health', evidence would be needed establishing that, in the Member State wishing to rely on such ground of justification, 'such an addiction *has reached the point* amongst the population at which it could be considered to constitute a danger to public health'.[1011] In *Lindman*, the Court deplored the lack of evidence

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[1004] The Court has only applied Article 52 TFEU in cases involving discriminatory measures, see Case C-64/08 *Engelmann* [2010] EU:C:2010:506, para 34; *Commission v Spain* (n 785), para 37.
[1005] See *Stoß* (n 863), para 74.
[1006] *Liga Portuguesa* (n 643), para 63.
[1007] See *Schindler* (n 632), para 58; *Läära* (n 645), para 33; *Zenatti* (n 635), para 31; *Placanica* (n 644), para 46; *Ladbrokes* (n 861), para 26; Case C 3/17 *Sporting Odds* [2018] EU:C:2018:130, para 25.
[1008] *Läära* (n 645), para 32.
[1009] *Zenatti* (n 635), para 35.
[1010] *Liga Portuguesa* (n 643), para 56; *Sjöberg and Gerdin* (n 908), para 36; *Ladbrokes* (n 861), para 18. Emphasis added.
[1011] *Commission v Spain* (n 785), para 40, emphasis added.

establishing 'the gravity of the risks connected to playing games of chance'.[1012] Contrary to alcoholism, the gravity and prevalence of which has never been questioned, the Court needed to be convinced that gambling addiction was a real public health issue. It is only in *Stoß* that the Court finally recognised, without any qualification, the fight against gambling addiction as a suitable ground to defend national restrictive measures.[1013]

2.2. Source of the justification

Articles 36, 52(1) and 62 TFEU provide for express grounds of justification allowing Member States to derogate from the prohibition contained in Articles 34, 35, 49 and 56 TFEU and to lawfully restrict the free movement of goods and services and the freedom of establishment. Pursuant to these provisions, Member States may adopt restrictive measures that protect public health or, under Article 36, the 'health and life of humans'. As appears from the various cases analysed in this chapter, the Court uses the two terms interchangeably. Unsurprisingly, Member States use this ground of justification the most when attempting to defend their lifestyle risks measures. Public policy and public security, although rarely used,[1014] may also provide Member States with additional grounds of justification, which are usually ultimately linked to the harmful nature of the product or service at stake. Available under Article 36 TFEU to justify restrictions to the free movement of goods, public morality as an express ground of justification has never been used in relation to Member State lifestyle risks measures.[1015]

Alongside these Treaty-based grounds of justifications, the Court has, since the *Cassis de Dijon* judgment, formally recognised the existence of additional case-based grounds of justification, known as 'mandatory requirements'[1016] or, as they tend to be named now, 'overriding reason[s] in the public interest'.[1017] From the vast and open-ended list of these additional grounds of justification, consumer protection offers a prima facie useful addition or alternative to public health arguments, since the protection of consumers' interests also extends to the protection of their health.[1018] Yet, in free movement cases, the Court usually treats concerns related to consumers' health separately, under the public health defence, from those more strictly connected to consumer protection, related for instance to unfair commercial practices or the

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[1012] *Lindman* (n 786), para 26.
[1013] This would be confirmed in later cases, see e.g. Case C-212/98 *Zeturf* [2011] EU:C:2011:437, *Ladbrokes* (n 861).
[1014] See e.g. *Heinonen* (n 501), para 35, where the Court referred to 'combating disturbances of public order connected with the consumption of alcohol'; *Josemans* (n 650), para 65, where the Court considered that combating drug tourism concerned 'both the maintenance of public order and the protection of the health of citizens'.
[1015] A mere reference can be seen in *Heinonen* (n 501), where the Court does not formally rely on it in its analysis of the justification and the proportionality of the national measure.
[1016] *Cassis de Dijon* (n 612), para 8.
[1017] Case C-649/18 *A (Advertising and sale of medicinal products online)* [2020] EU:C:2020:764, para 66. For services and establishment, see *Stanley International Betting* [2015] (n 644), para 47.
[1018] See in that regard Article 169 TFEU.

protection of consumers' legitimate expectations.[1019] As we shall see, it is only in the field of gambling that health-related aspects have been subsumed under a broader consumer protection mandatory requirement, in early cases especially. In gambling cases, the Court has also recognised broad mandatory requirements linked to the preservation of public order, strongly associated to public morality concerns.

The distinction between Treaty-based and case-law based justifications is grounded on the Court's long-standing position that 'imperative requirements can […] be taken into account only in the case of measures which apply without distinction to both domestic and imported products'.[1020] Distinctly applicable measures, or directly discriminatory measures,[1021] those distinguishing in law between domestic and imported products, could only be defended by the express derogations contained in Article 36 TFEU. Regarding services and establishment, the Court held equally that Member States adopting discriminatory measures could only avail themselves of the formal grounds contained in Article 52(1) TFEU.[1022]

For several reasons, however, this Chapter will not distinguish cases according to which of these two categories, Treaty-based or case-law based justifications, is used. First, public health is a ground of justification that is open to any measure that genuinely purports to reduce exposure to lifestyle-related health risks. As a formal ground contained in the Treaty, it applies to all national measures irrespective of their nature. Second, the Court's position reserving the use of case-law-based justification to non-discriminatory measures, if not openly renounced, has been watered down over the years. In its most recent cases, the Court has often refrained from making a difference between case-law based justifications and Treaty-based justifications.[1023] It is hence not even certain that this once strict separation still holds. Finally, proportionality, although it can be applied more or less strictly according to the circumstances of the case, is not applied differently according to the category of justifications used.

2.3. Proving the risk: the role of evidence

[1019] See *Cassis de Dijon* (n 612) ; *Commission v France (Milk substitutes)* (n 911) ; *Commission v Germany (Meat products)* (n 929).

[1020] Case C-2/90 *Commission v Belgium (Walloon Waste)* [1992] EU:C:1992:310, para 34. See also Case 788/79 *Gilli* [1980] EU:C:1980:171, para 6; Case 6/81 *Groep v Beele* [1982] EU:C:1982:72, para 7, in which the Court mentions measures that apply 'without discrimination'.

[1021] We take the position here with Barnard that distinctly applicable and directly discriminatory are 'loosely equivalent' concepts, see Barnard (n 664) 77. More generally, discrimination is far from being a clear and straightforward concept in free movement law, and EU law in general, see Poiares Maduro (n 665) 36-43.

[1022] *Commission v Spain* (n 785), paras 36-38.

[1023] See *Austria v Germany* (n 666), para 122, regarding goods: 'national legislation which constitutes a measure having equivalent effect to quantitative restrictions can be justified on one of the grounds of public interest laid down in Article 36 TFEU or by imperative requirements', and similarly regarding services para 139. For further reflections on this development, see Barnard (n 664) 82-83; Poiares Maduro (n 665) 52. The latter doubted that this distinction had ever been taken seriously by the Court of Justice. For a positive view on this development: see Schütze, *From International to Federal Market: The Changing Structure of European Law* (n 665) 216–218. See however Case C-695/21 *Recreatieprojecten Zeeland BV and Others v Belgische Staat* [2023] EU:C:2023:144.

These developments show that the Court is willing to accept reliance on a range of objectives linked to the harmfulness of certain lifestyles for human health and the connected damages to society. These risks must however be proven. Through this evidentiary requirement, the Court polices the risk assessment process, understood, as previously discussed, as 'the process or method to identify hazard that has the potential to cause harm and to analyse risk associated with that hazard'.[1024] Although the Court has not, in most cases, devised precise guidelines as to how the risk assessment needed to be performed, it still requires that some sort of process takes places and that certain evidence be adduced.

Importantly, what we are interested in here are questions pertaining to the standard of proof – what kind of evidence is required from Member States to substantiate their claims– rather than questions linked to the burden of proof – who should prove what and at what stage of the discussion –[1025] or questions of procedures – rules determining the admissibility of evidence and the various ways in which it can be brought before the Court. [1026] It is also possible to distinguish between the standard of proof and the standard of review, the latter referring to the manner in which the Court scrutinises the evidence that is adduced by national authorities.[1027] As we shall see, if the Court has said much on the standard of proof, the same is not true regarding the standard of review. This also holds as regards the evidence requirement pertaining to risk management (see below section 3.4).

It is a long-standing principle in free movement case-law that 'the reasons which may be invoked by a Member State by way of justification must be accompanied by *appropriate evidence* or by an analysis of the appropriateness and proportionality of the restrictive measure adopted by that State, and *specific evidence* substantiating its arguments'.[1028] What appears generally from free movement case-law is that mere unsubstantiated assertions on the part of Member States do not suffice to prove the existence of a legitimate interest.[1029] To justify their lifestyle measures, Member States must prove that the product, substance or activity regulated

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[1024] European Commission, 'Better Regulation Toolbox' (n 103) 101.
[1025] For elements on the burden of proof in free movement cases and further references, see Niamh Nic Shuibhne and Marsela Maci, 'Proving Public Interest: The Growing Impact of Evidence in Free Movement Case-law' (2013) 50 Common Market Law Review 965, 968-971.
[1026] For a brief discussion see ibid 975–978. For a discussion on the role of experts before EU courts, see Eric Barbier de La Serre and Anne-Lise Sibony, 'Expert Evidence before the EC Courts' (2008) 45 Common Market Law Review 941.
[1027] According to Craig, it is important to distinguish between issues pertaining to the standard of proof 'to be required of the initial or primary decision-maker before it makes the decision' and that pertaining to the standard of review 'applied by the reviewing court in deciding whether the primary decision-maker has met the standard of proof required of it': Craig, *EU Administrative Law* (n 130) 469–470. Arguably, it is true that 'EU Courts have never drawn a clear line' between standard of proof and standard of review, which 'are not wo separate notions but two aspects of a single control system': Fernando Castillo de la Torre and Eric Gippini Fournier, *Evidence, Proof and Judicial Review in EU Competition Law* (Edward Elgar Publishing 2017) 16–17. Whatever Member States have to prove is what the Court is empowered to verify. Yet, the distinction remains useful in the sense that it is the intensity of the review which determines how a court of law engages with specific pieces of evidence.
[1028] *Scotch Whisky* (n 612), para 54, emphasis added. See also *ANETT* (n 675), para 50.
[1029] Nic Shuibhne and Maci (n 1025) 980.

poses a risk to human health,[1030] or to any other relevant protected interest. Yet, the Court has not applied a similar standard of proof depending on the objective put forward by Member States and the risk alleged.

In cases involving food risks, the Court is unwilling to accept general assertions regarding the risk to health posed by a given nutrient or product.[1031] This can be seen in *Van der Veldt*, where the Belgian government failed to produce scientific evidence showing that the salt level permissible in the Netherlands for bread and bakery products was dangerous to human health, justifying a prohibition of their marketing on its territory. Belgium confined itself to declaring that this salt level was 'too high' and that due to the consumption of Dutch products 'the daily intake [of salt] would amount to 3.1 g, which represents, not counting those who eat bread in large quantities, a daily increase of 0.6 g of salt for the average person'.[1032] According to the Court, '*general conjecture of that nature* does not prove that increasing salt intake by such an amount poses a risk for public health', which must be measured 'on the basis of *relevant scientific research*'.[1033] The Court concluded that by failing 'to produce scientific data on the basis of which the Belgian legislature would have been justified in enacting and retaining the measures at issue, the Belgian authorities have failed to demonstrate the risk to public health of a salt content in excess of 2%'.[1034]

In *Commission v Germany (Beer purity),* the German government relied on a number of expert reports mentioning 'the risks inherent in the ingestion of additives *in general*' and referred to the particular eating habits prevailing in Germany, namely the consumption of beer in 'considerable quantities', to defend its rule prohibiting the use of certain additives in beer.[1035] For the Court, however, 'mere reference to the potential risks of the ingestion of additives in general and to the fact that beer is a foodstuff consumed in large quantities' did not suffice to justify the German measure.[1036]

The Court's position in relation to gambling risks appears more fragmented. In early cases, the Court never referred to specific evidence Member States needed to put forward to prove a threat to public order or establish the risks gambling poses to consumers. In *Commission v Spain* and *Lindman*, though, the Court regretted the absence of evidence. In *Lindman*, it deplored in particular the lack of '*statistical or other evidence* which enables any conclusion as to the gravity of the risks connected to playing games of chance',[1037] echoing the position it had taken

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[1030] See *Deutsche Parkinson* (n 694), para 42: 'the existence of a genuine risk to human health must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research'.
[1031] For a recent illustration outside the field of lifestyles, see *A (Advertising and sale of medicinal products online)* (n 1017), para 112.
[1032] *Van der Veldt* (n 928), para 16.
[1033] ibid, para 17, emphasis added.
[1034] *Van der Veldt* (n 928), para 18.
[1035] *Commission v Germany (Beer purity)* (n 612), para 48, emphasis added.
[1036] ibid, para 49.
[1037] *Lindman* (n 786), para 26, emphasis added.

in relation to food.[1038] This could have signalled a change of tack, but the Court was yet fast to rule, in *Stoß*, that it should not 'be inferred from that case-law [*Lindman*] that a Member State is deprived of the possibility of establishing that an internal restrictive measure satisfies [the requirement of proportionality], solely on the ground that that Member State is not able to produce studies serving as the basis for the adoption of the legislation at issue'.[1039] Still, in subsequent cases, the Court required from national Courts reviewing the legality of Member State measures 'to ascertain in particular whether, first, criminal and fraudulent activities linked to gambling and, second, addiction to gambling could have been a problem' at the time where the restrictive measures had been adopted.[1040] The standard of proof in gambling cases remains therefore unclear.

The situation is different in alcohol cases, where the Court readily accepts any argument based on the need to combat alcohol consumption or alcohol abuse without requiring that the risks posed to human health be substantiated by any kind of evidence. As the Court said in *Franzen*, 'the protection of human health against the harmful effects of alcohol […] is *indisputably* one of the grounds which may justify derogation from Article [36 TFEU]'.[1041] Indeed, according to Advocate General Poiares Maduro, the existence of adverse effects on human health arising from the consumption of alcohol 'has been *common knowledge* since at least as far back as the time of the Old Testament',[1042] which would explain why it does not need to be proven.

It seems therefore that once sufficiently made aware of the reality of certain risks, the Court ceases to expect the production of specific evidence when confronted to Member States' defences related to those risks. For others, the principle, recently reaffirmed in the *CBD* case, remains the following:

> Since Article 36 TFEU contains an exception, which must be narrowly interpreted, to the free movement of goods within the European Union, it is for the national authorities which invoke it to demonstrate in *each case* […] that their legislation is necessary in order effectively to protect the interests referred to in that provision, and, in particular, that the marketing of the products in question poses *a genuine threat to public health that must undergo an in-depth assessment*.[1043]

In situations where the Court *does* require Member States to substantiate their claims as to the presence of a risk, the next question that arises pertains to the nature of the evidence that should be produced. What constitutes, in the Court's own words, 'specific' or 'appropriate'[1044]

[1038] The Court's stricter stance as regards evidence in *Commission v Spain* and *Lindman* could also be explained by the discriminatory nature of the measures at stake, although the nature of the restriction should ideally not have an influence on the need for Member States to substantiate their claim.
[1039] *Stoß* (n 863), para 72. See also *Pfleger* (n 873), para 51.
[1040] Case C-347/09 *Dickinger and Ömer* [2011] EU:C:2011:582, para 66; *Berlington* (n 649), para 71. In *Pfleger* (n 873), para 53, the Court referred to a 'significant problem'.
[1041] *Franzen* (n 797), para 76, emphasis added.
[1042] Case C-434/04 *Ahokainen and Leppik* [2006] EU:C:2006:462, Opinion of Advocate General Poiares Maduro, para 20.
[1043] *CBD* (n 650), para 87.
[1044] *Scotch Whisky* (n 612), para 54.

evidence? The Court usually refers to the 'latest scientific data available' at the date of the adoption of the measure[1045] and requires that 'the results of *international* scientific research' be considered.[1046]The latter requirement can be seen as a way for the Court to prevent reliance on purely 'national' evidence, hence potentially tainted by non-scientific, protectionists interests. Throughout its case-law, the Court has 'developed an increasingly suspect position towards nationally determined versions of hazard'.[1047] The Court does not generally go as far as requiring a certain quantum of studies or a specific type of study to be performed or produced.[1048] Where a Member State produces appropriate evidence, it falls on other parties, such as the Commission, to explain why such evidence would be insufficient to ground that Member State's claim.[1049]

In some cases, most often related to foodstuffs, the Court's guidance as regards evidence takes a more procedural turn, requiring that a proper risk assessment, a 'detailed assessment of the risk alleged',[1050] be conducted. As regards food additives, the purpose of that risk assessment is 'to appraise *the degree of probability* of *harmful effects* on human health from the addition of certain nutrients to foodstuffs and *the seriousness* of those potential effects'.[1051] Here appear the basic elements of the risk assessment procedure: the identification and characterisation of the hazard linked to the addition of certain nutrients and the characterisation of the risk – not only the seriousness of the possible negative consequences but also the probability of their occurrence. [1052]

Where the risk assessment reveals that 'scientific uncertainty persists as regards the *existence* or *extent* of real risks to human health',[1053] the Court accepts reliance on the precautionary principle, meaning that Member States may 'take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated'.[1054] The risk assessment,

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[1045] *Commission v Denmark* (n 872), para 48 ; *Commission v France* (n 872), para 55 ; *Commission v Netherlands* (n 872), para 49 ; *CBD* (n 650), para 88.
[1046] *Commission v Denmark* (n 872), para 46; *Commission v France* (n 872), para 53; *Commission v Netherlands* (n 872), para 47, emphasis added. See also *Commission v Germany (Beer purity)* (n 612), para 44, *Commission v Greece* (n 872), para 38; *CBD* (n 650), para 87.
[1047] Hervey and McHale (n 37) 407.
[1048] For a rare case where the Court sets a high threshold as regards the standard of proof, see Case C-73/08 *Bressol e.a.* [2010] EU:C:2010:181. In this case, Belgium restricted the enrolment of non-resident students in university courses in the public health field, claiming that this was necessary to ensure the quality of education and to ensure that resident would be trained for ensuring medical staff on the territory. The Court required 'an objective, detailed analysis, supported by figures' to be performed, 'capable of demonstrating, with solid and consistent data, that there are genuine risks to public health', see para 71.
[1049] *Commission v France* (n 872), paras 70, 72.
[1050] *Commission v Denmark* (n 872), para 47; *Commission v France* (n 872), para 54 ; *Commission v Netherlands* (n 872), para 48.
[1051] *Commission v Denmark* (n 872), para 48; *Commission v France* (n 872), para 55; *Commission v Netherlands* (n 872), para 49, emphasis added.
[1052] See Alemanno 'The Shaping of European Risk Regulation by Community Courts' (n 495) 18-19.
[1053] *Commission v Denmark* (n 872), para 49; *Commission v France* (n 872), para 56, emphasis added. See also *Commission v Netherlands* (n 872), para 51; *CBD* (n 650), para 90
[1054] *Commission v Denmark* (n 872), para 49; *Commission v France* (n 872), para 56. See also *Commission v Netherlands* (n 872), para 52; *CBD* (n 650), para 90.

however, cannot be based on 'purely hypothetical considerations'.[1055] In such cases, precisely to avoid the precautionary principle turning into a *carte blanche* for Member States, the Court reinforces its control over the risk assessment procedure and the quality of the evidence adduced:

> A correct application of the precautionary principle presupposes, first, *identification of the potentially negative consequences* for health of the proposed use of the substance at issue and, second, a *comprehensive* assessment of the risk to health based on the *most reliable* scientific data available and the *most recent* results of international research.
>
> Where it proves to be *impossible to determine with certainty* the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but *the likelihood of real harm to public health persists* should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective.[1056]

As regards the standard of review, the Court is not nearly as clear in explaining what its role should be in controlling the evidence adduced to ensure that it conforms to the standard of proof. This may be explained by the fact that, in preliminary reference procedures, it is ultimately up to the national court to rule on substance and to determine whether the standard of proof is met. Yet, the question of the standard of review is a fundamental one as regards the relationship between courts and science, and the ability of judges to evaluate the scientific evidence produced.[1057] It is one thing to require that a certain kind of evidence be produced, but it is another to be able to deal with that evidence in a proper way. Judges are neither experts nor scientists. One would therefore expect a certain degree of deference from the Court towards national risk assessors. Although it has never been clearly expressed in this way, the Court's approach can be considered deferent, insofar as it limits itself to pointing at the absence of evidence without openly discussing the quality of a report or study, or referring, on its own motion, to alternative pieces of evidence. The Court also tries, as regard the existence of specific risks to human health, to refrain from relying too much on common knowledge or personal opinion.

Not all Advocate Generals have been so cautious and some have exposed themselves to the risk of mismanaging evidence. This can be seen in two instances. The first one is the selective use of evidence, whereby an Advocate General relies on a part of the available body of evidence, doing away with the complexity of the issue and potentially reaching wrong conclusions. On other occasions, an Advocate General takes a stance on the reality of a risk relying solely on their layperson knowledge or beliefs, without grounding it in any specific evidence.

Both can be seen in *Franzen*, where Advocate General Elmer made the following observation:

> On the other hand, *I think* that alcohol consumption can hardly be likened to alcohol abuse. New studies indicate that a certain daily consumption of wine has beneficial effects on health.

[1055] ibid.
[1056] *CBD* (n 650), paras 91-92, emphasis added. See also *Commission v Denmark* (n 872), paras 51-52.
[1057] See Barbier de la Serre and Sibony (n 1026); Bartlett and Macculloch (n 34). For more general reflections on the role of science in law, see Feldman (n 54).

> A *recent Danish study* published in, inter alia, the British Medical Journal reached the following conclusion: '*Light to moderate consumption of wine* (up to three to five glasses a day) is associated with *a significant reduction*, virtually proportionate to intake, *of the risk of dying from all causes*, unlike consumption of beer and spirits. […]' As regards beer, no consistent difference was found in relation to the relative risk of 1 for those who never drink beer; *the study does not therefore support the assumption that normal consumption of beer is injurious to health*.[1058]

Relying on a single study, Advocate General Elmer concludes that 'normal' wine consumption has beneficial effects on health and that 'normal' beer consumption is not injurious to health,[1059] taking a definitive stance on an issue which was, even then, highly debated within the scientific community. Worse, this provides him with an argument to declare the Swedish retail monopoly system disproportionate as regards these categories of drinks specifically,[1060] although he was not ultimately followed by the Court on that point. Further, when Advocate General Elmer declares that *he* thinks that alcohol consumption can hardly be likened to alcohol abuse, he also asserts his personal opinion, grounded in his own experience and knowledge of this social phenomenon, which may not reflect the reality of it. It is now clearly established, perhaps more than in 1997, that there is a continuum between alcohol consumption and alcohol abuse (see Chapter 1, Section 4.2). Kurzer observed that Elmer's opinion 'provoked obvious consternation in official Swedish circles and received extended criticism' and that he was himself 'ridiculed […] for citing medical scientific data of which he knew nothing and could claim no expertise'.[1061]

In *Josemans*, Advocate General Bot's use of evidence appears contrasted. On the one hand, he relies on a number of different studies to conclude that 'intensive and prolonged use of cannabis may have damaging physical and psychological effects'.[1062] On the other hand, in order to stress the harmfulness of cannabis, he makes statements on several occasions which, as he acknowledges himself, are based on his personal opinion rather than scientific evidence:

> Whilst, as will be explained, the policy of tolerance adopted by the Netherlands Government is based on a distinction between the consumption and the respective dangers of 'soft drugs' and 'hard drugs', *in my view* this comparison has lost all pertinence in view of the new forms of cannabis present on the market and the risks to human health entailed by their consumption.[1063]
>
> Lastly, cannabis consumption exposes users to more potent drugs. *Whilst the 'gateway' or 'escalation' theory is criticised in some quarters, the fact remains* that a person who has already experienced the hallucinogenic effects of cannabis will be more readily disposed to try drugs with stronger properties.[1064]

[1058] *Franzen*, Opinion of Advocate General Elmer (n 814), para 113, emphasis added.
[1059] See also ibid, para 118.
[1060] ibid, para 118.
[1061] Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 85.
[1062] *Josemans,* Opinion of Advocate General Bot (n 659), para 15.
[1063] ibid, para 13, emphasis added.
[1064] ibid, para 16, emphasis added.

> In addition, although the sale of hard drugs in coffee shops is prohibited, coffee shops nevertheless constitute a centre of attraction for dealers and therefore encourage, rather than prevent, the transition from 'soft drugs' to 'hard drugs'.[1065]

Although the Court usually refrains from making such 'personal' statements, it is not immune to making similar kinds of mistakes, as will appear in particular from section 3.4. There would be everything to gain, for the Court and its Advocate Generals, to engage in a more coherent and predictable manner with evidence and to rely less on intuition and personal opinion.[1066]

3. Proportionality – *risk management*

In order to benefit from the grounds of justification contained in the Treaty and those recognised by the Court in its case-law, Member States measures must comply with the principle of proportionality. According to Tridimas, proportionality fulfils three distinct but inter-related functions in the EU legal order: it serves as a market integration mechanism to determine the legality of national measures restricting free movement, it protects civil liberties and fundamental rights against undue encroachment from public authorities, EU and national alike, and, finally, as expressed in Article 5(4) TEU,[1067] it is one of the principles governing the exercise of its competence by the EU.[1068] 'Proportionality as a constitutional principle enables courts to reconcile conflicting rights and norms by considering their relative value'.[1069] Of interest here is the free movement function proportionality serves, whereby the relative value of the internal market and other competing, non-market interests, health in particular, are considered.

From a risk regulation perspective, proportionality can also be construed as a risk management tool, defined, as previously discussed, as 'the process of weighing policy alternatives in the light of the results of risk assessment and, if necessary, selecting and implementing appropriate control options, including regulatory measures'.[1070] Risk managers must determine the risk threshold acceptable for society and the necessary measures to be adopted in consideration.

[1065] ibid, para 97.

[1066] In that regard, Barbier de La Serre and Sibony point to the scarcity of EU procedural rules on evidence as compared with that of the United States. 'Pursuant to the U.S. Federal Rules of Evidence, a judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. […] The [EU] courts […] seem to enjoy a great discretion as to the amount of personal experience or knowledge they can put into their judgments in order to establish the factual background of the case. Judges do use this power and sometimes reach conclusions on the basis of their personal experience even though they concern issues of facts that could warrant additional fact-finding': De la Serre and Sibony (n 1026) 958-959.

[1067] Pursuant to Article 5(4) TEU: 'Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.'.

[1068] Takis Tridimas, 'The Principle of Proportionality' in Robert Schütze and Takis Tridimas (eds), *Oxford Principles of European Union Law - Volume 1: The European Union Legal Order* (Oxford University Press 2018) 244.

[1069] Wolf Sauter, 'Proportionality in EU Law: A Balancing Act?' (2013) 15 Cambridge Yearbook of European Legal Studies 439, 441.

[1070] Alemanno, 'The Shaping of European Risk Regulation by Community Courts' (n 495) 33.

This has been recognised by the Court, which has repeatedly held that it was the Member States' responsibility 'to *determine the level of protection which they wish to afford to public health* and the way in which that level is to be achieved' and to adopt, with a '*measure of discretion*', appropriate measures in this regard.[1071] Hence, in theory, national risk managers are granted with a substantial margin of autonomy and are free to determine how market and non-market concerns, health in particular, should be balanced. This needs to be confronted to the reality of the case-law, which does not always point in that direction.

The Court's approach to proportionality also shapes other dimensions of the national risk management process, namely the ability for Member States to integrate broader political concerns in their decision-making, going beyond risk, and, at this stage as well, the evidence requirement that must be met by national authorities to establish that their measures are proportionate to the objective pursued.

3.1. Structure and standard application of the proportionality test

Proportionality review in EU law is usually construed as a three-pronged test involving sub-tests of suitability, necessity and proportionality *stricto sensu*,[1072] or 'true' proportionality.[1073] This is essentially a doctrinal reconstruction of the Court's practice which, in the myriad of cases involving proportionality, has made different applications of this principle and has structured its reasoning in various ways, not always distinguishing between these three steps.

To comply with the requirement of proportionality, a measure must first 'be *suitable* actually to protect the interest that requires protection. There must, as it were, be a causal relationship

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[1071] *Visnapuu* (n 703), para 118. See also *Heinonen* (n 501), para 43; *Ahokainen* (n 869), paras 32-33; *Rosengren* (n 817), para 39; *Scotch Whisky* (n 612), para 35. According to Advocate General Poiares Maduro, 'national authorities enjoy discretion as regards decisions taken in the light of a scientific assessment of risk': Case C-41/02 *Commission v Netherlands* [2004] EU:C:2004:520, Opinion of Advocate General Poiares Maduro, para 32.

[1072] See Jan H Jans, 'Proportionality Revisited' (2000) 23 Legal Issues of Economic Integration 238, 240–241; Takis Tridimas, 'Proportionality in Community Law: Searching for the Appropriate Standard of Scrutiny' in Evelyn Ellis (ed), *The Principle of Proportionality in the Laws of Europe* (Hart Publishing 1999) 68. For judicial support see *Ahokainen*, Opinion of Advocate General Poiares Maduro (n 1042), paras 23-26; Case 159/90 *Grogan* [1991] EU:C:1991:249, Opinion of Advocate General Van Gerven, para 35. See contra, defending a four-pronged test : Sauter (n 1069) 448. For other alternative approaches, see Ségolène Barbou Des Places, 'Le contrôle de proportionnalité des mesures nationales restrictives des Échanges. La Marge d'appréciation du juge national varie-t-elle selon la qualification de la mesure ?' in Eleftheria Neframi (ed), *Renvoi préjudiciel et marge d'appréciation du juge national* (Larcier 2015) 186-187.

[1073] Jukka Snell, 'True Proportionality and Free Movement of Goods and Services' (2000) 11 European Business Law Review 50.

between the measure and its object.'[1074] Second, the measure must not go beyond what is necessary to meet the objective that it purports to achieve. This means that no other measure which is equally capable of attaining that objective but is less restrictive of, in our case, free movement should exist. It is the criterion of the 'least restrictive alternative'.[1075] Finally, proportionality 'stricto sensu' refers to the genuine balancing act contained in proportionality, ensuring that the restriction or burden caused by the measure is not disproportionate to the benefits awaited from it. This exercise, the 'true' act of reconciling conflicting interests by considering their relative value, is more sensitive and difficult to perform than the two first tests, in the sense that it requires the Court to weigh the respective importance of different political objectives. This is probably why, as will be shown below, the proportionality test for national measures restricting free movement is almost always limited to its two first indents. Routinely then, in free movement cases, a national measure will be deemed proportionate if it is '*appropriate* for securing the achievement of the objective pursued and does not go beyond what is *necessary* in order to attain it'.[1076]

Proportionality assessment in free movement cases varies widely between judgements. It is very difficult, if not impossible, to offer a reliable description of the way in which this principle is applied. It is possible, at most, to discern general patterns and to make general observations. This also holds true in the field of lifestyles, where long, structured and detailed analyses of proportionality cohabit with judgments where proportionality is done away with in a couple of sentences. A good example of the latter is the *Franzen* judgment, where the Court struck down the Swedish rule in a single paragraph:

> Although the protection of human health against the harmful effects of alcohol, on which the Swedish Government relies, is indisputably one of the grounds which may justify derogation from Article 30 of the Treaty, the Swedish Government has not established that the licensing system set up by the Law on Alcohol, in particular as regards the conditions relating to storage capacity and the high fees and charges which licence-holders are required to pay, was proportionate to the public health aim pursued or that this aim could not have been attained by measures less restrictive of intra-Community trade.[1077]

Sometimes, as in *Gourmet*, the Court even declines to assess the proportionality of the measure, leaving that analysis entirely to the referring national court.[1078]

3.1.1. Suitability

To comply with the requirements of proportionality, a national measure must first be suitable, meaning that a sufficient link must be established between the effect of the measure and the objective pursued. The idea of suitability, or appropriateness, is not devoid of any ambiguity in that regard.[1079] Is it only required that a measure appears, prima facie, able to meet the objective or should it be somehow proven that the measure's effect is indeed the one that is

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[1074] Jans (n 1072) 240.
[1075] ibid.
[1076] *Scotch Whisky* (n 612), para 33. See also, *Josemans* (n 650), para 69; *ANETT* (n 675), para 45.
[1077] *Franzen* (n 797), para 76.
[1078] *Gourmet* (n 879), para 33.
[1079] See Jans (n 1072) 243.

claimed by the Member State? The Court usually understands suitability loosely: Member States must show a sufficient degree of connection between the measure and the objective put forward. This appears for instance in *Scotch Whisky*, where the Court held, regarding the appropriateness of the Scottish MUP, 'that […] *it does not seem unreasonable* to consider that a measure that sets a minimum selling price of alcoholic drinks, the very specific aim of which is to increase the price of cheap alcoholic drinks, is *capable* of reducing the consumption of alcohol'.[1080] In *Heinonen* and *Ahokainen*, the Court declared that Member States 'enjoy a margin of discretion in determining […] the measures which are *likely to achieve concrete results*'.[1081] This approach appears particularly justified in the field of lifestyles, where 'scrutinising the appropriateness of a national restrictive measure in attaining its declared objective presents […] inherent difficulties […] such as the multifactorial nature of the phenomena regulated (e.g. physiological, socio-economic and other factors driving harmful consumption of alcohol)' and 'the difficulty in pinpointing the exact contribution of each individual policy intervention to the policy objective'.[1082]

That being said, the Court, where justified, does not hesitate to strike down measures that appear totally unrelated to their alleged aim. This was the case in *Cassis de Dijon*, where Germany claimed that the fixing of a minimum alcohol content for spirits was necessary to avoid the proliferation on its national market of beverages with a low alcohol content, which, allegedly, more easily induced a tolerance towards alcohol than beverages with a higher alcohol content.[1083] Without explicitly mentioning suitability, the Court expressed its doubts as to how preventing drinks with a lower alcohol content to penetrate the market could ever be a helpful measure to fight alcohol abuse.[1084] In *ANETT*, Spain failed to explain, regarding its rule requiring tobacco retailers to obtain their supply from authorised wholesalers, 'in what respect offering [the retailers] the possibility of importing tobacco products themselves would constitute an obstacle to the application of fiscal, customs, and health control measures to those products'.[1085]

The application of the suitability part of the proportionality test has not given rise to particular difficulties, in free movement generally and for lifestyle measures too. Determining whether a measure is connected to its proclaimed aim and capable of attaining it is in most cases a straightforward exercise and the Court is usually satisfied with a reasonable degree of connection. Some measures have generally been recognised by the Court as appropriate means to protect public health, meaning that, when confronted to such measures, the Court will not

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[1080] *Scotch Whisky* (n 612) 36, emphasis added.
[1081] *Heinonen* (n 501), para 43; *Ahokainen* (n 869), para 32, emphasis added.
[1082] Alberto Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (2016) 53 Common Market Law Review 1037, 1053. See also Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 157-158.
[1083] *Cassis de Dijon* (n 612), para 10.
[1084] ibid, para 11.
[1085] *ANETT* (n 675), para 51.

perform an in-depth suitability analysis. This is the case for rules restricting the advertising of alcoholic beverages[1086] or for taxes on tobacco and alcohol, the latter constituting for the Court 'an important and effective tool' to discourage the consumption of alcoholic drinks and tobacco products.[1087]

An exception to this rather hands-off approach can be seen in *Rosengren*, where the Court applied an unusually 'high level of scrutiny'[1088] to the Swedish measure prohibiting the direct import of alcohol by private individuals and reserving this right to the State monopoly *Systembolaget*. Sweden argued that this rule fulfilled two objectives of limiting the consumption of alcohol in the general population and, more specifically, of preventing access to alcoholic beverages for underage persons.

Regarding the first objective, the Court observed that the rule in place simply required individuals to place an order with *Systembolaget*, something which the Swedish monopoly had never refused to execute.[1089] The Court accepted the fact that 'the prohibition on private individuals directly importing alcoholic beverages reduces the sources available to the consumer and *may contribute, to a certain extent, because of the difficulty of supply*, to prevention of the harmful effects of those beverages'.[1090] It considered however that this measure had, at best, a marginal effect on the reduction of alcohol consumption and was therefore unsuitable to achieving the objective of limiting the general consumption of alcohol in the country.[1091] The Court's conclusion here is not devoid of criticisms, for there is a clear difference between ordering a product directly from one's home and having to visit a specific shop to do so. The Court itself seemed to acknowledge this when declaring, for the purpose of establishing the restrictive effect of the measure, that 'when consumers use the services of Systembolaget to have alcoholic beverages imported, those concerned are confronted with a *variety of inconveniences with which they would not be faced were they to import the beverages themselves'*.[1092] Making access to the product more difficult is the very logic underlying various measures on tobacco or alcohol control. This type of interventions, which add excessive friction to people's choices, is recognised in the behavioural literature as an effective tool to impede decision-making.[1093] There was clearly a reasonable degree of connection here between the measure and its purported goal, which unfortunately left the Court unimpressed.

[1086] *Commission v France* (n 881), para 17; *Aragonesa* (n 884), para 15; *Gourmet (*n 879), para 27; *Bacardi France* (n 896), para 37-38.
[1087] With regards to alcohol taxation, see *Scotch Whisky* (n 612), para 44. With regards to tobacco taxation, see *Valeško* (n 679), para 58; Case C-197/08 *Commission v France* [2010] EU:C:2010:111, para 52.
[1088] Tridimas, 'The Principle of Proportionality' (n 1068) 247.
[1089] *Rosengren* (n 817), paras 45-46.
[1090] ibid, para 45.
[1091] ibid, para 47.
[1092] ibid, para 34, emphasis added.
[1093] Sina Shahab and Leonhard K. Lades, 'Sludge and transaction costs' (2021) Behavioural Public Policy, FirstView <https://www.cambridge.org/core/journals/behavioural-public-policy/article/sludge-and-transaction-costs/D09206BF9B36C129F40A27A9E749074B> accessed 11/05/2023.

Regarding the second objective, the Court recognised 'that, by limiting […] the sale of imported alcoholic beverages to the Systembolaget shops, the national legislation seeks to make distribution of such beverages subject to *a centralised and coherent operation* which must allow the monopoly's agents […] to *satisfy themselves in a consistent manner that the goods are provided only to persons of more than 20 years of age'*.[1094] Yet, after observing that age checks were carried out by third parties when alcoholic beverages were supplied outside the monopoly's shops and that the performance of such checks could not clearly be established and verifiable in all circumstances, the Court considered that the system failed to attain an '*irreproachable level of effectiveness'* and that the objective pursued was therefore 'met only in part'.[1095] Here again, the degree of scrutiny applied stands in stark contrast with the likeliness and reasonableness expected by the Court in other cases.[1096] An explanation for the stricter approach taken in *Rosengren* may lie in the particularly restrictive effect of the Swedish measure at stake on the free movement of goods, an import ban on individuals, which the Court categorised as a quantitative restriction to imports.

As part of its suitability control,[1097] the Court increasingly verifies the consistent and systematic character of national measures. [1098] According to the standard formula, 'a restrictive measure can be considered to be an *appropriate* means of securing the achievement of the objective pursued only if it *genuinely* reflects a concern to secure the attainment of that objective in a *consistent* and *systematic* manner',[1099] which supposes to 'carry out a global assessment of the circumstances in which the restrictive legislation at issue was adopted and implemented'.[1100]

It is still not entirely clear from the case-law what the requirements for consistency and systematicity precisely entail and how these two elements relate to one another. With Mathisen, the test can be understood in the following way: the requirement for consistency implies that 'nothing is allowed to counteract the attainment of a public interest objective (purportedly) pursued by a given measure' while systematicity, which Mathisen prefers to rename coherence, is 'the fact that a measure makes sense, fits, is intelligible – as a means to attain its (purported) public interest objective'.[1101] This means, first, that there should be no contradiction that affects the achievement of the purported goal of the measure and, second, that the measure should be

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[1094] ibid, para 52, emphasis added.
[1095] ibid, paras 53-54, emphasis added.
[1096] See in particular, in a comparable fact situation, the higher degree of deference showed by the Court in *Visnapuu* (n 703), paras 121-122.
[1097] The idea of coherence and systematicity can also be linked to the other parts of the proportionality test, or even to the very existence of a legitimate objective: see in this regard Gjermund Mathisen, 'Consistency and Coherence as Conditions for Justification of Member State Measures Restricting Free Movement' (2010) 47 Common Market Law Review 1021.
[1098] In the field of health specifically, see Estelle Brosset, 'L'Union européenne de la santé - L'Union détermine-t-elle le niveau de protection de la santé ? – Introduction' (2017) 2017 Revue des Affaires Européennes 595, 596.
[1099] *Scotch Whisky* (n 612), para 37; *CBD* (n 650), para 84, emphasis added. See also Case C-500/06 *Corporación Dermoestética* [2008] EU:C:2008:421, para 39; Case C-169/07 *Hartlauer*, [2009] EU:C:2009:141, para 55; *Liga Portuguesa* (n 643), para 61; *Berlington* (n 649), para 64.
[1100] *Berlington* (n 649), para 73.
[1101] Mathisen (n 1097) 1023- 1024.

fit for purpose. While it is difficult to establish a clear dividing line between the two terms – the Court anyway applies the test as a whole without actually controlling for consistency and systematicity separately[1102] – it appears that systematicity, what Mathisen refers to as 'coherence', is inherently linked to the idea of appropriateness.[1103] It is only the requirement for consistency which brings something additional to the proportionality test.

The consistency requirement, which has now pervaded various areas of free movement, is usually said to originate from the gambling case-law.[1104] Though it was indeed first formalised in *Gambelli*, where the Court declared that 'restrictions […] must also be suitable for achieving those objectives [at stake], inasmuch as they must serve to limit betting activities in a consistent and systematic manner',[1105] this requirement arguably dates back from earlier case-law outside the field of gambling. In *Cassis de Dijon*, the Court also objected to Germany's plea – that its rule was necessary to prevent liqueurs with a too low alcohol content from penetrating its market – by pointing to the fact that other types of alcoholic beverages with a similarly low alcoholic content were already available on the German market.[1106] In *Commission v France (Milk substitutes),* the Court rebutted the French rule prohibiting the import and sale of milk substitutes, grounded on the lower nutritional value of these products, by observing that products composed substantially of the same fats that those used in milk substitutes were actually authorised on the French market.[1107] In *Debus*, finally, the Court opposed the Italian rule banning sulphur dioxide in beer since Italy authorised 'the use of much higher proportions of sulphur dioxide in other beverages, notably wine, the consumption of which seems to be much higher in the Member State concerned than that of beer'.[1108]

What these examples show is that the Court will not tolerate cases of plain inconsistency or outright duplicity, where Member States' general behaviour indicates that the restrictive measure has not been put in place to pursue a legitimate objective but rather for other, often protectionist, motives.[1109] This appears in particular from the gambling case-law, as will be further explored below (see 3.2).

Inconsistency can be assessed from an internal point of view – the measure whose justification is attempted displays inconsistency – or an external one – other measures or actions taken by the Member State threaten the consistency and hence the achievement of the stated

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[1102] See Jurian Langer and Wolf Sauter, 'The consistency requirement in EU law' (2017) 24 Columbia Journal of European Law 39, 41.
[1103] As recognised by Mathisen himself, see Mathisen (n 1097) 1037.
[1104] Mathisen (n 1097) 1027–1208; Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1054.
[1105] *Gambelli* (n 640) para 67.
[1106] *Cassis de Dijon* (n 612), para 11.
[1107] *Commission v France (Milk substitutes)* (n 911), para 15.
[1108] *Debus* (n 919) para 25. See also *Commission v Germany (Beer purity)* (n 612) para 49; *Commission v Greece* (n 872), para 42.
[1109] In such cases, Member States only actually fail if the alleged objective is not met. If Member States adopt a measure to pursue another objective than the alleged one but actually manage to fulfil the latter, the measure should be upheld. See Mathisen (n 1097) 1035-1036.

objective.[1110] In gambling cases, on the one hand, Member States are for instance externally inconsistent insofar as, alongside their restrictive policies towards foreign gambling operators, they advertise for the domestic legal offer and hence incite consumers to participate in gambling activities.[1111] The *CBD* case, on the other hand, provides a good illustration of an internally inconsistent rule. The French measure prohibited the marketing of products derived from parts of the cannabis plant other than its fibre and seeds, hence prohibiting the marketing of cannabidiol extracted from the plant. The Court observed that the rule did not affect the marketing of synthetic CBD, even though both varieties of CBD had the same properties and could be substituted.[1112] This made the rule inconsistent and uncapable of attaining the goal of protecting consumers against the, alleged but ultimately unproven, harmfulness of the product. The rule adopted was in itself defective: it was underinclusive and could therefore not meet its stated objective.

In *CBD*, there was no reason to believe that France had any other intention than protecting health when adopting this measure. The measure was simply too poorly designed to attain its objective. From this point of view, the requirement for consistency appears therefore to be a good addition to the Court's proportionality toolbox, insofar as it requires Member States to ensure that their measures are adequately designed to attain their purported objective. The consistency requirement should not however come to sanction Member States conducting a policy which, while perfectly appropriate to achieve its stated goal, would simply not go far enough towards attaining that goal. The case-law on lifestyles illustrates this point particularly well.

In *Scotch Whisky*, to reach the conclusion that the Scottish measure pursued the objective of public health protection in a consistent and systematic manner, the Court relied on the fact that the MUP was part of a package of forty other measures aiming at reducing alcohol consumption.[1113] The Court may have made that point only to highlight that nothing in the case at hand suggested inconsistency, but one may wonder what would have been said had the MUP been the only measure adopted for the purpose of reducing alcohol consumption? Would that have rendered the measure inconsistent and hence inappropriate? Such logic would constitute undue interference, neglecting the necessary pitfalls and limitations of the political process and leading to the disapplication of useful, albeit insufficient, public health measures.[1114] This would not only go against the very idea of suitability, but deny Member States responsibility for setting their desired level of public health protection. In case a measure is unable to achieve

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[1110] Mathisen (n 1097) 1039
[1111] See *Ladbrokes* (n 861), *Stoß* (n 863).
[1112] *CBD* (n 650), para 94.
[1113] *Scotch Whisky* (n 612), para 38.
[1114] Alemanno makes the opposite conclusion that 'this additional requirement is expected to favour measures, such as a lifestyle risk measures', since a measure is more likely to be found appropriate in the framework of a package of measure than if assessed on its own. See Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1054. The measure is however ultimately assessed on its own.

the desired policy goal on its own, it is sufficient to declare it unsuitable, without the need to check for consistency.

The Court echoed this very clearly in *Bacardi France*, where it dealt with the French rule prohibiting indirect television advertising for alcoholic beverages, in particular that resulting from the appearance on screen of hoardings visible during the retransmission of sporting events taking place in other Member States. Bacardi claimed that this rule was inconsistent insofar as it did not cover 'advertising for alcoholic beverages visible in the background on film sets'. The Court rejected the argument, considering that the 'option [lied] within the discretion of the Member States to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved'.[1115]

In *Rosengren*, the Commission argued that the Swedish rule prohibiting personal imports of alcoholic beverages was disproportionate because of various inconsistencies in the Swedish public health policy. The Commission pointed in particular to the fact that 'persons over the age of 20 may also, unless obviously intoxicated, purchase liquor in unlimited quantities from the monopoly'.[1116] To this, Advocate General Tizzano answered the following:

> For my part, I readily concede that some of the decisions made by the Swedish legislature may indeed appear questionable. In particular, there is no doubt that allowing persons over the age of 20 to purchase unlimited quantities of alcohol, even if only in Systembolaget's shops and sales outlets, may diminish the impact of the State's action to protect public health.
>
> It does seem to me, however, that *those decisions to some extent fall within the freedom of Member States 'to decide on the degree of protection which they wish to afford* to public health and on the way in which that protection is to be achieved', and are therefore, in that respect, among the options available to Member States for attaining that objective.[1117]

The Commission also mentioned another alleged inconsistency, the fact that 'unlike liquor, tobacco products [were] not subject to any prohibition in Sweden as to their importation and distribution',[1118] a point ultimately not discussed by the Court or the Advocate General. A similar argument was made in *Commission v France*, where the Commission claimed that the French measure, the alcohol advertising rule also discussed in *Bacardi France*, was inconsistent since it did not apply to tobacco advertising. The point was in this case openly rebuffed by the Court.[1119]

The rejection by the Court of that line of argumentation is to be commanded, for it would turn the consistency requirement and the control of proportionality into a sort of 'inappropriate demand of perfection'.[1120] This would deprive Member States of their prerogatives regarding the level of public health protection chosen and neglect the political difficulties inherent to the establishment of a coherent lifestyle risks policy. Moreover, such an approach would be conceptually problematic insofar as it assumes that tobacco and alcohol call for the same level

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[1115] *Bacardi France* (n 896), para 40.
[1116] *Rosengren*, Opinion of Advocate General Tizzano(n 800), para 73.
[1117] ibid, paras 75-76, emphasis added.
[1118] ibid, paras 73.
[1119] *Commission v France* (n 896), para 33.
[1120] De Witte (n 611) 1573.

of intervention. Consistency must remain a tool used to uncover dishonest manoeuvres from Member States or sanction ill-conceived rules, not one that discourages Member States to adopt useful, if insufficient, measures.

3.1.2. Necessity

A rule that is suitable to achieve the objective put forward by a Member State will only be deemed proportionate if it does not go beyond what is necessary for the achievement of that objective and is therefore not unduly restrictive of free movement. This part of the proportionality test is essentially a comparative exercise:[1121] Member States must ensure that the objective cannot 'be achieved with *at least an equivalent level of effectiveness* by less restrictive methods'.[1122] '[T]he question of necessity is thus intrinsically linked to the question of the permissible standard of protection'.[1123] In public health matters especially, where it is for Member States to decide of this standard, the application of the necessity part of the proportionality test should therefore not result in a lowering of the level of protection sought. This appears clearly from the *Commission v France (Loi Evin)* judgment, where the Court, regarding the French rule prohibiting television advertising for alcoholic beverages, considered that:

> [A]lthough there are less restrictive measures to ensure the protection of public health, […] there is not currently any measure which is less restrictive which can exclude or conceal indirect television advertising for alcoholic beverages resulting from hoardings visible during the retransmission of sporting events.[1124]

Less restrictive rules existed that would also protect public health but would not grant the same level of protection that France had decided to achieve, by eliminating all direct and indirect advertising for alcoholic beverages on television. A corollary of that principle – Member States retaining responsibility as to the level of protection – is, as appears further in the same judgment, that 'the fact that one Member State imposes less strict rules than another Member State does not mean that the latter rules are disproportionate'.[1125]

When considering the Member States' margin of appreciation recognised by the Court in public health matters, coupled with the difficult nature of the necessity analysis in a field such as lifestyle risks – 'notably in the light of the multi-sectoral and multi-level approaches characterizing this policy action', which requires 'not only the identification of other policy alternatives but also the identification of their individual contribution to the declared goal' –

[1121] Miguel Poiares Maduro famously argued that this application of the proportionality test resulted in 'majoritarian activism', an approach under which the Member State's rule under scrutiny is compared to rules in place in other Member States and would be discarded if it happened that a majority of other States had made a different regulatory choice, see Poiares Maduro (n 665) 72–78. For a refutation of this view, see Robert Schütze, 'Judicial Majoritarianism Revisited: "We, the Other Court"?' (2018) 43 European Law Review 269.
[1122] *Visnapuu* (n 703), para 119, emphasis added.
[1123] Schütze, *From International to Federal Market* (n 665) 219.
[1124] *Commission v France* (n 696), para 34.
[1125] ibid, para 37.

[1126] one could expect the Court to adopt a prudent approach, as for suitability, respectful of Member State's prerogatives. This has been the case in a number of judgments.[1127]

The *Josemans* judgment, rendered in a particularly sensitive area for health and public policy, provides a good illustration of this. Regarding the necessity of the Dutch measure, which barred access to non-residents to the coffee- shops of the city of Maastricht, the Court identified several alternative measures, less restrictive of free movement, but accepted the reply by the Dutch authorities and the city of Maastricht that those measures had 'proved to be insufficient and ineffective in the light of the objective pursued.'[1128] Further, as regards the possibility of granting non-residents access to coffee-shops whilst reserving the purchase of cannabis to residents only, the Court observed that such a solution would create enforcement problems, as it would not be 'easy to control and monitor with accuracy that that product is not served to or consumed by non-residents'.[1129] It added that Member States could not 'be denied the possibility of pursuing the objective of combating drug tourism and the accompanying public nuisance by *the introduction of general rules which are easily managed and supervised by the national authorities*',[1130] even if, in this case, another rule that would be less restrictive of non-residents' free movement rights was clearly available.

Advertising restrictions are an example of measures whose necessity to achieve a high level of public health protection has generally been recognised by the Court. In *Aragonesa*, the Court upheld the Spanish partial ban on alcohol advertising, relying on two specific features of the measure. First, it applied only to beverages having an alcoholic strength of more than 23 degrees.[1131] Second, it did not prohibit 'all advertising of such beverages but merely prohibit[ed] it in specified places some of which, such as public highways and cinemas, are particularly frequented by motorists and young persons, two categories of the population in regard to which the campaign against alcoholism is of quite special importance'.[1132] In *Bacardi France* and *Commission v France (Loi Evin)*, the French ban on television advertising for alcoholic beverages was also found necessary to the objective pursued.[1133] In these cases, the Court dealt with partial bans which did not completely restrict alcohol advertising. In *Gourmet*, the ban was total, save for 'insignificant exceptions'.[1134] Advocate General Jacobs conducted a very detailed analysis of the proportionality of the measure, ultimately doubting that it was wholly necessary.[1135] He considered in particular that the ban, insofar as it applied to magazines

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[1126] Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1055.
[1127] In the field of lifestyle risks, for alcohol in particular, see *Aragonesa* (n 884); *Gourmet* (n 879); *Heinonen* (n 501); *Commission v France* (n 696); *Bacardi France* (n 696).
[1128] *Josemans* (n 650), para 80.
[1129] ibid, para 81.
[1130] ibid, para 82, emphasis added.
[1131] *Aragonesa* (n 884), para 17.
[1132] ibid, para 18.
[1133] *Commission v France* (n 696), paras 34-37; *Bacardi France* (n 696), para 38.
[1134] *Gourmet* (n 879), para 20.
[1135] Case C-405/98 *Gourmet*, Opinion of Advocate General Jacobs [2000] EU:C:2000:690, paras 48-63. Advocate General Jacobs seems to hold the view that adults who are allowed to purchase drinks should be recognised the

devoted to food and drink, affected readers which deliberately purchased publications where they could expect to find content on alcohol and whose purchases of alcoholic beverages would therefore not be influenced by advertising for those beverages.[1136] The Court however declined to give guidance on proportionality, considering that it required an analysis of the circumstances of law and of fact specific to the Member State concerned, which the national court was in a better position to carry out.[1137]

In some cases, however, the Court, while not formally denying Member States their responsibility for setting the appropriate level of protection, applies necessity in such a way that actually translates into a lowering of this level. This can be seen, again, in *Rosengren*. Regarding the second objective pursued by the Swedish measure prohibiting individual import of alcoholic beverages – the protection of youth against the harmful effects of alcohol – the Court, after having expressed doubts as to the suitability of the measure, investigated its necessity:

> In that regard, the Commission of the European Communities submits, without being contradicted on that point, that *age check could be carried out by way of a declaration* in which the purchaser of the imported beverages certifies, on a form accompanying the goods when they are imported, that he is more than 20 years of age. The information before the Court *does not, on its own, permit the view to be taken that such a method*, which attracts appropriate criminal penalties in the event of non-compliance, *would necessarily be less effective than that implemented by Systembolaget*.[1138]

Strikingly, the Court fails to see that a system whereby age checks are carried out centrally by the public monopoly's professional staff is more effective to ensure compliance with Sweden's age limit than a simple declaration made by purchasers when importing a beverage,[1139] and declares the measure to be disproportionate.[1140]

Throughout its case-law, the Court has repeatedly and mistakenly opposed two kinds of measures on grounds of their lack of necessity and their disproportionate effect on the free movement of goods: minimum price measures for tobacco products and alcoholic beverages and composition requirement for foodstuffs.

In a series of cases involving the EU legal framework on excise duties for tobacco products (see Chapter 5, Section 4.1), Member States had enacted rules imposing a minimum retail selling price for cigarettes.[1141] An increase in excise duty, they argued, was less effective than

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capacity to make their own choices: 'although it must be remembered that anyone over 20 appears to be deemed, by the Swedish legislature, to possess sufficient maturity to be able to reach a decision as to whether to consume alcohol and to what extent', para 52.

[1136] ibid, para 59-60.

[1137] *Gourmet* (n 879), para 33.

[1138] *Rosengren* (n 817), para 56, emphasis added.

[1139] See *Rosengren*, Opinion of Advocate General Tizzano (n 800), paras 81-82.

[1140] *Rosengren* (n 817), para 57.

[1141] Case C-216/98 *Commission v Greece* [2000] EU:C:2000:571 ; *Commission v France* (n 731); *Commission v France* (n 1087); Case C-198/08 *Commission v Austria* [2010] EU:C:2010:112 ; Case C-221/08 *Commission v Ireland* [2010] EU:C:2010:113; Case C-571/08 *Commission v Italy* [2010] EU:C:2010:367.

a minimum price to ensure a raise in the final price paid by consumers, since manufacturers and importers could decide, by reducing their profit margin, to absorb the increase so as not to pass it on to consumers.[1142] The Court disagreed and discarded the minimum price measures, considering that the 'ability of manufacturers and importers not to pass on increases in excise duty on their products is in any event limited by the extent of their profit margin, with the result that *excise duty increases are sooner or later incorporated in retail selling prices*.'[1143] It added that:

> [I]f the Member States wish to exclude once and for all any possibility for producers or importers to absorb, even temporarily, the impact of taxes on the retail selling price of manufactured tobacco products by selling them at a loss, it is inter alia open to them, while allowing those producers and importers to make effective use of the competitive advantage resulting from any lower cost prices, to prohibit the sale of manufactured tobacco products at a price below the sum of the cost price and all taxes.[1144]

In *Scotch Whisky*, the Court followed a similar reasoning regarding the Scottish MUP for alcoholic beverages. Relying on the aforementioned cases on tobacco excise duties, the Court reiterated that 'the objective of ensuring that the prices of [alcoholic] drinks are set at high levels can adequately be pursued by their increased taxation, since increases in excise duties must sooner or later be reflected in increased retail selling prices, without impinging on the free formation of prices'.[1145] An increase in taxation, the Court continued, 'is liable to be less restrictive of trade' than an MPU since the latter measure 'significantly restricts the freedom of economic operators to determine their retail selling prices' and therefore constitutes 'a serious obstacle' to market access and to the operation of fair competition.[1146]

As appears from the *Scotch Whisky* judgment, the Court's reticence to accept the proportionality of national minimum price measures can be explained by the importance given to price competition in EU law, as a central feature of a well-functioning market economy.[1147] 'In contemporary European economies the direct regulation of prices is not normally seen as being the role of the State.'[1148] Notwithstanding the restrictive nature of price measures for free movement, the Court's reasoning in these various cases appears misguided on multiple accounts.

The idea that an increase in excise duties will sooner or later be passed on to consumers neglects the fact that tobacco companies can use a variety of techniques to continue supplying cheap

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[1142] *Commission v Greece* (n 1141), para 29; *Commission v Austria* (n 1141), para 37; *Commission v Ireland* (n 1141), para 49.
[1143] *Commission v Greece* (n 1141), para 32, emphasis added. See also *Commission v France* (n 1087), para 52; *Commission v Austria* (n 1141), para 42; *Commission v Ireland* (n 1141), para 54 ; *Commission v Italy* (n 1141), para 51.
[1144] *Commission v France* (n 1087), para 53; *Commission v Austria* (n 1141), para 43, *Commission v Ireland* (n 1141), para 55; *Commission v Italy* (n 1141), para 52.
[1145] *Scotch Whisky* (n 612), para 44.
[1146] ibid, para 46.
[1147] MacCulloch (n 672).
[1148] ibid 190.

products on the market, over-shifting for instance the increase on more expensive premium brands, for which demand is less elastic.[1149] Similarly, an increase in excise duties for alcoholic beverages does not prevent supermarkets from continuing to offer discounts on cheaper products or the industry to absorb the increase and to cross-subsidise products.[1150] Only minimum price measures can ensure that the cheapest products, those who are most consumed, are swiftly driven out of the market. This is especially good for low-income consumers, the category of the population that is most price sensitive, and for hazardous drinkers who consume in particular cheaper products. The Member States made an argument along those lines in the tobacco excise duties cases, referring to a 'price competition which has led to a greater supply of cheap cigarettes and […] is not desirable in terms of health policy'.[1151]

The Court's reasoning in *Scotch Whisky* contains further problematic elements.[1152] In particular, the Court was told that the solution found in the tobacco excise duties cases would not necessarily hold true for alcoholic beverage, to which it replied that '[i]n the context of national measures which have as their objective the protection of human life and health, and *irrespective of the particular characteristics of each product*, an increase in the prices of alcoholic drinks can be achieved, as was the case with respect to tobacco products, by increased taxation'.[1153] This is a regrettable mistake, for they are large differences between the markets in tobacco products and alcoholic beverages, which actually render the adoption of a minimum price measure even more pertinent for the latter.[1154] The market for tobacco products is far more homogenous than that for alcoholic beverages. Cigarettes, the category by far the most

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[1149] See Ian McLaughlin and others, 'Reducing Tobacco Use and Access Through Strengthened Minimum Price Laws' (2014) 104 American Journal of Public Health 1844; Ross Whitehead and others, 'Rapid Evidence Review: Strengths and Limitations of Tobacco Taxation and Pricing Strategies' 28; Timea R Partos and others, 'Impact of Tobacco Tax Increases and Industry Pricing on Smoking Behaviours and Inequalities: A Mixed-Methods Study' (2020) 8 Public Health Research.

[1150] See Peter Rice and Colin Drummond, 'The Price of a Drink: The Potential of Alcohol Minimum Unit Pricing as a Public Health Measure in the UK' (2012) 201 The British Journal of Psychiatry 169; Ian Gilmore, 'A Minimum Unit Price: The "Holy Grail" of Alcohol Policy' (2015) 15 Clinical Medicine 5. See also Luca A Panzone, 'Alcohol Tax, Price–Quality Proxy and Discounting: A Reason Why Alcohol Taxes May Rebound' (2012) 63 Journal of Agricultural Economics 715.

[1151] Cases C-197/08 *Commission v France*, C-198/08 *Commission v Austria* and C-221/08 *Commission v Ireland* [2009] EU:C:2009:646, Joined Opinion of Advocate General Kokott, para 54.

[1152] The *Scotch Whisky* case also raises the question of the way devolution is treated in internal market law. Member States as a whole are held responsible for the measures adopted by their regional or local entities and the measures adopted by the latter are assessed *as if* they had been adopted by the Member State as a whole. Yet, in *Scotch Whisky*, the Scottish government who had enacted the MUP did not have the power to regulate excise duties. Hence, the proportionality test was conducted *in abstracto* and the measure favoured by the Court, an increase in excise duties, was in any way unavailable to the Scottish government. See Niamh Dunne, 'Minimum Alcohol Pricing: Balancing the "Essentially Incomparable" in Scotch Whisky' (2018) 81 The Modern Law Review 890, 901; Eleanor Spaventa, 'Drinking Away Our Sorrows?: Regulatory Conundrums after Scotch Whisky' in Amtenbrink and others (eds), *The Internal Market and the Future of European Integration* (n 665) 198–199.

[1153] *Scotch Whisky* (n 612), para 45, emphasis added.

[1154] See Oliver Bartlett, 'Minimum Unit Pricing for Alcohol May Not Be a Proportionate Public Health Intervention' (2016) 7 European Journal of Risk Regulation 218, 220; Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1057; Bartlett and Macculloch (n 34) 113–114.

widely consumed, present very similar level of harm and a fairly limited price-range. Alcoholic beverages, on the contrary, display significant variations in strength, prices and organoleptic properties. This means that price measures which target specific categories of cheap products may be even more warranted for alcoholic beverages than for tobacco products.

Finally, the Court considers that an increase in taxation would not only be equally capable of attaining the objectives sought by the MUP – 'reducing, in a targeted way, […] the consumption of alcohol by consumers whose consumption is hazardous or harmful' and reducing 'generally, the population's consumption of alcohol' – [1155] but would actually procure 'additional benefits as compared with the imposition of an [MUP]',[1156] as it would equally impact both categories of the population.[1157] That, however, was a clear misunderstanding of the objective of the Scottish authorities, which was to target drinkers whose consumption of alcohol is moderate '*only secondarily*'.[1158] The Court fails here to appreciate the granularity of the Scottish rule and its focus on a specific, particularly at risk sub-group. The approach taken thus threatens the adoption of measures that are particularly suited to a 'just transition'.

A second type of measures which the Court has routinely opposed are those related to the composition of foodstuffs. The Court has repeatedly considered that composition requirements were not necessary to protect consumers' legitimate expectations as to the content of products, and that appropriate labelling was sufficient to inform consumers in this regard.[1159] For the Court, labelling 'enable[s] the consumer to make his choice in full knowledge of the facts'.[1160] In most of these cases, Member States measures sought to protect the use of certain product denominations, such as pasta, beer or vinegar, on grounds of consumer protection, but did not clearly involve any public health aspect, such as limiting the intake of certain nutrients or substances.[1161] In some cases however, the measures were prompted by nutrition-based considerations. This can be seen in *Van der Veldt*, where the Court ruled, regarding the Belgian rule limiting salt in bread and bakery products, that:

[1155] *Scotch Whisky* (n 612), para 34.
[1156] ibid, para 48.
[1157] ibid, para 47.
[1158] ibid, para 34. This point seems overlooked by a number of authors who have claimed that the outcome of the case could have been different had the Scottish authorities insisted on a single objective, that of targeting hazardous drinkers. See Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1052; Bartlett and Macculloch (n 34) 125–126. Yet, this would most likely not have changed the Court's appraisal since it anyway considers taxation to be as efficient as minimum pricing to raise the price of all alcoholic beverages.
[1159] Case 193/80 *Commission v Italy (Vinegar)* [1981] EU:C:1981:298, para 27; *Commission v Germany (Beer purity)* (n 612), para 35; *Zoni* (n 927), para 16. The same reasoning is applied in cases involving packaging requirements, see Case 261/81 *Rau v De Smedt* [1982] EU:C:1982:382, para 17; Case 16/83 *Criminal proceedings against Karl Prantl* [1984] EU:C:1984:101, para 29; Case 179/85 *Commission v Germany (Sparkling wine)* [1986] EU:C:1986:466, para 12.
[1160] *Commission v Italy* (n 1159), para 27; *Commission v Germany (Beer purity)* (n 612), para 35.
[1161] Some authors have argued that the Court's position had led to a lowering of the quality of the food available on the European market, see Brouwer (n 924); Caoimhín MacMaoláin, 'Reforming European Community Food Law: Putting Quality Back on the Agenda' (2003) 58 Food and Drug Law Journal 549. Quality is used in that context to refer to the organoleptic properties of foods rather than its nutritional aspect.

> [I]nstead of prohibiting and penalizing the marketing of bread and other bakery products whose salt content is higher than 2%, *the Belgian legislature could have prescribed suitable labelling* to give consumers the desired information regarding the composition of the product. *The protection of public health would thus have been ensured* without such serious restrictions on the free movement of goods.[1162]

In *Commission v France (Milk substitutes),* the Court held a similar reasoning regarding the French prohibition of milk substitutes, considering that 'appropriate labelling informing consumers about the nature, the ingredients and the characteristics of the milk substitutes on offer would enable persons liable to be adversely affected by vegetable fats or other constituents of the milk substitutes to decide for themselves as to whether to use them'.[1163]

The Court's trust in the capacity of consumers to process the information given on products' labelling and packaging derives from a vision of 'an average consumer who is reasonably well-informed and reasonably observant and circumspect'[1164] and who reads labels when their purchasing decisions depend on the composition of the products in question.[1165] This has led to the development of an 'information paradigm',[1166] whereby the provision of information is seen as an ideal regulatory solution which allows consumers' interests to be protected while imposing little burden on economic operators.

The problem with this approach is twofold. First, as already exposed at greater length in Chapter 1, the Court's vision of the average consumer is at odds with behavioural reality.[1167] Most consumers, especially in a retail environment, lack the time and interest to properly check the information given on labels. Where they do so, they do not necessarily possess the appropriate knowledge to process that information and make a fully informed decision. Taking the *Van de Veldt* case as an example, it seems highly improbable that all consumers would carefully read the labels indicating the amount of salt present in bread and that, upon realising that the salt content is higher than 2%, would refrain from buying the product. Yet, that is

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[1162] *Van der Veldt* (n 928), para 19.

[1163] *Commission v France (Milk substitutes)* (n 911), para 16. See also the similar line of argumentation held by the Commission in *Commission v Italy* (n 930), para 18: 'Finally, a mere obligation for the producer of the drinks in question to provide the consumer with accurate information as to their caffeine content is an effective way to protect persons at risk.'

[1164] Case C-210/96 *Gut Springenheide* [1998] EU:C:1998:369, para 31; Case C-220/98 *Estée Lauder* [2000] EU:C:2000:8, para 27.

[1165] Case C-51/94 *Commission v Germany* [1995] EU:C:1995:352, para 34 ; Case C-465/98 *Darbo* [2000] EU:C:2000:184, para 22.

[1166] Sibony and Helleringer (n 470) 214; Helleringer and Sibony (n 470) 623–624. As rightly point out by Helleringer and Sibony, the case *GB-INNO-BM* offers one of the clearest illustration of this approach. In this case the Court seems indeed to rule out the mere possibility that limiting information could ever be beneficial to consumers: see *GB-INNO-BM* (n 883), para 18. See also para 15.

[1167] In the EU context, see e.g Rossella Incardona and Cristina Poncibò, 'The Average Consumer, the Unfair Commercial Practices Directive, and the Cognitive Revolution' (2007) 30 Journal of Consumer Policy 21; Sibony and Helleringer (n 470) 214–215. See contra Stephen Weatherill, 'Who is the 'Average Consumer''in Stephen Weatherill and Ulf Bernitz (eds), *The Regulation of Unfair Commercial Practices under EC Directive 2005/29 : New Rules and New Techniques* (Hart Publishing 2007) 123–133. It must be also noted that the Court's case-law has matured on this specific point, see for instance the discussion of Case C-195/14 *Teekanne* [2015] EU:C:2015:361 in Chapter 6, Section 3.2.1.1.

precisely what labelling should achieve to be considered as efficient as a mandatory salt limit. The Court's approach therefore results in a lowering of the degree of protection afforded to public health, a choice supposedly remaining firmly in the hands of the Member States.

The second problem lies with the existence of the average consumer in itself as an 'autonomous European standard'[1168] against which Member State measures are analysed. Regardless of the characteristics given to this average consumer, its very existence denies Member States the possibility to set their own level of protection. There will always be Member States who adopt a more protective version of the average consumer and whose measures risk then to appear disproportionate if compared to the European benchmark.

It is true that the Court has recognised the existence of specific categories of 'vulnerable consumers', whose vulnerability may warrant the adoption of more protective and hence more restrictive measures, which would not be deemed necessary if judged from the perspective of the average consumer. This was the case in *Buet*, for instance, a case dealing with a rule banning canvassing at home for the sale of educational materials. There, the Court considered that potential purchasers of these materials belonged 'to a category of people who, for one reason or another, are behind with their education and are seeking to catch up', which made them 'particularly vulnerable when faced with salesmen of educational material who attempt to persuade them that if they use that material they will have better employment prospects'.[1169] The Court therefore upheld the ban.

The case-law on lifestyle risks does not openly refer to any category of vulnerable consumers, but a similar reasoning emerges from certain cases. A good illustration is *Aragonesa*, where the Court observed that the measure at issue did not prohibit all alcohol advertising but brought restrictions to specific places, 'some of which, such as public highways and cinemas, are particularly frequented by *motorists and young persons, two categories of the population in regard to which the campaign against alcoholism is of quite special importance*'.[1170] It followed that the measure could 'in any event [not] be criticized for being disproportionate to its stated objective'.[1171] The absence of a more systematic approach regarding vulnerability in health and lifestyles may be regretted. It might explain the unsatisfactory outcomes of the kind reached in *Rosengren* and Scotch *Whisky*.

It has been argued that the Court's stance on labelling as an equally suitable objective was mostly confined to cases that did not involve any risk to health, like the product denomination cases, and that it was open to stronger regulatory action in cases that did involve such risks.[1172] That may be true, but, as the *Van der Veldt* and *Commission v France (Milk substitutes)* judgments show, the Court appeared equally sanguine to prioritise labelling over composition requirements or bans in cases involving health risks. Similarly, in *Cassis de Dijon*, a case

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[1168] Schütze, *From International to Federal Market* (n 665) 222.
[1169] Case 382/87 *Buet* [1989] EU:C:1989:198, para 13.
[1170] *Aragonesa* (n 884), para 18, emphasis added.
[1171] ibid.
[1172] Snell (n 1073) 54. See in that regard *Sandoz* (n 871); Case 53/80 *Kaasfabriek Eyssen* [1981] EU:C:1981:35.

involving alcoholic beverages, the Court followed its usual approach and ruled that 'it is a simple matter to ensure that suitable information is conveyed to the purchaser by requiring the display of an indication of origin and of the alcohol content on the packaging of products'.[1173]

3.1.3. Proportionality stricto sensu

As long as the control of proportionality is limited to suitability and necessity, Member States can freely set the level of health protection they wish to attain, regardless of how much the measures adopted for this purpose restrict free movement. A measure can only be deemed disproportionate if it does not adequately fulfil the objective advanced by the Member State or if less burdensome alternatives exist allowing to attain that objective in an equally satisfactory manner. So the theory goes, for we have seen that the way in which suitability and necessity, especially, are applied results sometimes in a lowering of the level of protection chosen.

In that sense, as rightly observed by Gareth Davies, '[w]herever a state loses on proportionality grounds, which happens in many (perhaps most) free movement cases, the Court acknowledges the importance of the national interest and may well concede that it would take precedence if there was no way to reconcile it with free movement, but the Court concludes, instead, that the policy goes beyond what is necessary to achieve its purpose. *Hence free movement and the national policy can be reconciled by adopting national measures of a different form*.'[1174]

The control of proportionality would be of a fundamentally different nature if a genuine balancing act was performed to arbitrate between Member State interests and the preservation of the EU internal market. Such an exercise would mean that a national measure perfectly fit for the achievement of the objective pursued could be discarded because of the magnitude of its restrictive effect on free movement.[1175] In the words of Advocate General Poiares Maduro, under the third limb of the proportionality test:

> [T]he Member State must demonstrate that *the level of protection it decides to afford to its legitimate interests is commensurate with the degree of interference this causes in intra-[Union] trade*. The difference with the second test is that, as a result of the third test, a *Member State may be required to adopt a measure that is less restrictive of intra-[Union] trade, even if this would lead to a lower level of protection of its legitimate interests*.[1176]

Applying 'true' proportionality is always a delicate exercise, whichever Court performs it, for it entails a greater scrutiny of the legislator's choices and the performance of some sort of cost-benefit analysis of the measure at stake. This becomes even more sensitive where a European Court is called to judge the balance struck by a national legislator. It should hence come as no surprise that there has been very little application of this part of the proportionality test in free

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[1173] *Cassis de Dijon* (n 612), para 13.
[1174] Gareth Davies, 'Internal Market Adjudication and the Quality of Life in Europe' (2015) 21 Columbia Journal of European Law 289, 317, emphasis added. See also Gareth Davies, 'Free Movement, the Quality of Life and the Myth that the Court Balances Interests' in Koutrakos, Nic Shuibhne and Syrpis (n 648).
[1175] For a discussion on the opportunity to apply the 3rd part of the proportionality test in free movement cases, see Snell (n 1073).
[1176] *Ahokainen*, Opinion of Advocate General Poiares Maduro (n 1042), para 26, emphasis added.

movement cases, save for some specific situations.[1177] In *Schmidberger*, for instance, where the national measure restricting the free movement of goods was presented as necessary to respect the freedom of assembly and the freedom of expression, the Court considered that 'the interests involved must be weighed having regard to all the circumstances of the case in order to *determine whether a fair balance* was struck between [them]'.[1178] This type of formulation is rarely found in internal market judgments and the Court has wholly refrained from openly conducting this balancing act in the field of lifestyle risks. It is only for the control of measures emanating from the EU that 'true' proportionality has found its way in the Court's review of proportionality, as will be addressed in Chapter 7.

Scotch Whisky provides a very good illustration of the difficulties that would arise were the Court to start applying pure proportionality to national measures. In his opinion, Advocate General Bot defended the application of proportionality's third limb to national measures restricting free movement, a test 'which assumes *a balancing of the advantages and disadvantages* of that measure while ascertaining, in particular, whether *the extent of the restriction* on trade within the European Union *is proportionate to the importance of the objectives* pursued and the expected gains.'[1179] His analysis of the measure at stake would ultimately not reach this last part of the proportionality test, for he concluded, as the Court, that the Scottish MUP went beyond what was necessary to achieve its purported objective. The Court however, as it does in most free movement cases, only referred to suitability and necessity. Without formally rejecting Advocate General Bot's approach, it made no mention of proportionality *stricto sensu*.

The express and vocal rejection of the application of proportionality's third limb to the measure at issue, and to any public health measure for that matter, came from the Supreme Court of the United Kingdom, the last court to intervene in the legal proceedings pertaining to the Scottish MUP. It is worth quoting it lengthily, for it perfectly exposes the reasons to oppose the application of pure proportionality in this context. According to Lord Mance:

> It is clear that the Court of Justice refrained deliberately from endorsing the Advocate General's analysis of a three-stage approach. While that is so, and whether or wherever it fits into the legal analysis, it is nonetheless appropriate to address the basic point, that an appreciation of the likely EU market impact seems on the face of it a sensible precondition to action interfering with EU cross-border trade and competition. *Put rhetorically, can it be that, provided an objective is reasonable and can only be achieved in one way, it is irrelevant how much damage results to the ordinary operation of the EU market*?
>
> The first response that can be made to this rhetorical question is that *the proposed comparison is, in the present case, between two essentially incomparable values.* One is the value of health, in terms of mortality and hospitalisation, coupled moreover with the evident desirability of reducing socioeconomic inequalities in their incidence. The other is the market and economic impact on producers, wholesalers and retailers of alcoholic drinks across the European Union. A second observation is that this comparison is yet further complicated by the fact that *it is not*

[1177] An exception is to be found in cases involving fundamental rights. See *Schmidberger* (n 629); *Laval* (n 631), para 105; *Viking* (n 630). A 'hidden' pure proportionality test can also be seen in some cases, see Snell (n 1073).
[1178] *Schmidberger* (n 629) para 81. See also for a reference to a 'balance' of interests *Laval* (n 631) para 105; *Viking* (n 630) para 79.
[1179] *Scotch Whisky*, Opinion of Advocate General Bot (n 675), para 76, emphasis added. See also ibid, para 93.

> *for any court to second-guess the value which a domestic legislator may decide to put on health*. […] *Would or should a court intervene because it formed the view that the number of deaths or hospitalisations which the member state sought to avoid did not "merit" or was not "proportionate to" the degree of EU market interference which would be involved? I very much doubt it.* Any individual life or well-being is invaluable, and I strongly suspect that this is why the Court of Justice did not endorse the Advocate General's third stage enquiry, and treated the issue very lightly indeed.[1180]

An exception to the absence of the third stage enquiry in the field of lifestyle risks can be seen in two cases dealing with national measures contravening EU rules on the taxation of tobacco products. In *Commission v Portugal*, Portugal had adopted a rule prohibiting the marketing and sales of packets of cigarettes after March of the year following that in which they were released for consumption (for greater details on the applicable legal framework, see Chapter 5, Section 4.1).[1181] The aim of the measure was to remove incentives for economic operators to release excessive quantities of tobacco products in anticipation of a future increase of excise duty. It thus pursued a public health objective. After analysing the suitability and necessity of the measure, the Court sought to ascertain 'whether the contested measure adversely affect[ed] the interests of the economic operators in a disproportionate manner'.[1182] Reviewing the costs borne by economic operators arising from the measure, the Court considered that the Commission had failed to establish that those costs were disproportionate to the objectives pursued.[1183]

In *Valeško*,[1184] Austria used the power granted by Directive 69/169/CEE to lower the threshold regarding the quantities of tobacco that could be exempted from the payment of VAT and excise duty when purchased in third countries and brought back to be consumed on the EU territory.[1185] The Court acknowledged the existence of 'a certain tension […] between that power and the general aim of Directive 69/169, which […] is to liberalise the system of taxes on imports in travel in order to facilitate such travel.'[1186] Thus, it added, '[i]n making use of that power, the Member States are therefore required to limit as far as possible the negative effects which the measures adopted could have on the realisation of the general aim of [the Directive] and thus to strike a *reasonable balance* between that aim and [the aim pursued by the Austrian measure]'.[1187] The Court found that such balance had been properly struck in that

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[1180] *Scotch Whisky Association and others (Appellants) v The Lord Advocate and another (Respondents) (Scotland)* [2017] UKSC 76, paras 47-48.
[1181] Case C-126/15 *Commission v Portugal* [2017] EU:C:2017:504.
[1182] ibid, para 81.
[1183] ibid, paras 87-88.
[1184] *Valeško* (n 679).
[1185] Council Directive 69/169/EEC of 28 May 1969 on the harmonisation of provisions laid down by Law, Regulation or Administrative Action relating to exemption from turnover tax and excise duty on imports in international travel [1969] JO L133/6.
[1186] *Valeško* (n 679), para 55.
[1187] ibid, para 56, emphasis added.

case,[1188] although the test applied was couched in terms of necessity rather than pure proportionality.

According to Advocate General Poiares Maduro, it is only in areas where EU law identifies a common level of protection of the legitimate interest under consideration that the Court applies a three-stage proportionality test to national measures.[1189] This would explain why it is not applied in the field of public health, where Member States remain, nominally, responsible for setting the level of protection to be achieved. Although this position cannot be defended as a general rule, the example put forward by Poiares Maduro appears particularly interesting:

> [I]n a series of cases concerning consumer protection, the Court, in effect, found an infringement of the principle of proportionality stricto sensu. Notably in its ruling in *Estée Lauder*, the Court held that Member States, when they adopt measures affecting intra-Community trade for the purpose of consumer protection, should adjust the level of protection to "the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect".[1190]

The cases that Advocate General Poiares Maduro refers to were, as previously discussed, decided and ultimately lost by Member States at the stage of necessity and were devoid of any language suggesting the application of the third limb of proportionality. Yet, it is true that, by mobilising the concept of the average consumer, the Court de facto harmonises the level of protection that can lawfully be pursued, leading to the disapplication of national measures that are considered to cause too much of an impediment to free movement.[1191] Something similar can be said of cases involving price measures, where the Court, under the cover of a – mistaken – necessity test, actually considers that price measures are too restrictive of free movement if considering the additional benefits brought compared to tax measures. This is not what the Court openly says, but this is what it amounts to in practice.

As Gareth Davies says, the Court's rhetoric of reconciliation is not ultimately convincing, as 'no-one really believes that different is always equal, and it is widely argued that the Court has reduced levels of protection of the consumer, sometimes the environment, sometimes of the employee, and of diffuse social interests'.[1192] The Court refrains from frontally pitting the requirement of free movement against the legitimate interests put forward by Member States, health in particular, and hence avoids openly addressing the kind of awkward questions such as those suggested by Lord Mance. Yet, it cannot be denied that its forceful defence of the interests of importers or consumers engaged in intra-Union trade has in some cases resulted in the disapplication of legitimate measures, on grounds precisely of their disproportionate effect on free movement.

[1188] ibid, paras 57-65.
[1189] *Ahokainen*, Opinion of Advocate General Poiares Maduro (n 1042), para 26.
[1190] ibid.
[1191] Snell (n 1073) 53.
[1192] Davies, 'Internal Market Adjudication and the Quality of Life in Europe' (n 1174) 320.

3.1.4. Second sentence of Article 36 TFEU

Pursuant to the second sentence of Article 36 TFEU, quantitative restrictions and measures having equivalent effect must not, in order to benefit from the express derogation grounds contained in this provision, 'constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'. This, according to the Court, 'is designed to prevent restrictions on trade mentioned in the first sentence of that article from being diverted from their proper purpose and used in such a way as either to create discrimination in respect of goods originating in other member states or indirectly to protect certain national products'.[1193]

Two examples in the field of lifestyles, both dealing with restrictions on alcohol advertising, illustrate what constitutes and does not constitute an arbitrary discrimination and a disguised restriction on trade. In *Commission v France (Alcohol advertising)*, France had adopted a discriminatory rule, whereby national natural sweet wines enjoyed unrestricted advertising while imported natural sweet wines and liqueur wines were subjected to a system of restricted advertising. France argued that this difference in treatment was based on the distinction between drinks habitually consumed for 'aperitif' purposes and drinks consumed for 'digestive' purposes, the former being more of danger to public health than the latter 'owing to the fact that they are taken on an empty stomach.'[1194] The Court accepted that the measure could, in principle, be justified on grounds of public health, but considered in this case that it constituted an arbitrary discrimination 'to the extent to which it authorizes advertising in respect of certain national products whilst advertising in respect of products having comparable characteristics but originating in other Member States is restricted or entirely prohibited'.[1195] It added that 'legislation restricting advertising in respect of alcoholic drinks complies with the requirements of Article 36 only if it applies in identical manner to all the drinks concerned whatever their origin'.[1196]

In *Aragonesa*, however, the Court rejected an argument based on a breach of the last sentence of Article 36 TFEU. The measure at stake prohibited the advertising of beverages having an alcoholic strength of more than 23 degrees in the media and various public places. The plaintiff in the main action argued that this constituted a disguised restriction on trade since most of alcoholic beverages originating from Catalonia, the region where the rule had been adopted, had a volume of alcohol lower than the 23 degrees limit and could hence still resort to advertising.[1197] The Court objected. Since the rule was indistinctly applicable to all products regardless of their origin, the fact that Catalonia produced more beverages having an alcoholic strength of less than 23 degrees than beverages with a higher alcohol content was 'not in itself sufficient to cause such legislation to be regarded as liable to give rise to arbitrary

[1193] *Henn et Darby* (n 910), para 21. See also *Aragonesa* (n 884), para 20.
[1194] *Commission* v *France* (n 881), para 15.
[1195] ibid, para 18.
[1196] ibid.
[1197] *Aragonesa* (n 884), para 22.

discrimination or a disguised restriction on intra-Community trade'.[1198] The Court considered that a well-founded public health argument had been made and that potential protectionist effects were a mere unforeseen side effect.

These two cases show that the analysis under the last sentence of Article 36 TFEU, rather than being based on a specific aspect of a given measure, very much depends on whether a disguised protectionist motive can be identified. Yet, it is certain that distinctly applicable rules are more likely to constitute disguised restrictions that indistinctly applicable ones. What this second indent really adds to Article 36 TFEU is unclear, as an undue discrimination and a disguised restriction on trade would in any way not be justified by a legitimate objective or not comply with the principle of proportionality.[1199] This is corroborated by the ruling in *Harpegnies*, where the Court expressly derived the principle of proportionality from the last sentence of Article 36.[1200] This link is also made by Advocate General Poiares Maduro, who considers that a measure which does not satisfy the overall proportionality review constitutes a disguised restriction on trade between Member States or a means of arbitrary discrimination.[1201]

3.1.5. Fundamental rights

As for all areas of EU law, respect for fundamental rights must be observed in free movement law, an obligation which applies both to Member States and the Court of Justice. Fundamental rights may affect the ability of Member States to defend their lifestyle risks measures, in particular through the application of the proportionality principle.

Where Member States seek to derogate from the prohibitions contained in the free movement provisions, their measures must not only pursue a legitimate objective and be proportionate to the realisation of that objective, but also respect the fundamental rights that are part of the EU legal order.[1202] This was first expressed in the *ERT* judgment, where the Court held that:

> [W]here a Member State relies on the combined provisions of Articles [52 and 62 TFEU] in order to justify rules which are likely to obstruct the exercise of the freedom to provide services, such justification, provided for by Community law, must be interpreted in the light of the general principles of law and in particular of fundamental rights. Thus the national rules in question can fall

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[1198] ibid, para 25. See also *Visnapuu* where the retail sale licencing scheme was only open to manufacturers established in Finland, thus excluding manufacturers established in other Member States. The Court acknowledged that the provision could have the effect of protecting the national production of fermented alcoholic beverages but considered that 'the existence of such an effect [did] not however suffice to establish that the health and public policy grounds on which the Finnish authorities [relied had] been diverted from their purpose and used in such a way as to discriminate against goods originating in other Member States or indirectly to protect certain national products': *Visnapuu* (n 703), para 126.

[1199] For an arbitrary discrimination and disguised restriction on trade analysed under the prism of proportionality, see Case 42/82 *Commission v France* (*Franco-Italian Wine war)* [1983] EU:C:1983:88, paras 54-63.

[1200] Case C-400/96 *Harpegnies* [1998] EU:C:1998:414, para 34. See also Craig, *EU Administrative Law* (n 130) 670.

[1201] *Ahokainen* (n 869), paras 27-28.

[1202] For further developments on this, see Koen Lenaerts and José A Gutiérrez-Fons, 'The EU Internal Market and the EU Charter: Exploring the "Derogation Situation"' in Fabian Amtenbrink and others (eds), *The Internal Market and the Future of Europea n Integration* (n 665).

> under the exceptions provided for by the combined provisions of Articles [52 and 62] only if they are compatible with the fundamental rights the observance of which is ensured by the Court.[1203]

The fundamental rights recognised by the Court of Justice as part of the general principles of law originally comprised the constitutional traditions common to the Member States[1204] and the international treaties for the protection of human rights,[1205] in particular the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR),[1206] to which the Charter of Fundamental Rights of the European Union would be later added ('the Charter' or CFR). The Court confirmed in *Pfleger* that the *ERT* ruling also applied to the Charter of Fundamental Rights of the European Union, whose scope of application covers Member State measures derogating free movement.[1207] These measures are considered as implementing Union law within the meaning of Article 51(1) of the Charter. The following developments focus on the Charter, whose content is largely inspired by the ECHR. Rights under the Charter corresponding to rights guaranteed by the ECHR must be given the same meaning and scope.[1208]

A number of rights and freedoms contained in the Charter may be adversely affected by national measures restricting free movement. Any lawful limitation of these rights and freedoms 'must be provided for by law and respect the essence of those rights and freedoms' and comply with the principle of proportionality, meaning that 'they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others'.[1209] Rights and freedoms of an economic nature are those who are most obviously affected by national rules restricting free movement. Those include the freedom to choose an occupation and right to engage in work,[1210] the freedom to conduct a business[1211] and the right to property.[1212] Unsurprisingly, the Court has ruled that a national

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[1203] Case C-260/89 *ERT/DEP* [1991] EU:C:1991:254, para 43. The Court here only mentioned Treaty-based justifications, later case-law clarified that this applied to both Treaty-based and case-law-based justifications. See *Familiapress* (n 634) and Lenaerts and Gutiérrez-Fons (n 1202) 53–54.
[1204] Case 11/70 *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel* [1970] EU:C:1970:114.
[1205] Case 4/73 *Nold KG v Commission* [1974] EU:C:1974:51.
[1206] Case 36/75 *Rutili v Ministre de l'intérieur* [1975] EU:C:1975:137.
[1207] *Pfleger* (n 873), para 36.
[1208] Article 52(3) CFR. This article further provides that: 'This provision shall not prevent Union law providing more extensive protection.'
[1209] Article 52(1) CFR.
[1210] Pursuant to Article 15 CFR: '1. Everyone has the right to engage in work and to pursue a freely chosen or accepted occupation. 2. Every citizen of the Union has the freedom to seek employment, to work, to exercise the right of establishment and to provide services in any Member State. 3. Nationals of third countries who are authorised to work in the territories of the Member States are entitled to working conditions equivalent to those of citizens of the Union.'
[1211] Pursuant to Article 16 CFR: 'The freedom to conduct a business in accordance with Union law and national laws and practices is recognised.'
[1212] Pursuant to Article 17 CFR: '1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest. 2. Intellectual property shall be protected.'

measure that cannot be justified or appears disproportionate under free movement law also constitutes an unlawful limitation of the rights guaranteed by Articles 15 to 17 of the Charter.[1213]

A most interesting question is whether the Charter, and fundamental rights in general, offer greater protection to economic operators than that provided by free movement provisions alone. In other words, could a measure considered as lawful under free movement provisions still fall foul of the Charter's provisions? The case has never materialised. It seems yet fair and logical to conclude, with Advocate General Sharpston, that 'Articles 15 to 17 of the Charter impose no greater obligations to be satisfied for a restriction on the freedom to provide services to be permitted than is already established by the case-law of the Court in relation to Article 56 TFEU',[1214] a solution that can also be extended to other free movement provisions. Hence, the Charter does not appear to grant an additional protection to economic operators whose free movement rights are restricted by national authorities.[1215] This is altogether not surprising since free movement provisions are considered to be 'fundamental freedoms' by the Court of Justice.[1216]

The limited additional protection offered by fundamental rights also appears regarding advertising restrictions and their effect on the freedom of expression, a freedom guaranteed by Article 11 CFR[1217] and Article 10 ECHR.[1218] In *Karner*, the Court held that where the exercise of the freedom of expression '*does not contribute to a discussion of public interest* and, in addition, arises in a context in which the Member States have a certain amount of discretion, review is limited to an examination of the reasonableness and proportionality of the interference. This *holds true for the commercial use of freedom of expression*, particularly in a field as complex and fluctuating as advertising'.[1219] This is undoubtedly the case in relation to lifestyle risks, where advertising certainly does not contribute to a discussion of public interest and where Member States benefit from a measure of discretion.

In *Landespolizeidirektion Steiermark and Others*, the Court discussed the compatibility of the Austrian provisions imposing penalties for infringement of a monopoly in the sector of games of chance with Article 49(3) of the Charter on the proportionality of criminal offences and

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[1213] Regarding the freedom to provide services, see *Pfleger* (n 873), para 59; *Berlington* (n 649), para 90.
[1214] Case C-390/12 *Pfleger* [2013] EU:C:2013:747, Opinion of Advocate General Sharpston, para 70. This can also be inferred from the joint application of the Charter and free movement provisions in Case C-201/15 *AGET Iraklis* [2016] EU:C:2016:972.
[1215] For Lenaerts and Gutierrez-Fons, references to the EU Charter in the free movement case-law strengthens the rule of law and reinforces the legitimacy 'of the EU as a whole': Lenaerts and Gutiérrez-Fons (n 1202) 64.
[1216] *ADBHU* (n 625), para 9.
[1217] Pursuant to Article 11CFR: 'Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. 2. The freedom and pluralism of the media shall be respected.'
[1218] Pursuant to Article 10(1) ECHR: 'Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.'
[1219] *Karner* (n 671), para 51, emphasis added.

penalties. Pursuant to this article, '[t]he severity of penalties must not be disproportionate to the criminal offence'. Compliance with this provision requires that 'the severity of the penalties imposed […] be commensurate with the seriousness of the infringements for which they are imposed, in particular by ensuring a genuinely deterrent effect, while not going beyond what is necessary to attain that objective'.[1220] The Court analysed various aspect of the penalty system and left the final word regarding its overall proportionality to the national court.[1221] It nonetheless considered that the imposition under the Austrian provisions of a minimum fine per unauthorised gaming machine was not in itself disproportionate 'given the seriousness of the infringements at issue, since *the illegal supply of gaming machines* […] is capable […] of *having particularly serious harmful effects on society*'.[1222] It added, regarding the imposition of a contribution to the costs of proceedings amounting to 10% of the fines imposed, that it was for the referring court to verify that this aspect of the penalty system did not infringe the right of access to a tribunal enshrined in Article 47 of the Charter.[1223] What this judgment shows is that, while not providing an autonomous source of rights in the context of free movement, the Charter does give texture to free movement provisions, in the sense that it may inform the interpretation made by the Court of these provisions.

If now adopting a different perspective, not that of the traders whose free movement rights are restricted by national lifestyle measures, but that of the individuals whose freedom to engage in a risky activity or consume a hazardous product is restricted, a question arises as to whether the Charter provides protection that cannot be afforded under free movement provisions. After all, a ban on a given product does not only limit the possibility for foreign manufacturers to export them in the Member State where the ban is enacted, it is also a restriction on people's freedom to access this product. This has never been argued in relation to lifestyle risks and, to the knowledge of the author, not in any other free movement case either.

The only freedom that could offer a potential avenue to individuals to oppose the State's limitation on their freedom seems to be the respect for private and family life enshrined at Article 7 CFR[1224] and Article 8 ECHR. The 'right to liberty' contained at Article 6 CFR only 'guarantees the physical liberty of the person and is thus a right against unlawful or arbitrary imprisonment'[1225] and does not represent a general right not to have one's freedom curtailed by the State. Article 8 ECHR, whose scope determines that of Article 7 CFR, is particularly large[1226] and can be construed as imposing to public authorities to 'abstain from any unjustified

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[1220] *Landespolizeidirektion Steiermark and Others* (n 963), para 45, emphasis added.
[1221] ibid, paras 46-58.
[1222] ibid, para 46, emphasis added.
[1223] ibid, para 57.
[1224] Pursuant to Article 7 CFR: 'Everyone has the right to respect for his or her private and family life, home and communications.'
[1225] Tobias Lock 'Article 6 CFR – Right to liberty and security' in Kellerbauer, Klamert and Tomkin (n 524) 2111. See also Christine Guillain and David Ribant, 'Article 6. Droit à la liberté et à la sûreté', in Picod, Rizcallah and Van Drooghenbroeck (n 532) 147-184.
[1226] Maris Burbergs, 'How the Right to Respect for Private and Family Life, Home and Correspondence Became the Nursery in Which New Rights Are Born: Article 8 ECHR' in Eva Brems and Janneke Gerards (eds), *Shaping*

interference in people's private sphere of autonomy'[1227] or a 'right to be left alone'.[1228] As such then, it could be potentially be relied on to oppose a paternalistic lifestyle measure.[1229] Whether this right could be used to effectively challenge a Member State measure is an open question, although one must not forget that it would need to be put into balance with Article 35 CFR on the right to health, which provides a solid justification for any measure addressing the harmful consequences of lifestyles.[1230]

This last point shows that fundamental rights may not only be relied on to oppose lifestyle risks measures but also to defend them. In some cases, the Court explicitly relies on Article 168(1) TFEU and Article 35 of the Charter, according to which a high level of protection for human health is to be ensured in the definition and implementation of all policies and activities of the Union, to stress the importance of the objective of protecting public health.[1231] The reference to Article 35 of the Charter, some have argued, has led to greater consideration given to public health as a justification for limitations on free movement.[1232] Such a conclusion appears however difficult to draw. First, reference to Article 35 CFR is not made systematically and does not appear in the latest judgements involving public health matters.[1233] Second, nothing in the cases where such a reference has been made suggests a relaxation of the control of proportionality.[1234]

3.2. Specificities of gambling

Gambling is an economic activity to which free movement provisions apply. Member State measures constitute restrictions that may be justified if pursuing a legitimate public interest and proportionate. However, unlike rules on other lifestyle risk factors, national rules on gambling are subject to a far lighter standard of scrutiny. The proportionality test, in particular, is applied in such a way as to leave a significant margin of discretion to Member States in the organisation of gambling activities on their territory. From the significant number of judgments handed down by the Court of Justice in this field over the years, the Court has only on rare occasions

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Rights in the ECHR: The Role of the European Court of Human Rights in Determining the Scope of Human Rights (Cambridge University Press 2014).

[1227] Translated from Nicolas Cariat, 'Article 7. Respect de la vie privée et familiale', in Picod, Rizcallah and Van Drooghenbroeck (n 532): 's'abstenir de toute ingérence injustifiée dans la sphère d'intimité et d'autonomie des personnes'. See also Tobias Lock 'Article 7 CFR - Respect for private and family life' in Kellerbauer, Klamert and Tomkin (n 524) 2115-2117.

[1228] Burbergs (n 1226) 324.

[1229] Anne van Aaken, 'Constitutional Limits to Regulation-by-Nudging' in Straßheim and Beck (n 353) 310.

[1230] On Article 35 CFR generally, see Brosset, 'Article 35. Protection de la santé' (n 532) 885–904.

[1231] *Blanco Pérez* (n 966), para 65. See also *Venturini* (n 966), para 41.

[1232] Alasdair Young (n 507) 103.

[1233] *Venturini* seems to be the last judgement in the field of free movement where a reference to Article 35 CFR is made.

[1234] See *Blanco Pérez* (n 966) ; *Venturini* (n 966) ; Case C-84/11, *Susisalo* [2012] EU:C:2012:374. For a similar appraisal concerning the use of the Charter and other fundamental rights instruments in free movement cases in general, see Marc Fallon, 'La proportionnalité des entraves aux libertés économiques de circulation sous le prisme de la Charte, valeur ajoutée ou décorative ?' in Paschalis Paschalidis and Jonathan Wildemeersch (eds), *L'Europe au présent !: Liber amicorum Melchior Wathelet* (Bruylant 2018).

declared a national rule to be unlawful pursuant to Article 49 or 56 TFEU.[1235] Access to the various national gambling markets remains difficult for foreign service providers, which puts into question the very existence of an internal market for cross-border gambling activities.[1236]

This specific treatment, unique with regards to the application of internal market provisions, is grounded in what the Court considers to be the special nature of gambling: an activity giving rise to a number of risks for individuals and society, to which particular moral and cultural considerations apply. This is clearly laid down by Advocate General Bot in *Liga Portuguesa*:

> First, in all the Member States, *moral, religious or cultural considerations* tend to restrict, or even prohibit, such games to prevent them from being a source of private profit. Secondly, games of chance and gambling involve *a high risk of crime or fraud*, given the size of the potential winnings. In addition, they are an encouragement to spend which may have *damaging individual and social consequences*. Finally, [...] it is not without relevance that lotteries may make a significant contribution to the financing of benevolent or public interest activities such as social works, charitable works, sport or culture.[1237]

The Court not only recognises the diversity of Member States' 'scale of values'[1238] regarding gambling but has also adopted its own stance, denying it the status of a fully legitimate economic activity. The Court considers the morality of lotteries to be 'at least questionable'[1239] and gambling in general to have 'morally […] harmful consequences'.[1240] It has recognised in particular 'the idea of the moral superiority of allocating gambling proceeds to good causes compared to mere private profit'.[1241] This appears most clearly from the *Sjöberg and Gerdin* judgment, where the Court accepted that 'it might be considered unacceptable to allow private profit to be drawn from the exploitation of a *social evil* or the weakness of players and their misfortune'.[1242] This position stand in stark contrast with the absence of similar concerns regarding other types of trade in harmful commodities, such as tobacco and alcohol, for which allowing private profit to be made out of consumers' misfortune might appear equally unacceptable or, to the very least, objectionable.[1243]

[1235] For such occasions, see *Placanica* (n 644); *Commission v Spain* (n 785); *Lindman* (n 786); *Engelmann* (n 1004); *Stoß* (n 863).
[1236] See Dimitrios Doukas, 'In a bet there is a fool and a state monopoly: are the odds stacked against cross-border gambling?' (2011) 36 European Law Review 243, 262.
[1237] Case C-42/07 *Liga Portuguesa* [2008] EU:C:2008:560, Opinion of Advocate General Bot, para 62, emphasis added. See also *Schindler* (n 632), para 60; *Zenatti* (n 635), para 14.
[1238] *Placanica* (n 644), para 48; *Sjöberg and Gerdin* (n 908), para 43.
[1239] *Schindler* (n 632), para 32.
[1240] *Gambelli* (n 640), para 63.
[1241] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 69. See e.g. *Schindler* (n 632), para 57; *Zenatti* (n 635), para 30.
[1242] *Sjöberg and Gerdin* (n 908), para 43.
[1243] See in that regard the statement of reasons of the Swedish law on alcohol: 'The fundamental aim of Swedish alcohol policy throughout the twentieth century has been to limit the effect of market forces, namely competition and private profits. The reason for this was the conviction that competition and private profits encourage active marketing and active selling, which lead to increased consumption.' *Franzen*, Opinion of Advocate General Elmer (n 814), para 6.

For the Court, all these factors 'justify national authorities having a sufficient degree of latitude to determine what is required to protect [gambling] players and, more generally, in the light of the specific social and cultural features of each Member State, to maintain order in society'.[1244] Member States benefit from a 'margin of appreciation'[1245] or even a 'wide discretion'[1246] when defining the level of protection sought in relation to gambling and adopting the necessary measures to that effect. The Court only pays lip service to the principle of proportionality. As Van den Bogaert and Cuyvers put it, 'although the Court follows the structure of the "standard test", each individual requirement of the test is relaxed to introduce some form of additional margin', resulting in particular in the necessity test being 'virtually abolished'.[1247] In early cases, the Court altogether declined to perform any proportionality assessment of the measures before it, leaving this responsibility to the national courts.[1248] This is no longer the case and the Court has strengthened its control over the years, so as not to give complete free rein to Member States. Yet, even if national authorities are not granted with a *carte blanche*, the balance in gambling cases still remains largely tilted in their favour.

Regarding proportionality, the most striking feature of the gambling case-law is the near absence of any necessity assessment on the Court's part.[1249] It is for Member States to decide whether 'it is necessary to prohibit [gambling activities], totally or partially, or only to restrict them and to lay down more or less rigorous procedures for controlling them'.[1250] In that regard, 'the mere fact that a Member State has chosen a system of protection different from that adopted by another Member State *cannot affect* the appraisal as to the need for and proportionality of the provisions adopted'.[1251] Member States are free to prohibit whole or parts of the gambling offer on their territory, to set up a system of exclusive rights, to distribute licences or require a prior authorisation for the provision of gambling services. The gambling case-law is largely devoid of the comparative exercise, seen in relation to other lifestyle risks factors, whereby the Court assesses, lengthily at times, the respective merits of different regulatory options.[1252] This is reinforced by the Court's own recognition that a monopoly

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[1244] *Schindler* (n 632), para 61.
[1245] *Gambelli* (n 640), para 63, *Zenatti* (n 635), para 33,
[1246] *Dickinger and Ömer* (n 1040), para 99; *Stanley International Betting* [2018] (n 644), para 40.
[1247] Van den Bogaert and Cuyvers (n 35).
[1248] *Schindler* (n 632), para 61; *Läära* (n 645), paras 35-36; *Anomar* (n 649), paras 86-88.
[1249] Sibony and Michail mention a necessity test with 'little depth': Anne-Lise Sibony and Nikitas Michail, 'Les jeux de hasard au regard du droit européen : les Etats membres ont carte blanche… à condition de respecter les règles du jeu' in Denis Philippe, Geneviève Schamps and Alain Strowel (eds), *Droit des jeux de hasard* (Larcier 2018) 36.
[1250] *Zenatti* (n 635), para 33. See *Schindler* (n 632), para 61; *Läära* (n 645), para 35.
[1251] *Zenatti* (n 635), para 34, emphasis added. See also *Läära* (n 645), para 35. In other areas of free movement, the Court simply states that 'the fact that one Member State imposes less strict rules than another Member State does not mean that the latter rules are disproportionate', see *Commission v France* (n 896), para 37. In some consumer protection cases, the Court directly compares the rule under scrutiny with the standard in place in other Member States to assess its proportionality. See e.g. *GB-INNO-BM* (n 883), para 12; Case C-136/91 *Yves Rocher* [1993] EU:C:1993:191, para 18.
[1252] For some exceptions in relation to monopolies, see *Stoß* (n 863), para 82 and *Dickinger and Ömer* (n 1040), para 49. *Placanica* and *Engelmann* constitute rare occasions where a national gambling rule is deemed to go

system, 'an unusually restrictive measure',[1253] is likely to allow Member States to better 'tackle the risks connected with the gambling sector and pursue the legitimate objective of preventing incitement to squander money on gambling and combating addiction to gambling more effectively' than would be the case with another regulatory framework.[1254] When reviewing the proportionality of Member States' gambling monopolies, the Court only requires the national authorities to show that they effectively intended to ensure 'a particularly high level of protection'.[1255]

The leeway left to Member States to choose their favoured regulatory model, without ever having to ponder its relative merits and restrictive effects, can also be seen at the stage of the suitability assessment. Recognising that 'various types of games of chance can exhibit significant differences, particularly as regards the actual way in which they are organised, the size of the stakes and winnings by which they are characterised, the number of potential players, their presentation, their frequency, their brevity or repetitive character and the reactions which they arouse in players',[1256] the Court authorises Member States to adopt different regulatory models for the different games of chance operated on their territory. A particularly popular and harmful type of gambling could be subject to a monopoly system while another that does not raise similar concerns would simply be subject to a system of prior authorisation. This, according to the Court, does not affect the suitability of the most restrictive system chosen.[1257]

Another notable feature of the gambling case-law is the rejection of any duty of mutual recognition for the Member State where a foreign operator seeks to provide services, as regards the requirements and controls to which this operator is subjected in its Member States of origin. This was first expressed in *Liga Portuguesa*, regarding online gambling, where the Court held that:

> [T]he sector involving games of chance offered via the internet has not been the subject of [Union] harmonisation. A Member State is therefore entitled to take the view that the mere fact that an operator such as Bwin *lawfully offers services* in that sector via the internet in another Member State, in which it is established and where it is in principle already *subject to statutory conditions and controls* on the part of the competent authorities in that State, *cannot be regarded as amounting to a sufficient assurance* that national consumers will be protected against the risks of fraud and crime, *in the light of the difficulties liable to be encountered in such a context by the authorities of the Member State* of establishment in assessing the professional qualities and integrity of operators.[1258]

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beyond what is necessary and another less restrictive measure is identified, *Placanica* (n 644), para 62; *Engelmann* (n 1004), paras 37-38.

[1253] *Dickinger and Ömer* (n 1040), para 71.

[1254] *Stoß* (n 863), para 81. See also *Dickinger and Ömer* (n 1040), para 48.

[1255] *Dickinger and Ömer* (n 1040), para 54. See also ibid, para 71.

[1256] Case C-46/08 *Carmen Media Group* [2010] EU:C:2010:505, para 62.

[1257] ibid, para 63. See also *Sporting Odds* (n 1007), para 23; *Stanley International Betting* [2018] (n 644), para 50.

[1258] *Liga Portuguesa* (n 643), para 69, emphasis added. See also *Dickinger and Ömer* (n 1040), para 96.

In *Stoß*, the Court declared, this time regarding gambling in general, that 'a duty mutually to recognise authorisations issued by the various Member States cannot exist having regard to the current state of EU law'.[1259]

The principle originating from *Cassis de Dijon* is that a good 'lawfully manufactured and marketed' in one Member State should see its standards recognised in other Member States, save for the application of certain mandatory requirements. This means that the standards of the home Member State should be given consideration by the host Member State when applying its legislation and is deemed, in principle, as providing sufficient guaranties. Here, on the contrary, without having to look at the specific situation in the home Member State, the fact that an operator lawfully offers service in that Member State cannot, in principle, be considered as providing sufficient assurance that consumers in the host Member State will be adequately protected. The host Member State can safely ignore the standards of the home Member State when requiring a foreign service provider to obtain a licence or an authorisation or when denying it access to its market. As appears from *Liga Portuguesa*, the Court itself questions the capacity of Member States to adequately control the quality and integrity of online gambling services providers.[1260]

Thus doing, the Court ostensibly departs from its general case-law on the freedom to provide services, where, as expressed for the first time in *Säger*, it considers that this freedom may only be limited 'by rules which are justified by imperative reasons relating to the public interest […] *in so far as that interest is not protected by the rules to which the person providing the services is subject in the Member State in which he is established*'.[1261] It also opposes its Advocate Generals, Advocate General Colomer in particular, who argued in *Placanica*, regarding the access of a British gambling operator to the Italian market, that the British authorities '[were] in a *better* position than the Italian authorities to check that the activities [were] lawful, and [that] there appear[ed] to be no reason for a double check' of its licence, referring directly to the judgment in *Säger*.[1262] As rightly pointed out by Sibony and Michail, the Court's emphatic rejection of any duty of mutual recognition in the field of gambling appears even more striking when considering that this principle finds its origin in *Cassis de Dijon*, a case dealing with another activity involving risks to health and risks of addiction.[1263] Further, as rightly argued by Planzer, it is also noteworthy that the Court's argument regarding the inherent risks arising from internet gambling are absent in other areas involving public health and the internet, such as in cases dealing with the online sale of medical devices or medicines,[1264] where the Court

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[1259] *Stoß* (n 863), para 112.
[1260] For further considerations in that regard, see *Dickinger and Ömer* (n 1040), para 98.
[1261] Case C-76/90 *Säger v Dennemeyer* [1991] EU:C:1991:331, para 15, emphasis added.
[1262] Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica* [2006] EU:C:2006:324, Opinion of Advocate General Colomer, para 132, emphasis added. See also Case C-67/98 *Zenatti* [1999] EU:C:1999:261, Opinion of Advocate General Fenelly, para 21; Case C-176/11 *HIT* [2012] EU:C:2012:208, Opinion of Advocate General Mazak, paras 24-26.
[1263] Sibony and Michail (n 1249) 40.
[1264] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 221–223. See Case C-108/09 *Ker-Optika* [2010] EU:C:2010:725 ; Case C-322/01 Deutscher Apothekerverband [2003] EU:C:2003:664.

does not seem to consider the absence of medical advice as necessarily involving a greater risk of abuse or mistake by consumers.

That being said, the gambling case-law is not all about deference towards Member States. Two developments have shown in particular a willingness on the Court's part to police Member States rules a little more closely.

The first of these developments has been the Court's increasing insistence that Member States adopt a consistent policy. As previously discussed, the requirement that measures be consistent and systematic has first been formalised in the gambling case-law, starting with *Gambelli*,[1265] before being extended to other areas of free movement. In gambling cases, the Court has used the consistency requirement in order to oppose Member States' double standards: restricting the access of foreign operators to their markets so as to, allegedly, limit gambling opportunities while at the same time 'incit[ing] and encourage[ing] consumers to participate in lotteries, games of chance and betting' on their territory, 'to the financial benefit of the public purse'.[1266]

The difficulty, in these cases, is that Member States may justify their domestic expansionists policies by the need to divert consumers from the illegal offer and channel them to the existing legal one. The legitimacy of such a policy of 'controlled expansion', used so that the legal offer 'represent[s] a reliable, but at the same time attractive, alternative to a prohibited activity', was first recognised in *Placanica*, justified only by the objective of preventing criminal activity.[1267] According to the Court, this objective 'may as such necessitate the offer of an extensive range of games, advertising on a certain scale and the use of new distribution techniques'.[1268] In later cases, the Court recognised that a policy of controlled expansion could also be used to pursue an objective of consumer protection or prevention of gambling addiction.[1269]

Finding the right balance between what is necessary to channel consumers towards a legal and controlled offer, thereby preventing crime and fraud and providing greater guarantees for the protection of consumers, and what constitutes an undue incitement to gamble, which would not only disclose a Member State's true financial motive but also put the protection of consumers' health in jeopardy, is no easy task. The Court requires that an equilibrium be found. The controlled expansion must be intended '*solely to inform* potential customers of the existence of products and […] to ensure regular access to games of chance by *channelling gamblers into controlled circuits*' and not to '*invite and encourage active participation in such games*'.[1270] In particular, any advertising benefitting the authorised gambling networks cannot *'aim to encourage consumers' natural propensity to gamble by stimulating their active participation in it*, such as by trivialising gambling or giving it a positive image due to the fact that revenues derived from it are used for activities in the public interest, or by increasing the attractiveness

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[1265] *Gambelli* (n 640), para 37.
[1266] *Gambelli* (n 640), para 69.
[1267] *Placanica* (n 644), para 55.
[1268] ibid.
[1269] *Ladbrokes* (n 861) para 26; *Dickinger and Ömer* (n 1040), para 63.
[1270] *Dickinger and Ömer* (n 1040), para 69, emphasis added. See also *Ladbrokes* (n 861), para 28.

of gambling by means of enticing advertising messages depicting major winnings in glowing colours'.[1271] In *Stoß*, the authorities tolerated the operation of other games of chance than those subject to the public monopoly, some of which, like automated games and casinos, actually presented a higher risk of addiction. The holder of the monopoly was engaged in intensive advertising. The Court considered that the establishment of this monopoly was no longer suitable to the objective of preventing incitement to squander money on gambling and combating addiction.[1272]

The second aspect of the gambling case law which reveals the Court's more sanguine approach is the firm rejection of national measures that discriminate against foreign operators. This is particularly visible in the Court's insistence that gambling concessions, licenses and authorisations be attributed through fair and open procedures. The award of such operating rights must comply with the principles of equal treatment, of non-discrimination on grounds of nationality and transparency.[1273] It must therefore be based on 'objective, non-discriminatory criteria known in advance, in such a way as to circumscribe the exercise of the authorities' discretion so that it is not used arbitrarily'. [1274] Member States are not obliged to make a formal call for tenders to attribute rights to gambling operations but are required to ensure a sufficient degree of publicity so that access to these rights is opened up to competition and that the impartiality of the award procedures can be reviewed.[1275]

The Court's rejection of arbitrary or discriminatory criteria used in tendering procedures appears from a number of cases dealing with the Italian system of gambling licences. In *Placanica*, the Italian licensing system excluded from the tendering procedures all companies quoted on the regulated markets. The Court considered that this blanket exclusion went beyond what was necessary to prevent criminal activities in the gambling sector and explicitly referred to other less restrictive ways to monitor the accounts and activities of operators, 'one such possibility being the gathering of information on their representatives or their main shareholders'.[1276] In the following *Costa and Cifone* case, the Court was called to rule on the compatibility of the Italian measure adopted to remedy the breach of EU law arising from *Placanica*. Italy had decided to open a significant number of new licenses for those who had been previously excluded from their benefit and required that the new operators did not establish their gaming establishment in close proximity of the existing operators. This, for the Court, entailed discrimination against the newcomers, 'compelled to open premises in less commercially attractive locations than those occupied by the former' license holders.[1277] Even if a rule on minimum distances could in itself be justifiable, it could not be applied in such

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[1271] *Stoß* (n 863), para 103, emphasis added.
[1272] ibid, 106.
[1273] *Betfair* (n 861), para 39; *Engelmann* (n 1004), para 49; *Costa and Cifone* (n 644), para 54.
[1274] *Stanley International Betting* [2015] (n 644), para 38. See also *Engelmann* (n 1004), para 55; *Costa and Cifone* (n 644), para 56.
[1275] *Costa and Cifone* (n 644), para 55. See also *Betfair* (n 861), para 41; *Engelmann* (n 1004), para 50.
[1276] *Placanica* (n 644), para 62.
[1277] *Costa and Cifone* (n 644), para 58.

circumstances where newcomers would be put at a disadvantage. [1278] In *Engelmann*, the Court also objected to the Austrian rule categorically excluding operators established in other Member States from accessing concessions to operate gaming establishment.[1279]

Outside the context of tendering procedures, the Court has also opposed other types of discriminatory measures, such as the discriminatory tax arrangements seen in *Commission v Spain* and *Lindman* or the discriminatory criminal sanctions arising from the Swedish legislation in *Sjöberg and Gerdin* (see Chapter 3, Section 5.2). In *Recreatieprojecten Zeeland BV*, it ruled that a Belgian measure granting an automatic derogation from the advertising ban applicable to gaming establishments solely to operators located on the territory of that Member State was in breach of Article 56 TFEU.[1280]

3.3. Integrating non-risk concerns in the proportionality assessment

In its standard form and application, proportionality ensures that Member States pursue legitimate policy objectives without unduly restricting free movement. The proportionality of a given measure is analysed in relation to its purported goal and the interests that it is supposed to protect. In lifestyle risks cases, Member States have mostly relied on public health objectives, and, less frequently, if leaving gambling aside, on objectives linked to the preservation of public order, a concept encompassing a mixture of policy and security concerns and presenting at times a certain moral aspect.

Focusing on public health as a justification ground for lifestyle risks measures offers advantages, for both Member States and the Court. It is easier to defend a measure on the basis of scientific evidence establishing the reality of a risk to health than it is to argue for the protection of a certain vision of society, morally or culturally, elements which are less amenable to an objective review. For the Court, health and the related scientific evidence offer a supranational lens through which to deal with restrictions on free movement. It spares the Court from being embroiled in discussions about morals or culture, which are more difficult to rationalise.

The regulation of lifestyle risks however, as discussed in Chapter 1 and as apparent from the various judgments analysed until now, is never *only* about health. Rules may be in place not only on grounds of the harmful aspect of certain behaviours, but simply because society think that these practices are inherently wrong. Both aspects are often intertwined. Alternatively, an activity may be lightly regulated, despite its harmful nature, because it fulfils another cultural or social role which is deemed important enough and worthy of preservation. Risk management is never only about risk, science and harm, but also has to incorporate other concerns and strike a balance between those various interests. It is hence interesting to see whether the Court has recognised the existence of these other interests, which may potentially affect the

[1278] ibid, para 64. In *Stanley International Betting* [2015] (n 644), another case dealing with the Italian licensing system, the Court ruled however that Italy could lawfully decide to attribute new licences for a shorter period than that of the previously awarded licences, so as to align the expiration date of all licences, para 53-54.
[1279] *Engelmann* (n 1004), para 37.
[1280] *Recreatieprojecten Zeeland BV* (n 1023).

proportionality of a Member State rules. Aspects of a certain measure may appear disproportionate if considering only health, its stated objective, but may be justified on other grounds.

Leaving gambling aside, there has not been any case regarding lifestyle risks where the Court has openly discussed, as part of proportionality, a Member State argument which was not based on some objective, measurable degree of risk. The only exception is *Visnapuu*, where the Finnish retail sale licencing scheme allowing manufacturers of certain fermented alcoholic beverages to directly sell their own production was only open to manufacturers established in the country. The Court acknowledged that such feature could have the effect of protecting national production,[1281] to which the Finnish government answered that:

> [T]he licencing scheme in question pursued — *in addition to the health and public policy grounds* mentioned above — *the objective of promoting tourism*, since the measure is intended to allow a limited number of alcoholic beverage manufacturers established in Finland, *using traditional and artisanal methods*, to sell their products at the site of production.[1282]

Thus doing, the Finnish government relied on a more cultural argument to defend a measure which, even if part of a broader licensing scheme featuring clear health-related aspects, did not in itself pursue any health or public policy objective. The Court did not directly rule on the validity of such a defence, leaving it to the referring court to examine if, considering that aspect of the licencing scheme, it could be concluded that the health and public policy grounds relied on by the Finnish authorities had been diverted from their purpose in the sense of Article 36 TFEU, second indent.[1283] This, it would seem, shows that the Court is not in principle hostile to such arguments.

More generally, beyond the specific cultural or moral aspect of a given rule, different risk regulatory regimes also express a certain vision of what kind of behaviours are permissible or not to those who belong in a given society. 'The particular action to regulate drugs, [or] drinking […] reflect a very specific understanding of the relations between State and society, of the responsibility of the state to shield society from human passions and risky behavior, and of the self or personhood.'[1284] The Nordics' alcohol policies, Finland and Sweden, reflect for instance distinctive cultural traditions and historical experiences. These are countries where alcohol was traditionally used for intoxication rather than consumed for its organoleptic properties or to accompany meals. It 'symbolized moral degradation, poverty and social disorder, while temperance was considered a key to a better life, a sign of high social morality and general welfare'.[1285] This explains why these two countries were by the 1980s among the

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[1281] *Visnapuu* (n 703), para 126.
[1282] ibid, para 127, emphasis added.
[1283] ibid, para 128.
[1284] Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 5.
[1285] Trygve Ugland, 'Europeanisation of the Nordic Alcohol Monopoly Systems Collisions between Ideologies and Political Cultures' (1997) 14 Nordic Studies on Alcohol and Drugs 7, 9; Trygve Ugland, 'Promoting Policy Consistency and Continuity in the EU through the Trio: Alcohol-Related Harm on the Council Presidency

last ones in Europe to subject alcohol to a strict monopoly system covering the import, export, production, wholesale and retail sale of alcoholic beverages. The Dutch tolerance policy on drugs also reflects a specific understanding of the State's role as regards drug consumption, focusing on harm reduction rather than the prosecution of illegal behaviour.[1286]

This echoes the work done by Gareth Davies, in relation to the Court's treatment in free movement cases of what he calls 'quality of life' aspects.[1287] Davies is interested in the 'changes wrought by free movement […] on the texture of national life, on the wider social relations between individuals, and between individuals and their state', which 'are not captured merely by looking at the parties to transactions, but by understanding how market regulation affects society more broadly, for example by creating shared experiences, a sense of equality, and social bonds'.[1288] This 'quality of life' is made of 'traditions, practices, habits' and other matters 'such as the sense of a shared identity and belonging which arise when a community lives and consumes in a common way'.[1289]

These, he argues are interests that cannot currently be protected in free movement law, due in particular to the application of proportionality, since these interests cannot be easily rationalised in one of the grounds of justification available. As he says, what matters with these rules is not so much their purpose, which is essential to determine proportionality, but the simple fact that these rules exist and shape life in a certain country in a certain way.[1290] These rules are all about lifestyles, understood broadly, if not about lifestyle risks. The most telling example he uses is the series of cases dealing with composition requirements for food: beer,[1291] pasta,[1292] or foie gras.[1293] It is clear that allowing products manufactured in a different way to enter the German, Italian or French market does not *really* threaten the possibility for German, Italian or French consumers to keep consuming their traditional beer, pasta or foie gras. What is lost however, is the fact that *all* the beer, pasta and foie gras available on the market and are similar, solidifying shared cultural practices.

A similar argument can be made in relation to lifestyle risks. If one takes the Nordic's alcohol monopolies, the point may be made that the organisation of the monopoly itself, beyond its purpose of limiting access to alcoholic beverages, has become a central aspect of the Nordic lifestyle – visiting the same shops, at specific hours, having access to a standardised offer of

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Agenda' (2019) 29 Journal of European Social Policy 515, 520–521. See also Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 27–72.

[1286] Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 97–120.

[1287] Davies, 'Internal Market Adjudication and the Quality of Life in Europe' (n 1174); Davies, 'Free Movement, the Quality of Life and the Myth that the Court Balances Interests' (n 1174).

[1288] Davies, 'Internal Market Adjudication and the Quality of Life in Europe' (n 1174) 290.

[1289] Davies, 'Free Movement, the Quality of Life and the Myth that the Court Balances Interests' (n 1174) 220.

[1290] Davies, 'Internal Market Adjudication and the Quality of Life in Europe' (n 1174) 313–317.

[1291] *Commission v Germany (Beer purity)* (n 612).

[1292] *Zoni* (n 927); *3 Glocken* (n 927).

[1293] *Commission v France (Foie gras)* (n 621).

beverages, etc. This is an aspect which was not addressed, neither by the Court, nor by the Member States, in any of the cases specifically dealing with this issue.[1294]

Further, as Floris de Witte very well argues, questions of morality and ethics raise particular challenges for EU law, as they reflect an individual or collective sense of self that is particularly difficult to Europeanise.[1295] The EU cannot replicate the national 'community of fate', where highly divisive aspects of life can be debated and choices, regarding for instance what it is permissible to consume or not, are politically legitimised or delegitimised.[1296] 'As such, many moral or ethical choices reflect first principles, and do not lend themselves naturally to practices of transnational rationalization insofar as they are not necessarily universal but rather particular to a certain Member State, as a reflection of idiosyncrasies that exist within that polity.'[1297]

For De Witte, two opposite solutions exist as regards the treatment that free movement reserves to these ethically and morally loaded choices of regulation: one of 'self-determination', whereby Member States' choices are insulated and preserved from the potentially deregulatory influence of free movement, and one of 'containment', whereby Member States' autonomy is constrained, and the interests of out-of-State actors have to be incorporated into national regulatory choices.[1298] At the intersection of these two poles, questions arise such as 'whether a Polish citizen *ought* to be allowed to use soft-drugs in Amsterdam, a Swedish citizen *ought* to be able to circumvent alcohol retail monopolies and directly import alcohol, or an Austrian gambling company *ought* to be allowed to offer online gambling service in Rome'.[1299]

The 'containment' and 'self-determination' solutions are equally unappealing for the Court. As we have said, the Court tries to avoid, as much as possible, getting embroiled in moral and ethical disputes.[1300] That is why gambling and prostitution, despite the clear moral dimension of their regulation at the national level, are subject to the laws of free movement and why illicit drugs are sheltered from the application of free movement on grounds of their illegal character and *not* because of the moral disapprobation a country may have towards their consumption. At the same time, Member States, through the public morality ground of Article 36 TFEU and the 'public order' grounds contained in the various Treaty free movement provisions or recognised in the Court's case-law, are given the possibility to defend their restrictive measures, according to their own moral 'scale of values'.[1301] Hence, the Court usually refrains from openly sheltering an activity from free movement, thus denying companies or individuals

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[1294] In particular, *Franzen* (n 797) and *Rosengren* (n 817).
[1295] De Witte (n 611).
[1296] ibid.
[1297] ibid 1545–1546.
[1298] ibid 1546–1556. See also Poiares Maduro (n 665) 172.
[1299] De Witte (n 611) 1556.
[1300] In that regard, see also Doukas, 'Morality, Free Movement and Judicial Restraint at the European Court of Justice' (n 663).
[1301] Outside the field of gambling, see *Henn et Darby* (n 910), *Jany* (n 663), para 60. For further developments on how morality concerns pervade various grounds of justification advanced by Member States, see Doukas, 'Morality, Free Movement and Judicial Restraint at the European Court of Justice' (n 663).

the transnational rights that they derive from EU law, or, on the contrary, to subject an activity to a European ethical or moral standard.[1302]

Interestingly enough, as de Witte argues, traces of both these opposite solutions can be found in the same judgment, *Josemans*. Indeed, in *Josemans*, the Court followed Advocate General Bot in considering that the fight against drug tourism and the accompanying nuisance were legitimate objectives to be pursued as part of the protection of the national *and* the European public order,[1303] hence bringing the Dutch policy of combatting drug tourism under a common European umbrella. At the same time, by greenlighting the city of Maastricht's rule preventing non-residents to access coffee-shops in order to purchase the cannabis that they cannot purchase at home, the Court denied to these consumers the exercise of their basic free movement rights as European citizens. As de Witte says, this 'very strange legal fiction […] harks back to the anachronistic logic that attaches legal authority to the *status* of the citizen (nationality, originally; and residence, more recently) rather than his territorial *presence*'.[1304]

Drug tourism may create specific troubles that need to be addressed, but one may nonetheless wonder why Europeans should not be able to take advantage of free movement to take part in some activities that are prohibited in the Member States where they originate or reside but are lawful in other countries. This, it seems, is precisely what free movement and the recognition of ethical and moral diversity, not only collectively but also individually, are about. One cannot help but think that the Netherlands applied 'double standards to the moral evaluation of the same activity in its territory, depending on whether this is exercised by home nationals or by nationals from other Member States who cross the borders'.[1305] At the same time, by doing so, one could argue that the Netherlands helped its neighbours to enforce their own drug policy, whose effectiveness is undermined by free movement in such case. By upholding the residency rule, the Court not only shows deference towards the Dutch measure, but also towards the measures adopted by other Member States. In this way, *Josemans* may be construed as furthering the principle of sincere cooperation, as per Article 4(3) TEU.

Between these two opposite poles, containment and self-determination, the principle of proportionality offers a way to strike the balance between the autonomy of Member States in areas of sensitive ethical and moral concerns and the interests of out-of-State actors. De Witte is of the opinion that the 'substantive' proportionality test, the standard two-pronged test described above, is ill-suited to matters of moral and ethical dimension, as it 'contains a communitarian blindspot, in the sense that it cannot conceptually accommodate communal or collective interests'.[1306]

In sensitive areas, de Witte favours the application of a more procedural version of proportionality, a test of reasonableness focusing on 'policy coherence, consistency and

[1302] De Witte (n 611) 1557.
[1303] *Josemans* (n 650), para 65.
[1304] De Witte (n 611) 1564.
[1305] Doukas, 'Morality, Free Movement and Judicial Restraint at the European Court of Justice' (n 663) 157.
[1306] De Witte (n 611) 1569–1570.

transparency' rather than on the content of the rule, taking as an example the laxer test used in gambling.[1307] Indeed, the Court's general approach to gambling can be seen as a recognition of the moral and cultural specificities of this activity and its regulation, allowing Member States to maintain rules that may appear disproportionate from a pure risk perspective. The application of a more procedural version of the proportionality test in other areas would be a welcome development, providing Member States with a certain margin of discretion in their policy choices while ensuring that these do not adversely impact foreign actors if compared to domestic ones. The line the Court took regarding gambling licences and the policy of 'controlled expansion' is a good example of such an approach.

At the same time, the Court's approach to gambling and morality is open to criticism. One may wonder if the margin left to Member States in gambling is not too wide, and, similarly to what has been said about the *Josemans* judgment, does not allow the application of a double standard: drawing significant revenue from domestic gambling operators while denying foreign operators access to the market. Advocate General Bot considers that games of chances should not be subject to the normal functioning of the internal market[1308] because he 'fail[s] to see what progress there would be in making it easier for consumers to take part in national lotteries organised in each Member State and to bet on all the horse races or sporting events in the Union'.[1309] But if a Member State allows gambling operations on its territory, there should be no reason for consumers to be deprived of the possibility to bet on foreign horse races or sporting events, and no reason for foreign operators to be prevented from entering the market.

This begs the following question: is the Court's hands off approach really about moral or cultural diversity or is it rather about the preservation of the 'golden eggs' of gambling,[1310] or, as Planzer says, about 'the cutting of the copious cake'?[1311] 'The starting point of responsible gambling policies is the acknowledgment by both public authorities and the industry of their obvious financial interests and that each assume their responsibility when permitting and offering an activity that is proven to involve health and other risks.'[1312]

Further, if the sensitive moral aspect of an activity warrants a different approach from the Court and a lighter application of the proportionality principle, this should be done for all such activities, including for instance alcohol.[1313] This is especially true regarding Sweden and Finland, which happen precisely to be the countries where most of the cases regarding alcohol have arisen from. *Josemans*, even, regardless of one's appraisal of the outcome reached in that case, features a long and detailed proportionality assessment, the like of which has never been seen in relation to gambling. It is hard to think however of a policy area where moral and ethical discussions are rifer than the regulation of illicit drugs.

[1307] ibid 1571.
[1308] *Liga Portuguesa*, Opinion of Advocate General Bot (n 1236), para 245.
[1309] ibid, para 246.
[1310] Van den Bogaert and Cuyvers (n 35) 1211.
[1311] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 74.
[1312] ibid 80.
[1313] See in that regard Van den Bogaert and Cuyvers (n 35) 1995–1996.

3.4. Use of evidence

Member States must adduce evidence regarding the proportionality of their measures, in order to prove that these can adequately mitigate the risks identified and are not unduly restrictive of free movement. As said in *Pfleger*, 'it is the Member State wishing to rely on an objective capable of justifying the restriction of the freedom to provide services which must supply the court called on to rule on that question with *all the evidence of such a kind* as to enable the court to be satisfied that the measure does indeed comply with the *requirements deriving from the principle of proportionality*'.[1314]

The evidentiary requirement is generally not as high for proportionality as it is regarding the existence of a risk. Less guidance is to be found in the case-law as to what kind of evidence, if any at all, is required to establish the proportionality of a given measure.[1315] That the standard of proof is less demanding for risk management than risk assessment is to be commanded. It is indeed difficult, ex ante, to establish with certainty the effect of a particular measure, especially when it is part of a broader regulatory mix. As Advocate General Saugmandsgaard Øe argued in *A*, 'where a Member State relies, in support of a restrictive measure, on the need to avoid the materialisation of a risk […] it cannot be required to produce empirical evidence demonstrating unambiguously the existence of a causal link between the measure in question and the desired effect'.[1316] In the area of lifestyle risks in particular, 'the multifactorial nature of its underlying phenomena [and] the interdisciplinary character of the evidence at stake' renders 'the measurement of the effectiveness of the different policy options as well as the identification of the individual contribution of each one of them to the policy objective' difficult.[1317]

Regarding suitability, the Court usually satisfies itself with the existence of a sufficient degree of connection between the measure and its effect. Regarding necessity, it is established case-law that the 'burden of proof *cannot extend* to creating the requirement that […] national authorities […] must *prove, positively, that no other conceivable measure could enable the legitimate objective pursued to be attained under the same conditions*'.[1318] In a number of

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[1314] *Pfleger* (n 873), para 50, emphasis added. See also *Dickinger and Ömer* (n 1040), para 54.
[1315] For an instance where the Court gives clear guidance, see *Deutsche Parkinson* (n 694), para 36: 'where a national court examines national legislation in the light of the justification relating to protection of the health and life of humans under Article 36 TFEU, that court must examine objectively, *through statistical or ad hoc data or by other means*, whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods', emphasis added.
[1316] *A (Advertising and sale of medicinal products online)*, Opinion of Advocate General Saugmandsgaard Øe (n 894), para 131.
[1317] Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 155.
[1318] *Scotch Whisky* (n 612), para 55, emphasis added. See also *Trailers* (n 668), para 66. Although the Court mentions the *burden* of proof, what is referred to here is rather a matter of *standard* of proof, see Nic Shuibhne and Maci (n 1025) 982.

cases, such as *Aragonesa*, *Commission v France (Loi Evin)* or *Bacardi France*, the Court discusses and ultimately upholds the proportionality of the measures without any reference to specific evidence.[1319] In *Aragonesa*, it was for the Court 'sufficient to observe' that 'advertising acts as an encouragement to consumption'[1320] to establish the suitability of the advertising ban at stake, without the need being felt for any kind of evidence to be adduced regarding the relationship between advertising and consumption and hence the likely effect of a restriction on advertising.

It is only with *Scotch Whisky* that the Court made a bigger inroad into the role played by evidence at the proportionality stage and provided more detailed guidance to national courts.[1321] In particular, the Court held that:

> [I]t is for the national court called on to review the legality of the national legislation concerned to determine the relevance of the evidence adduced by the competent national authorities in order to determine whether that legislation is compatible with the principle of proportionality. On the basis of that evidence, that court must, in particular, examine objectively whether it may *reasonably* be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods.[1322]

An interesting feature of the *Scotch Whisky* case lies in the recognition of the role that uncertainty can play in the proportionality review:

> In this case, in the course of such a review, the referring court may take into consideration the possible existence of *scientific uncertainty as to the actual and specific effects on the consumption of alcohol of a measure* such as the MPU for the purposes of attaining the objective pursued. As the Advocate General stated in point 85 of his Opinion, the fact that the national legislation provides that the setting of an MPU will *expire six years* after the entry into force of the MPU Order, unless the Scottish Parliament decides that it is to continue, *is a factor that the referring court may also take into consideration*.[1323]

Without openly referring to it, the Court makes here application of the precautionary principle, not on the basis of an uncertainty regarding the existence or the extent of a risk but an uncertainty as regards the best way to tackle it.[1324] 'Although unorthodox, this approach […] may be praised insofar as it appears to do justice to the complexities, previously highlighted, related to the comparability of the effectiveness of various policy options, in particular in public health, and their individual contributions to their declared public interest objective.'[1325] It remain to be seen whether the Court confirms this application of the precautionary principle. It

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[1319] See Amandine Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' in Niamh Nic Shuibhne and Laurence W Gormley (eds), *From Single Market to Economic Union: Essays in Memory of John A Usher* (Oxford University Press 2012) 129.
[1320] *Aragonesa* (n 884), para 15.
[1321] See *Scotch Whisky* (n 612), para 51-65.
[1322] ibid, para 56, emphasis added.
[1323] ibid, para 57, emphasis added.
[1324] Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' (n 1082) 1061.
[1325] ibid.

was, shortly after *Scotch Whisky*, put into question by Advocate General Szpunar in *Deutsche Parkinson*,[1326] but most recently upheld by Advocate General Saugmandsgaard Øe in *A*.[1327]

In that regard, the reference to the sunset clause present in the Scottish legislation – the fact that the Scottish Parliament reviews the measure after six years to decide whether to continue with it or not – is also to be welcomed. Sunset clauses are a good proportionality tool, insofar as they allow Member States to experiment with new forms of regulation, hence relaxing the evidential requirement, while at the same time requiring that a measure be abandoned if it reveals not to be effective. This dynamic assessment is something that the Court actually insists on in *Scotch Whisky*. Addressing the referring court's question as to whether studies currently available but not examined by the legislature at the time of adoption of the measure should be taken into consideration, the Court answered positively : 'the referring court must take into consideration *any relevant information*, evidence or other material of which it has knowledge under the conditions laid down by its national law', such an assessment being 'all the more necessary in a situation […] where there appears to be *scientific uncertainty* as to the actual effects of the measures'.[1328]

The need for a dynamic assessment was also stressed by the Court of Justice in the context of gambling. In *Admiral Casinos*, where the national court referred a question similar as the one raised in *Scotch Whisky*, the Court answered that 'in a review of proportionality, the approach taken by the referring court must be *dynamic rather than static* in the sense that it must take account of the way in which circumstances have developed following the adoption of the legislation concerned',[1329] meaning that 'a review of the proportionality of restrictive national legislation in the area of games of chance must be based not only on the objective of that legislation at the time of its adoption, but also on *the effects of the legislation, assessed after its adoption*'.[1330]

Although the consequences of *Scotch Whisky* on the evidentiary requirement expected from national authorities as part of the proportionality assessment remains to be seen,[1331] 'it could provide a precedent from which the CJEU could extend its shift towards greater engagement with evidence into more highly sensitive policy fields'.[1332] Greater engagement with evidence

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[1326] See Case C-148/15 *Deutsche Parkinson* [2016] EU:C:2016:394, Opinion of Advocate General Szpunar, para 69: '[The precautionary principle] applies both where the extent of a risk is uncertain and where there is doubt as to its very existence. However, *it does not come into play in a situation of uncertainty surrounding the effectiveness of a policy option aimed at tackling a previously identified hazard*. Precaution is not to be confused with prevention. In the latter concept, there is no element of uncertainty as to the existence or extent of a risk. In prevention, the danger is identified.' Emphasis added.

[1327] See *A (Advertising and sale of medicinal products online)*, Opinion of Advocate General Saugmandsgaard Øe (n 894), para 131: 'Examination of the proportionality of national rules adopted in the particularly sensitive area of public health must take account of the complexity of the assessments which governed the choice made by the national authorities and *the degree of uncertainty which characterises the effects of such rules*.' Emphasis added.

[1328] *Scotch Whisky* (n 612), para 64, emphasis added.

[1329] Case C-464/15 *Admiral Casinos & Entertainment* [2016] EU:C:2016:500, para 36, emphasis added.

[1330] ibid, para 37, emphasis added.

[1331] See Bartlett and Macculloch (n 34).

[1332] ibid 116.

should not necessarily result in fewer opportunities for Member States to act, but hopefully lead to a more transparent and open discussion of the regulatory options chosen by Member States and their evaluation.[1333] It goes in the direction of what Nic Shuibhne and Maci coined as 'a marked shift in recent case-law towards *positive* expression of and engagement with the standard of proof, which contrasts with the *negative* guidance more prevalent before'.[1334]

Greater engagement with evidence could also lead the Court to rethink some of its assumptions. Some of them not only fail to be backed by specific evidence, but actually appear in contradiction with existing evidence and what is known about the relative effectiveness of various policy options. As previously discussed, this is the case with the Court's belief in the equivalent effectiveness of taxation for tobacco and alcohol if compared to price measures and in the effectiveness of labelling to convey information and prompt behavioural change. For those, 'the question remains: where did the Court get its knowledge from?'[1335]

In the context of gambling, Simon Planzer has shown that many of the Court's assumptions regarding gambling disorder and the respective effectiveness of different regulatory options to tackle it were far from being grounded in scientific evidence.[1336] This is for instance the case of the Court's position that a system of exclusive rights is more effective to pursue the legitimate objective of preventing incitement to gambling and combating addiction to gambling than a system of licences,[1337] even though 'hardly any research' has directly addressed this question.[1338] In the same vein, the Court also considers that competition in the gambling market leads to detrimental consequences, arising from the fact that operators are 'led to compete with each other in inventiveness in making what they offer more attractive and, in that way,

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[1333] For an early application of such an approach, see Case C-320/03 *Commission v Austria* [2005] EU:C:2005:684, paras 87-89.
[1334] Nic Shuibhne and Maci (n 1025) 978.
[1335] Norbert Reich, 'How Proportionate is the Proportionality Principle? Some critical remarks on the use and methodology of the proportionality principle in the internal market case-law of the ECJ' in Hans-Wolfgang Micklitz and Bruno De Witte (eds), *The European Court of Justice and the Autonomy of the Member States* (Intersentia 2012) 106
[1336] See Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 123–251.See also Simon Planzer, 'The ECJ on Gambling Addiction – Absence of an Evidence-Oriented Approach' (2010) 1 European Journal of Risk Regulation 289. It also happens that some of the Court's intuitions, regarding for instance the effectiveness of a policy of 'controlled expansion' to limit gambling addiction and the necessity to use a degree of advertising to promote the legal offer, are actually backed up by evidence. See Planzer (n 227) 174, 185–186.
[1337] See *Stoß* (n 863), para 81; *Dickinger and Ömer* (n 1040), para 48.
[1338] See Simon Planzer and Heather Wardle, 'What We Know about the Comparative Effectiveness of Gambling Regulation' (2012) 3 European Journal of Risk Regulation 410; Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 162–164; Virve Marionneau, Michael Egerer and Janne Nikkinen, 'How Do State Gambling Monopolies Affect Levels of Gambling Harm?' (2021) 8 Current Addiction Reports 225. In this latest review, Marionneau and others observe that: '[i]n terms of problem gambling, monopolistic configurations appear to be connected to lesser or at least similar levels of harms in comparison to licensing systems', although 'there remains a paucity particularly regarding empirical research on the effectiveness of different regulatory regimes in preventing and addressing gambling harms', 231. The authors conclude that 'rather than the regime, issues such as availability, accessibility, scope of preventive work, responsible gambling policies, the existence of a sufficiently resourced independent monitoring body, as well as the implementation of a public health approach to gambling may better predict the levels of harm in society', 232.

increasing consumers' expenditure on gaming and the risks of their addiction'.[1339] According to Planzer, this is a bold statement arguing for a chain of causality between competition, attractiveness and the risk of increased addiction, which is also not supported by evidence.[1340]

Finally, another example of these unfounded assumptions is the Court's stance that internet gamblers are more prone to addiction than those using other forms of gambling. In *Carmen Media*, the Court ruled that:

> [T]he characteristics specific to the offer of games of chance by the internet *may prove to be a source of risks of a different kind and a greater order in the area of consumer protection*, *particularly in relation to young persons and those with a propensity for gambling or likely to develop such a propensity*, in comparison with traditional markets for such games. Apart from the lack of direct contact between the consumer and the operator, previously referred to, the particular ease and the permanence of access to games offered over the internet and the potentially high volume and frequency of such an international offer, in an environment which is moreover characterised by isolation of the player, anonymity and an absence of social control, *constitute so many factors likely to foster the development of gambling addiction and the related squandering of money*, and thus likely to increase the negative social and moral consequences attaching thereto.[1341]

Here again, 'empirical evidence does not support the view that online gambling leads to sharply increased levels of gambling disorder'.[1342]

4. Conclusion

As should be clear to the reader by now, drawing general lessons from the application of free movement provisions to Member State lifestyle risks measures and the effect of these provisions on the risk regulation process at the national level is a difficult endeavour. This is especially due to proportionality, a principle 'surprisingly amorphous and notoriously difficult to understand', whose 'application is not consistent' and whose 'intensity of review […] seems to differ in light of the outcome that it can allow for'.[1343] No clear picture emerges from the multiple Court cases in the field. Nonetheless, a number of general observations can be made regarding the balance found by the Court between free movement, public health, and the preservation of Member State autonomy in an area of significant cultural and moral relevance. These observations will be made both from an internal perspective – analysing similarities and differences within the lifestyle risks case-law – and an external one – comparing lifestyle risks with other areas of free movement.

Save for some regrettable and perhaps outdated decisions regarding nutrition, the Court has generally recognised the health risks posed by unhealthy lifestyles and is willing to accept Member State justifications in that regard. Preventing the damaging consequences for individuals and society arising from unhealthy lifestyles may justify a restriction to the free

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[1339] *Betfair* (n 861), para 58.
[1340] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 168–170.
[1341] *Carmen Media* (n 1256), para 103, emphasis added.
[1342] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 216. For greater details, see ibid 192-202.
[1343] De Witte (n 611) 1567.

movement of goods, services or to the freedom of establishment. Successfully upholding these restrictions, however, appears highly circumstantial, depending on the way proportionality is applied.

Nothing illustrates this better than the different treatment reserved to alcohol and gambling, the two risk factors that have yielded the highest number of cases before the Court of Justice. In spite of their similarities – in terms of risk of addiction, threats to public order and possible moral reprobation – the Court handles the two risk factors very differently by the Court. While alcohol is mostly treated like any other commodity, gambling is insulated from the standard application of the proportionality principle, allowing Member States to greatly restrict or even prohibit gambling operations on their territory, without being required to offer much by way of justification. As observed by Planzer, '[t]he standard of review applied in *Rosengren* contrasts strongly with that in the case-law on gambling'.[1344] An argument could be made, regarding gambling, that the near absence of secondary law (see Chapter 5) and hence the largely retained character of Member State competence in this field justify the hands-off approach taken by the Court of Justice. But the same could be said of alcohol, a field which is only governed by a handful of secondary law provisions (see Chapter 5 and 6) and lightly regulated at the EU level. If anything, considering the much larger damaging consequences of alcohol consumption for society at large if compared to that of gambling, one could expect the opposite differential treatment and greater leeway to be left to Member States to conduct their alcohol policies. Furthermore, as already discussed above, regulating alcohol consumption also involves moral, religious or cultural considerations that could justify, if following the line taken for gambling, a certain degree of restraint on the part of the Court.

Regarding evidence, no coherent standard emerges either. Depending on the risk alleged, the Court expects Member States to provide precise evidence as to the existence of the risk or satisfies itself with general conjectures. Overall, the Court heavily relies on intuitionism. Some of its positions regarding the reality of certain risks or the respective effectiveness of different risk regulatory options appear at odds with existing scientific evidence. There is certainly no 'culture of proof' in the Court's case-law, meaning an approach 'which would be constructed by extensive and transparent flagging of and engagement with the evidence submitted in each case', allowing to know 'whether – and when – the Court relies on expert evidence in shaping its conclusions or applies a more intuitive rationale: essentially, common sense'.[1345] Relying on common sense on the part of a court of law is understandable, and perhaps inevitable, but it generates errors. The lack of a homogenous standard of proof in an area where scientific evidence is key undermines the legitimacy of the Court's case-law and leads to unsatisfactory outcomes: upholding measures whose restrictive effect does not appear warranted in light of evidence, like it has often been the case in gambling, or, on the opposite, preventing Member States from adopting measures that are necessary to reach the desired level of protection, as it has been the case in the food requirements or minimum prices cases. Whether a more

[1344] Planzer, *Empirical Views on European Gambling Law and Addiction* (n 35) 220.
[1345] Nic Shuibhne and Maci (n 1025) 985.

satisfactory culture of proof emerges after *Scotch Whisky*, both at the national and at the Court level, remains to be seen.

Regarding the application of proportionality more specifically, the case-law reveals a great deal of diversity, not only across risk factors but also within each of them. Alcohol is a case in point. Some judgments feature a rather long and detailed proportionality assessment[1346] while others contain much shorter ones.[1347] If focusing on preliminary references cases – in infringement proceedings, the Court must rule directly on the validity of a Member State measure – it appears that the Court decides at times to rule directly on the proportionality of the measure before it and, some other times, prefers to refer the issue back to the national court. The latter is usually done, where, according to the Court:

> [T]he decision as to whether the [measure] at issue in the main proceedings is proportionate, and in particular as to whether the objective sought might be achieved by less extensive prohibitions or restrictions or by prohibitions or restrictions having less effect on intra-[Union] trade, *calls for an analysis of the circumstances of law and of fact which characterise the situation in the Member State concerned, which the national court is in a better position than the Court of Justice to carry out*.[1348]

The argument could be made that the national court is *in principle* better positioned than the Court to conduct any complex assessment such as that required by proportionality.[1349] This especially true of lifestyles which are usually deeply engrained in national practices. In *Rosengren*, a case involving complex and localised facts, the Court would have had all the reasons to leave the Swedish court have the final word regarding proportionality but nonetheless decided to rule on the issue directly. This reinforces the feeling that the decision as to whether or not to refer back to the national Court is a case management tool used at the Court's discretion rather than a sound and reliable practice.

Many factors have been put forward to explain variations in the Court's proportionality assessment and to offer more predictability in this regard – how restrictive of free movement a national measure is, which defence is put forward by the Member State, etc. – [1350] none of which really offer a reliable yardstick. As it is the case for the rest of the free movement case-law, the fate of national lifestyle risks measure seems to be partly based on randomness. It is

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[1346] *Visnapuu* (n 703) in particular. See also *Commission v France* (n 896); *Ahokainen* (n 869) and *Scotch Whisky* (n 612).

[1347] *Franzen* (n 797), in particular, see also *Heinonen* (n 501) and *Bacardi France* (n 896). Regarding the latter judgment, the difference with Commission v France can be explained by the different procedures at stake in the two judgments, an infringement procedure for Commission v France, where the Court needs to rule directly on the validity of the Member States measures and needs to examine all the arguments made by the Commission; a preliminary reference procedure for Bacardi France, where the Court only gives guidance to the national court.

[1348] *Gourmet* (n 879), para 33, emphasis added. See also *Visnapuu* (n 703), para 119; *Scotch Whisky* (n 612), para 49. More generally on this issue, see Barbou Des Places (n 1072) 198–200; Valérie Michel, 'Contrôle de Proportionnalité et Balance des Intérêts : Variation du Contrôle Selon les Intérêts Invoqués par l'État' in Neframi (n 1072).

[1349] There may also be good reasons to have the Court ruling directly on proportionality, in particular to prevent too much variation in the application of EU law at the national level: see Craig, *EU Administrative Law* (n 130) 691–692.

[1350] For a good overview, see Barbou Des Places (n 1072).

also explained by the variations in Member States' argumentative strategies. After all, 'the scope of the discussion is framed by the arguments submitted'.[1351]

If now considering the lifestyle risks category as a whole, some elements of comparison can also be drawn with the rest of the free movement case-law. Save for the particular case of gambling, the Court follows mostly a two-pronged structure and applies proportionality in a similar fashion. The Court rarely declares a measure to be unsuitable to the achievement of the purported objective, save for cases of clear inconsistency. Member States lose their case either way because they do not show that their measure pursues a legitimate interest, failing to establish the reality of the risk alleged, or because their measure goes beyond what is necessary to protect this legitimate interest. There is no formal balancing act through a third 'true' proportionality test, meaning that, as can be seen in many other free movement cases, the Court usually resorts to a strict, and often misguided application of suitability or necessity to discard national measures whose restrictive effect is deemed too important.

This begs the question as to whether Member States really decide of the level of protection to be granted, as it is supposed to be the case in public health, and whether they do benefit from a more generous margin of appreciation than in other areas affected by free movement. Does an analysis of the lifestyle risks case-law support the idea that the Court applies a lighter degree of scrutiny in free movement cases involving public health arguments? [1352] The short answer is no.[1353] Nothing suggests a specific relaxation of the justificatory requirements and the proportionality test if compared to other fields.[1354] A margin of discretion can surely be identified in some cases,[1355] but it is not granted by the Court in a systematic way.

Some judgments, like *Rosengren* and *Scotch Whisky*, in their own ways, are a prime example of what Norbert Reich describes as a 'quasi-legislative' approach of proportionality, where the Court ventures deep into the choices made by the national legislator.[1356] The problem with this approach is that it disregards 'certain elements of a state measure [that] may be excessive if seen in isolation, but [that] may still be justified in a complex policy area where different public

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[1351] Nic Shuibhne and Maci (n 1025) 979.
[1352] See Estelle Brosset, 'La justification aux entraves aux libertés pour des raisons de protection de la santé' in Brosset, *Droit européen et protection de la santé – Bilan et perspectives* (n 499) 107.
[1353] This is also true for public health generally. See e.g Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes e.a.* [2009] EU:C:2009:316; *Blanco Pérez* (n 966); *Venturini* (n 966); *Deutsche Parkinson* (n 694).
[1354] Evaluating the intensity of the proportionality review is always challenging, for one must first decide which criterion to use to for this purpose: length of the analysis, discussion of alternative measures, standard of evidence required, tolerance of Member States' mistakes or not, etc. See Barbou des Places (n 1072) 192-195. For a similar appraisal that the Court's proportionality assessment in health cases is not necessarily less intense, see Michel (n 1348), 217-218.
[1355] This is very clear in *Heinonen* (n 501), *Bacardi France* (n 896). In *Heinonen*, Advocate General Saggio, unlike the Court, discussed alternatives to the Finish rule and seemed to believe that it went beyond what was strictly necessary to the attainment of its objective. Compare *Heinonen* (n 501), paras 42-44 and Case C-394/97 *Heinonen* [1999] EU:C:1999:10, Opinion of Advocate General Saggio, paras 34-45. See also Baumberg and Anderson, "Health, Alcohol and EU Law: Understanding the Impact of European Single Market Law on Alcohol Policies' (n 34).
[1356] Reich (n 1335).

interests are at stake and choices have to be made respecting democratic procedures'.[1357] In a number of cases, 'the Court's understanding of Member State legislation is not a political one where complex choices and preferences are decided, but […] one where the abstract market rationale prevails over the political bargaining process'.[1358] This effectively prevents national authorities from conducting risk management processes where all voices and interests are adequately taken into account.

It is hard to draw an overall conclusion as to the actual effect of free movement and the associated legal proceedings on the policy of Member States. In Sweden and Finland, it did result in a profound evolution of the monopoly on alcohol,[1359] leading to the abolition of the import, export and wholesale monopolies upon accession. This followed a demand by the European Commission, who considered the monopolies to be too restrictive of trade and not proportionate to their public health objective.[1360] In *Franzen* and *Rosengren*, important features of the Swedish alcohol monopoly had to be abandoned. Does this mean overall that the Court's case-law has led to a worsening of the health situation in the EU? Drawing a definitive conclusion would require an in-depth analysis of the effect of EU law on the situation at the national level, but it seems however unlikely to have been the case.[1361] Caoimhín MacMaoláin's contention that free movement 'has actually led to a depreciation in the nutritional value of food, or at the very least removed the possibilities for Member States to ensure that food marketed on their territory is of the highest nutritional standard'[1362] would need to be proven with hard evidence. Equally, it also seems difficult to identify a strong unification of regulatory practices. The Nordics retain their unique alcohol monopolies and France has successfully kept its Loi Evin in place, which is one of the strictest legislative measures regarding alcohol advertising in the EU.

Hence rather than a possible deregulatory effect, the main problem with the Court's case-law lies with the way in which the outcome in the various judgments is reached. It is a problem of throughput legitimacy rather than one of output legitimacy, to borrow concepts usually used to assess the democratic credentials of the EU, the former understood as 'the efficacy, accountability, openness and inclusiveness of the governance processes'.[1363] The Court treats comparable health problems or measures differently, offering little by way of understanding the variations in its decisions. More coherence and predictability would help. In particular, greater and more systematic engagement with evidence and better guidance given to the

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[1357] Reich (n 1335) 103.
[1358] ibid 111.
[1359] Kurzer, *Markets and Moral Regulation: Cultural Change in the European Union* (n 401) 84-85 ; Sébastien Guigner, 'L'influence de l'Union européenne sur les pratiques et politiques de santé publique : européanisation verticale et horizontale' (2011) *29 Sciences sociales et santé* 81, 88-89 ; Thomas Karlsson, *Nordic Alcohol Policy in Europe: The Adaptation of Finland's, Sweden's and Norway's Alcohol Policies to a New Policy Framework 1994–2013* (Doctoral thesis Åbo Akademi University 2014) 63-65.
[1360] *Franzen*, Opinion of Advocate General Elmer (n 814), paras 4-5. See also Ugland (n 1285).
[1361] Regarding alcohol, see Baumberg and Anderson, 'Health, Alcohol and EU Law: Understanding the Impact of European Single Market Law on Alcohol Policies' (n 34).
[1362] MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 222-233.
[1363] Vivien A Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and "Throughput"' (2013) 61 Political Studies 2, 3.

national courts would constitute welcome developments. For the first of these purposes, the Court could make greater use of the impact assessments drawn up at the national level, as it briefly did in *Scotch Whisky* and as it more routinely does when scrutinising measures adopted by the EU legislator (see Chapter 7). A more frequent recourse to experts could also be explored, as well as a reinforcement of the in-house research services of the Court of Justice. Ultimately, any such evolution would have important practical and procedural consequences. As for better guidance, it should apply both to the standard of proof and standard of review, to ensure that a greater role for national courts in preliminary references does not lead to more disparate outcomes.

Part III

Regulation of lifestyle risks at the EU level: the internal market as an auxiliary to health promotion?

Chapter 5

EU promotion of healthy lifestyles: policy objectives, restrictions and disincentives

1. Introduction

The EU has developed over the years a legal and policy framework aimed at fostering healthier lifestyles, complementing action undertaken at the national level. Diminishing the health burden on individuals and society resulting from hazardous lifestyles has progressively become one of the EU's main priorities in the area of public health. Three main risk factors, tobacco, alcohol and diets, are at the core of EU lifestyle risks policy. Gambling and illicit drugs, for different reasons, stand out. Gambling is still mostly envisaged as an economic activity rather than a public health risk and is only weakly regulated at the EU level. Trade in illicit drugs, conversely, does not constitute a legitimate economic activity. It is hence subject to an entirely different legal framework, part of the EU's policy on judicial cooperation in criminal matters.

To prevent or discourage unhealthy behaviours, the EU has adopted various measures, as part of a regulatory mix. These may be regrouped into four main categories: measures that restrict choice by prohibiting the placing on the market of certain products or setting the composition thereof, tax measures which disincentivise the unhealthy choice, rules that restrict or prohibit the use of commercial communications and, finally, rules which regulate the information given to the consumer. These types of interventions largely correspond, in a descending order, to that of the Nuffield ladder described in Chapter 1. The two first categories of measures are analysed in the present chapter, along with the general policy orientations adopted by the EU regarding lifestyle health promotion. The next chapter is devoted to rules on commercial communications and information, as well as non-binding rules or schemes adopted by the EU, which are situated at the lowest end of the intervention ladder.

Beyond the systematic description and classification of EU lifestyle interventions, the developments in Chapter 5 and 6, which should be considered together, serve three purposes. The first is to confront the regulatory tools used by the EU with the stated objectives of its lifestyle risks policy, to assess the adequacy of these tools and suggest, where pertinent, avenues for reform. The second is to highlight the vast regulatory differences that exist across lifestyle risk factors and to critically evaluate the justifications for such a differential treatment. The third, finally, linked to the overall theme of this thesis, is to show the intertwining of health and internal market objectives in EU lifestyle risks policy and to offer a first illustration of the legal frictions resulting from it.

2. EU lifestyle risks policy: strategies and objectives

This section provides an overview of EU policy on lifestyle risks, from its inception in the 1980s/1990s to its current state, both at a general level and specific to each risk factor. The myriad of policy and strategy documents adopted by the different EU institutions, in the form of communications, conclusions or resolutions, give an idea of how the EU envisions unhealthy

lifestyles and sees its role in addressing them. Overall, from a primarily internal-market driven policy, taking information and consumer empowerment as lodestars, EU action on lifestyle has progressively gained a more distinctive public health character. These common characteristics should not hide the diversity of approaches taken across risk factors, which will become more and more apparent as the chapter progresses.

2.1. The emergence and development of an EU policy on lifestyle risks

While health only formally became a competence of the Union with the Maastricht revision of the EC Treaty,[1364] which entered into force on 1 November 1993, health concerns were somewhat present from the early days of European integration.[1365] Action on health was conducted in a uncoordinated and patchy way, with most initiatives relating to the free movement of goods, services and economically active citizens: social security coordination, recognition of medical qualifications, safety of medicinal products, food safety, etc.[1366] Some early measures 'did have the potential to impact on lifestyles [but] were incremental and, as such, only by-products of the internal market rather than a systematic attempt to promote healthy lifestyles'.[1367]

A notable exception to this state of affairs was the EU's action against cancer, starting from the mid-80s, which constituted a first incursion of the Union in the area of health promotion (see also Chapter 2, Section 2.2). In 1986, the Council adopted a first Resolution on a programme of action against cancer.[1368] Despite its embryonic character, this resolution already laid down some of the defining features of EU lifestyle risks policy. It stated in particular that:

> [B]y ensuring a wider dissemination of knowledge of the causes, prevention and treatment of cancer […] in particular concerning the nature and degree of risk of cancer arising from exposure to given substances or processes, the programme will contribute to the achievement of Community objectives, *in particular the removal of nontariff barriers to trade*, *while contributing to the overall reduction of risks of cancer*.[1369]

The dual character of EU lifestyle risks action, improving the functioning of the internal market while contributing to a high degree of public health protection, is here for the first time clearly

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[1364] The first health legal basis was Article 129 EC, now Article 168 TFEU.
[1365] The creation of a 'European Health Community' had for instance been contemplated before the European Economic Community was even born in 1957, although it would ultimately not come to life. See Alban Davesne and Sébastien Guigner, 'La Communauté Européenne de la Santé (1952-1954) : Une Redécouverte Intergouvernementaliste du Projet Fonctionnaliste de « Pool Blanc »' (2013) 41 Politique Européenne 40.
[1366] See Mary Guy and Wolf Sauter, 'The History and Scope of EU health Law and Policy' in Hervey, Calum Young and Bishop (n 37) 23-29; Hervey and McHale (n 37) 31-40. See also Tamara Hervey and Anniek De Ruijter, 'The Dynamic Potential of European Union Health Law' (2020) 11 European Journal of Risk Regulation 726, 723-724.
[1367] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1747.
[1368] Council of the European Union, Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council of 7 July 1986, on a programme of action of the European Communities against cancer (Resolution on a programme of action against cancer) [1986] OJ C184/19.
[1369] ibid 19, emphasis added.

expressed. Further, the orientations contained in the 1986 programme against cancer are still very much reflected in today's EU regulatory landscape. The priority is set on tobacco, for which 'rules on advertising, rules on labelling, tax legislation, sponsorship, enforcement of no-smoking rules, extension of no-smoking areas' could be adopted, 'if appropriate', at the European level.[1370] Nutrition and alcohol are only briefly mentioned, the Resolution stressing the necessity, as regards alcoholic beverages, to 'tak[e] account of differing circumstances and habits in the Member States'.[1371] This would become one of the leitmotivs of the EU on alcohol.

A Commission statement from that period highlights the importance given to lifestyle health promotion in the fight against cancer.

> It is generally accepted that some 70% of deaths linked to cancer stem from *personal choices governing lifestyle* and environment. Consequently, regardless of medical advances there will be no major reduction in the incidence of cancers and mortality linked to this disease *unless the public can be persuaded to modify certain habits and attitudes*. Therefore, people need *information* to allow them to *choose a lifestyle* providing *maximum protection* against the risk of contracting certain cancers, although such risks can never be totally banished.[1372]

Here as well, a key feature of the EU's approach towards lifestyles can be identified: the emphasis on personal choice and the belief that individuals, once properly informed of the reality of a risk, are able to adjust their behaviour to protect themselves against it. This vision has profoundly shaped the EU's response in the field, although, as we shall see, it has moved beyond this naïve and limited view of what lifestyle health promotion entails.

Three action plans on cancer were adopted for the years 1987 to 1989, 1990 to 1994 and 1996 to 2000.[1373] The set goal was to reduce cancer mortality by 15% between 1987 and 2000.[1374] During this period, various incentive measures were adopted, relating in particular to the dissemination of information to the public, the sharing of data and good practices between Member States and the financing of European projects. EU legislative action was mainly concerned with tobacco, with the adoption of two instruments on the labelling of tobacco

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[1370] ibid 20.
[1371] ibid.
[1372] European Commission, 'Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Evaluation of the European cancer week 1995', COM (97) 19 final, 5.
[1373] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 [1987] OJ C50/1; Decision 90/238/Euratom, ECSC, EEC of the Council and the Representatives of the Governments of the Member States meeting within the Council, on 17 May 1990 adopting a 1990 to 1994 action plan in the context of the "Europe against Cancer" programme [1990] OJ L137/31; Decision No 646/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000) [1996] OJ L95/9.
[1374] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (n 1373), 8. A study found that 'the number of cancer deaths observed in 2000 compared with that expected based on mid-1980s age-specific mortality rates, was reduced by 10% in men in the EU, while in women it decreased by 8%'. It concluded that '[a]lthough the target of a 15% reduction was not met, the effects of the programme should by no means be viewed as a failure': Peter Boyle and others, 'Measuring Progress against Cancer in Europe: Has the 15% Decline Targeted for 2000 Come About?' (2003) 14 Annals of Oncology 1312, 1322.

products and the tar yield of cigarettes,[1375] and the introduction of an advertising ban for tobacco products on television.[1376]

It is only after Maastricht that a genuine EU health policy would be devised, starting with the release in 1993 of the Commission Communication on the framework for action in the field of public health.[1377] As can be read from the following excerpt, action on lifestyles is already a priority:

> [T]he scope of public health activities can be delineated by a consideration of the risks to the health of the members of a community, and of the steps needed to protect individuals within that community from those risks and to increase the likelihood of their living a full and healthy life. Apart from risks to health related to individual genetic, physical and mental make-up, risks to health derive both from *one's chosen lifestyle* and one's immediate surroundings, in particular at home and work, and *from the local environment* - the combination of social, economic and cultural conditions that provide the general context for people's lives. *Thus the steps required to protect individuals' health must address both of these "environments"*.
>
> While the actions and programmes of the public authorities have dominated the development of public health strategies, in the last three decades public health interest has focused increasingly on the *responsibility of the individual* for his/her own health and the *modifications he can make to his/her own behaviour* to prevent the onset of disease. Such considerations have been applied to *diet, the taking of sufficient exercise, the avoidance of dangerous and toxic substances, including drug abuse*, and the prevention of accidents.[1378]

Although the environmental and structural determinants of health are not ignored in that document, the focus on individual choice and responsibility is still very much present. Further in the Communication, emphasis is also laid on the rising health costs faced by Member States. A 'health is wealth' approach is taken, whereby 'health can be improved and demands upon health care and treatment services can be controlled [and] the Community's productive capacity can be maximised and simultaneously the costs of ill health reduced'.[1379] The text nonetheless stresses that 'most important[ly], safeguarding health, as well as producing economic advantages can also improve the quality of life, which will have inestimable benefits both for the individual as well as for society as a whole'.[1380]

[1375] Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products [1989] OJ L359/1; Council Directive 90/239/EEC of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes [1990] OJ L137/36.

[1376] Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities [1989] OJ L298/23 (Television without Frontiers (TWF) Directive), art 13.

[1377] European Commission, 'Commission Communication on the framework for action in the field of public health', COM (93) 559 final.

[1378] ibid 6.

[1379] ibid 4-5. See also European Commission, 'Together for Health: A Strategic Approach for the EU 2008-2013' (n 505) 5. On this 'health is the greatest wealth approach', see the analysis of Mark L Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart Publishing 2015) 49-54.

[1380] European Commission, Commission Communication on the framework for action in the field of public health (n 1377) 4-5.

Tackling unhealthy lifestyles has remained a key focus of EU health policy. In the 2000 Commission Communication on the health strategy of the European Community, action on health determinants features as a main priority, including measures addressing 'key lifestyle factors, such as smoking, alcohol, nutrition, physical activity, stress and drug abuse', with a focus on young people, 'since key decisions on lifestyle and health-related behaviour are taken in youth and adolescence'.[1381] This was continued in the three consecutive programmes for Community and Union action in the field of public health (2003-2008, 2008-2013, 2014-2020).[1382] During this period, the Council also adopted two sets of conclusions on lifestyles, the 2003 Conclusions on 'healthy lifestyles: education, information and communication'[1383] and the 2011 Conclusions on 'closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours'.[1384] In 2017, the three Commissioners for Health, Agriculture and Sports[1385] signed the 'Tartu Call for a Healthy Lifestyle', a pledge of fifteen commitments aimed at boosting the adoption of healthy lifestyles by Europeans, here focused mostly on physical activity and dietary choices.[1386] In 2018, to support Member States in reaching their objectives, the Commission created a Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases.[1387]

The fourth and current programme for Union action in the field of health, or 'EU4Health Programme', spanning from 2021 to 2027, while being heavily influenced by the Covid-19 pandemic and its consequences, also shows the enduring importance of action on lifestyles.[1388] The programme's first general objective remains to 'improv[e] and foster[…] health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting

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[1381] European Commission, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the health strategy of the European Community, COM (2000) 285 final, 3.1.

[1382] See Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) [2002] OJ L271/1, art 2(2)(c); Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) [2007] OJ L301/13, art. 2(2); Regulation 282/2014, art 3(1).

[1383] Council of the European Union, Council Conclusions of 2 December 2003 on healthy lifestyles: education, information and communication [2004] OJ C22/1.

[1384] Council of the European Union, Council Conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours [2011] OJ C359/5.

[1385] Tibor Navracsics, Commissioner for Education, Culture, Youth and Sport; Vytenis Andriukaitis, Commissioner for Health and Food Safety; Phil Hogan, Commissioner for Agriculture and Rural Development.

[1386] Available at <https://ec.europa.eu/sport/sites/sport/files/ewos-tartu-call_en.pdf> accessed 11/05/2023. The commitments consisted of incentives measures and not of concrete legislative action. For the evaluation of the action taken 2 years later, see <https://ec.europa.eu/commission/presscorner/detail/en/IP_19_3028> accessed 11/05/2023.

[1387] Commission Decision of 17 July 2018 setting up a Commission expert group 'Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases' and repealing the Decision setting up a Commission expert group on rare diseases and the Decision establishing a Commission expert group on Cancer Control [2018] OJ C251/9.

[1388] Regulation 2021/522.

health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare'.[1389]

After a 'loss of momentum'[1390] of over two decades, during which no specific programmes or action plans were adopted,[1391] the release of a new 'Europe's Beating Cancer Plan' in 2021 provided a new impetus for EU action in the field of cancer,[1392] and on lifestyles more generally. It is by far the EU's most ambitious cancer plan to date, reaffirming the importance of preventive action in view of the disease's growing burden in Europe:

> Cancer concerns us all in one way or another. In 2020, 2.7 million people in the European Union were diagnosed with the disease, and another 1.3 million people lost their lives to it. Cancer is an individual diagnosis that has important impacts on patients, but it also severely affects the lives of their families and friends. Today, Europe accounts for a tenth of the world's population, but a quarter of the world's cancer cases. *Unless we take decisive action, lives lost to cancer in the EU are set to increase by more than 24% by 2035, making it the leading cause of death in the EU*. The overall economic impact of cancer in Europe is estimated to exceed €100 billion annually.[1393]

In relation to lifestyles, the plan sets the three following objectives, 'achieving a tobacco-free Europe', 'reducing harmful alcohol consumption' and 'improving health promotion through access to healthy diets and physical activity',[1394] and puts forward a number of initiatives for each of these risk factors, to which we will refer in their respective sections.

The centrality of lifestyles in EU cancer prevention efforts appears nowhere more clearly than in the European Code Against Cancer, the '10 European commandments for cancer prevention',[1395] a rulebook containing simple and actionable recommendations for Europeans to limit their cancer risk. Twelve rules feature in the current fourth edition of the Code,[1396] adopted in 2015, out of which the first six are lifestyle-related:

1. Do not smoke. Do not use any form of tobacco.
2. Make your home smoke free. Support smoke-free policies in your workplace.
3. Take action to be a healthy body weight.
4. Be physically active in everyday life. Limit the time you spend sitting.

[1389] ibid, art 3(a).
[1390] Louise Trubek, Mark Nance and Tamara Hervey, 'The Construction of Healthier Europe: Lessons from the Fight against Cancer' (2008) 26 Wisconsin International Law Journal 804.
[1391] An exception to this stalemate is to be found in the European Partnership for Action Against Cancer, adopted in 2009 for a duration of four years, which provided a platform to support Member States' efforts to tackle cancer via the sharing of information and knowledge, and the holding of discussions between relevant stakeholders (Member States, health experts, civil society representatives, industry, etc.). See European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Action Against Cancer: European Partnership', COM (2009) 291 final.
[1392] European Commission, 'Europe's Beating Cancer Plan' (n 23).
[1393] ibid 2.
[1394] ibid 8-11.
[1395] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (n 1373), 32.
[1396] The first three editions of the Code were published in 1987, 1994 and 2003.

5. Have a healthy diet:
   - Eat plenty of whole grains, pulses, vegetables and fruits.
   - Limit high-calorie foods (foods high in sugar or fat) and avoid sugary drinks.
   - Avoid processed meat; limit red meat and foods high in salt.

6. If you drink alcohol of any type, limit your intake. Not drinking alcohol is better for cancer prevention.[1397]

This Code is interesting on several grounds. Once again, the emphasis on individual choice and responsibility is apparent,[1398] although the Code has changed in this regard, since it no longer invites Europeans to 'avoid becoming overweight',[1399] seemingly suggesting that being overweight is simply a matter of choice. The different amendments made to the Code reveal the evolution of scientific knowledge since it was first published in 1987. While the first version only invited Europeans to 'moderate [their] consumption of alcoholic drinks',[1400] the current version now clearly acknowledges that 'not drinking alcohol is better for cancer prevention'. The first version did also not mention processed or red meat,[1401] the consumption of which is now linked by a growing body of evidence to several types of cancer.[1402]

Most interestingly perhaps, the Cancer Code lays down some of the main orientations of EU lifestyle risks policy as regards specific risk-factors, to which we will turn in the next section. Tobacco should be avoided without any qualification, including in smokeless form. One should ideally not drink alcohol, but the overall statement is written so as to raise 'awareness of the increased risk of cancer resulting from consumption of any amount of alcohol, consistent with current evidence, [while] not recommending total abstinence'.[1403] Regarding nutrition, the words have also been carefully chosen. The terms 'avoid' and 'limit' were selected to reflect the fact that the authors of the Code did not expect the public to entirely cut on unhealthy foods, a suggestion that was seen as unrealistic.[1404] Hence, although it is based on robust scientific evidence regarding cancer risk, the Code incorporates other aspects that reflect the relative value held by some unhealthy habits if compared to one another. Whereas cutting drastically on alcohol consumption would bring far more benefits to Europeans and their societies than

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[1397] Available at <https://cancer-code-europe.iarc.fr/index.php/en/> accessed 11/05/2023. For the methodology and evidence underpinning the current version of the code, see Joachim Schüz and others, 'European Code against Cancer 4th Edition: 12 Ways to Reduce Your Cancer Risk' (2015) 39 Cancer Epidemiology 1.

[1398] Although a footnote to the Code does mention the following: 'The European Code Against Cancer focuses on actions that individual citizens can take to help prevent cancer. Successful cancer prevention requires these individual actions to be supported by governmental policies and actions.'

[1399] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (n 1373) 32.

[1400] ibid.

[1401] ibid 32-33.

[1402] Luis D Boada, LA Henríquez-Hernández and OP Luzardo, 'The Impact of Red and Processed Meat Consumption on Cancer and Other Health Outcomes: Epidemiological Evidences' (2016) 92 Food and Chemical Toxicology 236; Abou Diallo and others, 'Red and Processed Meat Intake and Cancer Risk: Results from the Prospective NutriNet-Santé Cohort Study' (2018) 142 International Journal of Cancer 230.

[1403] Schüz and others (n 1397) 6.

[1404] ibid.

avoiding smokeless tobacco, it is probably more realistic to expect a total abstinence from niche tobacco products than it is for alcohol.

2.2. Towards a smoke-free Europe

Since the 1980s, the EU has taken resolute action to reduce smoking prevalence in the EU population and positioned itself as a leader in global tobacco control. Reflecting the drastic evolution of tobacco's perception in the second half of the 20th century, from a fashionable and elitist practice to a habit scorned as filthy, early EU action was actually 'almost completely concerned with promotion rather than control'.[1405] Tobacco was included in the Common Agricultural Policy and became 'proportionately the most heavily EU-subsidized crop, with much greater financial support than tobacco reduction efforts'.[1406] Tobacco products, as other commodities, were also subject to free movement rules, constraining Member States in their regulatory choices.

It is only with the first cancer programme that the EU's grappling with tobacco gained a distinctive public health turn. Tobacco is from the onset the main priority of EU cancer policy.[1407] The first action plan identifies a wide range of policy options for EU level action: upward alignment of tobacco taxation, harmonisation of health warning and of products composition, rules restricting smoking in public places, etc.[1408] In 1989, in addition to the two directives on tobacco labelling and the tar yield of cigarettes,[1409] a prohibition of television advertising for tobacco products was adopted as part of the Television Without Frontiers (TWF) Directive.[1410] These texts significantly improved tobacco prevention in some countries that had not adopted any relevant legislation until then.[1411]

In 1996 and 1999, respectively, the Council adopted a resolution on the reduction of smoking and a set of conclusions urging the European Commission to adopt an overall strategy aimed at diminishing the prevalence of tobacco use in the European population,[1412] in reaction perhaps to the lack of new initiatives being launched on that front. Although no comprehensive EU strategy on tobacco would ever be devised by the Commission, contrary to what would be the case for nutrition, alcohol and illicit drugs, the early 2000s saw the adoption of two important

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[1405] Donley T Studlar, 'Tobacco Control: The End of Europe's Love Affair with Smoking?' in Greer and Kurzer (n 37) 186. See also Martin McKee, Tamara Hervey and Anna Gilmore, 'Public health policies' in Mossialos and others, *Health Systems Governance in Europe: The Role of EU Law and Policy* (n 37) 57.
[1406] Studlar (n 1405) 186. See also Hervey and McHale (n 37) 390.
[1407] Council of the European Union, Resolution on a programme of action against cancer, 20.
[1408] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (n 1373).
[1409] Council Directive 89/622 and Council Directive 90/239.
[1410] Television Without Frontiers Directive, art 13.
[1411] McKee, Hervey and Gilmore (n 1405) 257-258.
[1412] Council of the European Union, Council Resolution of 26 November 1996 on the reduction of smoking in the European Community [1996] OJ C374/4; Council of the European Union, Council conclusions of 18 November 1999 on combating tobacco consumption [1999] OJ C86/4.

instruments: Directive 2001/37 on tobacco products (the 2001 TPD),[1413] later revised and repealed, and the Tobacco Advertising Directive (TAD),[1414] still in force today.

Over the same period, the EU negotiated and concluded the Framework Convention on Tobacco Control (FCTC),[1415] the first and ever convention negotiated under the auspices of the WHO,[1416] which constitutes a distinctive effort of the international community to address the negative consequences of tobacco consumption. Due to the globalised nature of the tobacco epidemic, fuelled by a handful of powerful market players, the need was felt to have a common instrument in place that would help governments better coordinate their action and scale up their policies.[1417] An early actor in global tobacco control, the EU was a driving force in the negotiation and adoption of the FCTC.[1418] Along with the EU, the 27 Member States are also parties to it.[1419]

The FCTC is governed by the Conference of the Parties, whose main tasks is to regularly review the implementation of the FCTC and to take the necessary decisions in that effect.[1420] The Conference can adopt protocols and guidelines on specific FCTC articles. One protocol, the Protocol to Eliminate Illicit Trade in Tobacco Products, and eight guidelines have so far been adopted.[1421] The FCTC's core obligations are organised between demand reduction

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[1413] Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products [2001] OJ L194/26.

[1414] Directive 2003/33.

[1415] Council Decision of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control [2004] OJ L213/8.

[1416] The World Health Assembly, the decision-making body of the WHO, can adopt three kinds of normative instruments: conventions, regulations and recommendations. See Constitution of the World Health Organisation, Basic Documents (n 143) arts 19, 21 and 23.

[1417] The objective of the FCTC 'is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke': FCTC, art 3.

[1418] Hadii M Mamudu and Donley T Studlar, 'Multilevel Governance and Shared Sovereignty: European Union, Member States, and the FCTC' (2009) 22 Governance: An International Journal of Policy, Administration, and Institutions 73; Miriam Faid and David Gleicher, 'Dancing the Tango: The Experience and Roles of the European Union in Relation to the Framework Convention on Tobacco Control' (2011) Global Health Europe. The European Commission was tasked to negotiate the FCTC on behalf of the EU by a Council mandate in 1999 and is the body that represents the Union at the Conference of Parties today: see European Commission, 'Health and Consumer Affairs: Successful Council meeting on 2 December' (2002), <https://ec.europa.eu/commission/presscorner/detail/en/MEMO_02_278> accessed 11/05/2023. On the FCTC negotiation process, see Mamudu and Studlar (n 1418) 86-87; Faid and Gleicher (n 1418).

[1419] There are currently 182 parties to the FCTC, covering more than 90% of the world population. The list of parties is available at the following link: <https://fctc.who.int/who-fctc/overview/parties> accessed 11/05/2023. The EU is the only non-state party to the FCTC.

[1420] For further details on the development and functioning of the FCTC, see Suzanne Zhou and Jonathan Liberman, 'The Global Tobacco Epidemic and the WHO Framework Convention on Tobacco Control—the Contributions of the WHO's First Convention to Global Health Law and Governance' in Gian Luca Burci and Brigit CA Toebes (eds), *Research Handbook on Global Health Law* (Edward Elgar Publishing 2018).

[1421] The guidelines can be retrieved at <https://www.who.int/fctc/treaty_instruments/adopted/en/> accessed 11/05/2023.

provisions and supply reduction provisions. Demand reduction provisions (Articles 6 to 14) cover price and fiscal measures, rules on the protection from exposure to tobacco smoke, regulation of the contents of tobacco products and their disclosures, rules on packaging and labelling, measures aiming at informing and educating the public and, finally, measures restricting tobacco advertising, promotion and sponsorship. Supply reduction provisions (Articles 15 to 17) cover measures to fight illicit trade in tobacco products and to prevent sales to and by minors.[1422]

The FCTC has been hailed as a success and a model for international cooperation in other fields of health.[1423] A ten-year review of the application of the FCTC (2005-2015) found an overall positive impact on global tobacco control and an effectiveness of the recommended policies.[1424] It noted however that 'considerable variability [existed] in the overall rate and extent of progress in the implementation of tobacco control legislation across countries and policy domains'.[1425] Within its sphere of competence, the EU has largely implemented the FCTC.[1426]

The Tobacco Products Directive, adopted in 2014 as a revision of the former 2001 instrument, is the EU's main effort to implement the key demand and supply reduction measures contained in the FCTC.[1427] Wide in coverage – it includes tobacco products for smoking,[1428] smokeless tobacco products[1429] and non-tobacco related products,[1430] such as e-cigarettes – the TPD

[1422] In *Agenzia delle dogane* (n 132), the Court of Justice ruled that, in implementing Article 16 of the FCTC on the prohibition of sales to minors, Italy complied with the principle of proportionality. The Italian rule provided, in the case of a first infringement of the prohibition on selling tobacco products to minors, in addition to the imposition of an administrative fine, for the suspension, for a period of 15 days, of the trading licence authorising the economic operator who has infringed that prohibition to sell such products.

[1423] Zhou and Liberman (n 1420); Gian Luca Burci, 'A Global Legal Instrument for Alcohol Control: Options, Prospects and Challenges' (2021) 12 European Journal of Risk Regulation 499, 503–504.

[1424] Janet Chung-Hall and others, 'Impact of the WHO FCTC over the First Decade: A Global Evidence Review Prepared for the Impact Assessment Expert Group' (2019) 28 Tobacco Control 119. On the on the effectiveness of FCTC measures to lower smoking prevalence and bring positive health effects, see also Shannon Gravely and others, 'Implementation of Key Demand-Reduction Measures of the WHO Framework Convention on Tobacco Control and Change in Smoking Prevalence in 126 Countries: An Association Study' (n 448).

[1425] Janet Chung-Hall and others (n 1424) 121.

[1426] See the 2020 report of the European Union to the FCTC, accessible at <https://untobaccocontrol.org/impldb/wp-content/uploads/EU_2020_WHOFCTCreport.pdf> accessed 11/05/2023.

[1427] Tobacco Products Directive, art 1. See also recitals 7, 15, 24 and 29.

[1428] Under the TPD, tobacco products are defined as 'products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not': art 2(4). Tobacco is further defined as 'leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco': art 2(1).

[1429] Under the TPD, STPs are tobacco products that do not involve a 'combustion process': art 2(5). The term 'combustion' is not itself defined in the TPD, which has led to implementation difficulties for Member States, in particular in relation to HTPs and their heating process. This has prompted calls for the inclusion of a definition of that term in the next revision of the Directive. See European Commission, Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products, COM (2021) 249 final, 11; European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 25-26, 32 and 112.

[1430] These are herbal products for smoking and electronic cigarettes and their refill containers. Other products related to tobacco but that do not contain tobacco, such as nicotine pouches, are not currently regulated under the

introduced some of the key elements of the EU's current tobacco control framework: large and mandatory textual and pictorial health warnings, ban on characterising flavours in tobacco products, rules on e-cigarettes and traceability system to fight illicit trade.[1431] It is the main piece of EU tobacco legislation in vigour today.

Although ambitious on substance, the TPD illustrates the difficulty for the EU to prevent undue interference from the tobacco industry in its policy process. The TPD is considered to have been 'the most lobbied dossier in the history of the EU institutions'.[1432] The industry deployed a massive lobbying effort, securing access to the highest echelon of EU decision-making. This culminated with the resignation of the Health Commissioner John Dalli in 2012 following allegations of bribe solicitation from the tobacco manufacturer Swedish Match.[1433] It is considered that tobacco industry tactics managed to delay the TPD adoption process by several years and to have some provisions, such as plain packaging and tobacco display ban, removed from the final legislative proposal.[1434]

The permeability of the EU to tobacco corporate interests has been an enduring problem, putting the Union in breach of its obligations under Article 5(3) of the FCTC. This provision requires that tobacco control policies are protected from 'commercial and other vested interests of the tobacco industry', on grounds of a 'fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests'.[1435] The EU has failed to properly implement Article 5(3) FCTC and to comply with the specific guidelines attached to it.[1436] In a decision rendered in 2016, the European Ombudsman concluded that the Commission's refusal to publish online details of all the meetings held with the tobacco

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TPD. Nicotine pouches are a form of oral nicotine product, smokeless and tobacco-free, similar in use to tobacco for oral use. Nicotine pouches are far less toxic than cigarettes and estimates of exposure suggest that they may be positioned between snus and nicotine replacement therapies on the tobacco and nicotine toxicant continuum: see David Azzopardi, Chuan Liu and James Murphy, 'Chemical Characterization of Tobacco-Free "Modern" Oral Nicotine Pouches and Their Position on the Toxicant and Risk Continuums' (2022) 45 Drug and Chemical Toxicology 2246. Non-tobacco nicotine-containing products were included in the original TPD legislative proposal but were later excluded from the scope of the Directive during the legislative procedure. See European Commission, Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (TPD Proposal) COM (2012) 788 final, art 18.

[1431] See European Commission, '10 key changes for tobacco products sold in the EU' (2016), <https://ec.europa.eu/commission/presscorner/detail/en/IP_16_1762> accessed 11/05/2023.

[1432] Silvy Peeters and others, 'The Revision of the 2014 European Tobacco Products Directive: An Analysis of the Tobacco Industry's Attempts to "Break the Health Silo"' (2016) 25 Tobacco Control 108, 108. See also University of Bath, 'New tobacco directive "the most lobbied dossier" in EU history' (2015) Press Release, <https://www.bath.ac.uk/announcements/new-tobacco-directive-the-most-lobbied-dossier-in-eu-history/> accessed 11/05/2023; Florence Berteletti and others, 'Campaign for a Revised Tobacco Products Directive in the European Union: Lessons Learnt' (2017) 26 Tobacco Control 464.

[1433] ibid.

[1434] Peeters and others (n 1432) 109.

[1435] Conference of the Parties to the FCTC, 'Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry' (2008) Decision FCTC/COP3(7), Principle 1.

[1436] ibid.

industry constituted maladministration.[1437] It called on the institution to systematically inform the public of any meetings held between its staff, including junior officials, and tobacco lobbyists.[1438] These findings were repeated in 2023, after the Ombudsman conducted another probe into the European Commission's interactions with tobacco interest representatives.[1439] The Ombudsman observed in particular that the lack of proper record keeping made it difficult to assess whether the European Commission only interacts with the tobacco industry when and to the extent strictly necessary to regulatory endeavours, as per the FCTC guidelines on Article 5(3).[1440] More generally, a 2018 study showed a relative lack of awareness on the part of Commission officials and MEP as to the importance of keeping the political process free from tobacco industry interference and as to the various techniques used by the industry in this regard, due in part to the lack of a specific code of conduct.[1441]

Improvement on that front will prove all the more important as the EU is set to strengthen its tobacco control effort in the coming years.[1442] In the 2021 Beating Cancer Plan, the Commission spelled out for the first time its ultimate policy objective of creating a 'tobacco-free generation', with less than 5% of the European population using tobacco by 2040.[1443] This represents an ambitious target, as tobacco prevalence is still situated well over 20%. In that context, the Commission will make new proposals in all areas currently regulated under EU law: product regulation, taxation, commercial communications and smoke free environments.

The 'tobacco-free' objective pursued by the Commission can be associated with the 'endgame' strategy, a concept used within the public health community to suggest 'moving beyond tobacco control (which assumes the continued presence of tobacco as a common, widely available, ordinary consumer product) toward a tobacco-free future wherein commercial tobacco products would be phased out or their use and availability significantly restricted'.[1444] Proponents of the endgame solution, however, advocate measures that go far beyond those currently in place in the EU and those envisioned in the near future: decreasing or removing nicotine from cigarettes, setting up licences for smokers, selling cigarettes as prescription drugs

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[1437] European Ombudsman, 'Decision concerning the European Commission's compliance with the Tobacco Control Convention' (2016) Case 852/2014/LP. Regarding the European Ombudsman and its role, see Article 228 TFEU.

[1438] European Ombudsman, 'Decision concerning the European Commission's compliance with the Tobacco Control Convention', paras 21-22.

[1439] European Ombudsman, 'Preliminary findings in the OI/6/2021/KR on the European Commission's interactions with tobacco interest representatives' (2023).

[1440] ibid, p 3.

[1441] Benjamin Hawkins and Chris Holden, 'European Union Implementation of Article 5.3 of the Framework Convention on Tobacco Control' (2018) 14 Globalization and Health 79.

[1442] As regards current developments in EU tobacco policy and Article 5(3) of the FCTC, see the recent speech by the European Ombudsman: European Ombudsman, 'Importance of FCTC Article 5.3 in the EU context' (2021), <https://www.ombudsman.europa.eu/en/speech/en/139671> accessed 11/05/2023.

[1443] European Commission, 'Europe's Beating Cancer Plan' (n 23) 8.

[1444] Patricia A McDaniel, Elizabeth A Smith and Ruth E Malone, 'The Tobacco Endgame: A Qualitative Review and Synthesis' (2016) 25 Tobacco Control 594, 594. See also Ruth E Malone, 'The Race to a Tobacco Endgame' (2016) 25 Tobacco Control 607.

in pharmacies, restrict sales by year born, etc.[1445] In that regard, on 24 August 2022, the Commission officially registered a European citizen's initiative entitled 'Call to achieve a tobacco-free environment and the first European tobacco-free generation by 2030', whose first objective is to 'promote the first tobacco-free European generation by 2028, ending the sale of tobacco and nicotine products to citizens born since 2010'.[1446]

The Beating Cancer Plan also confirms the EU's approach towards alternatives to tobacco products, such as e-cigarettes and heated tobacco products, and its refusal to adopt a harm reduction strategy at the level of the general population.[1447] Whether a drastic reduction of smoking prevalence can be achieved without recourse to these tobacco alternatives, or even a form of promotion thereof, remains an open question which will undoubtedly be central in the coming years.[1448]

2.3. Promoting healthier diets and preventing obesity

Food has been a long-standing issue in EU law and policy. While the primary objective has always been to ensure that Europeans have access to a diversified and stable food supply, through the Common Agricultural Policy (CAP) and the establishment of the internal market, health and nutrition concerns have been progressively integrated to Union action in the field.[1449] The CAP, launched in 1962, pursued a nutrition objective from the onset, although framed in terms of food sufficiency rather than food quality, in a post-war context where shortages had not been completely eliminated. Early legislation from the 1970s and 1980s was primarily concerned with the free movement of foodstuffs. In the 1990s, health and safety concern raised to the top of the agenda with the Bovine spongiform encephalopathy (BSE), or 'mad cow disease', crisis,[1450] which resulted in the slaughter of millions of cattle and the deaths of dozens of people. It ultimately led to the creation of the European Food Safety Authority

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[1445] For more strategies and measures, see Yvette van der Eijk, 'Development of an Integrated Tobacco Endgame Strategy' (2015) 24 Tobacco Control 336; Patricia A McDaniel and others (n 1444).

[1446] Commission Implementing Decision (EU) 2022/1430 of 24 August 2022 on the request for registration of the European citizens' initiative entitled 'Call to achieve a tobacco-free environment and the first European tobacco-free generation by 2030', pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council [2022] JO L221/103, recital 2.

[1447] The Commission wants for instance to include e-cigarettes and HTP's in the 2009 Recommendation on Smoke-Free Environments (see Chapter 6, Section 4.2): European Commission, 'Europe's Beating Cancer Plan' (n 23) 9.

[1448] See Amy L Fairchild, Ronald Bayer and James Colgrove, 'The Renormalization of Smoking? E-Cigarettes and the Tobacco "Endgame"' (2014) 370 The New England Journal of Medicine 293; Malone (n 1444).

[1449] Tamara Hervey and Jean McHale distinguish four phases of EU food law: the creation of the Common Agricultural Policy (CAP), the building of an internal market for foodstuffs, the growing concern for food safety and, finally, the question of nutrition: Hervey and McHale (n 37) 404-405.

[1450] The BSE is a neurodegenerative disorder affecting cattle that can be transmitted to humans, leading to death on average after one year. For an overview of the crisis, see MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 124-32. For a critical discussion of the crisis and of EU's response, see Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (n 43); Chalmers, 'Risk, anxiety and the European mediation of the politics of life' (n 43).

(EFSA).[1451] The nutritional quality of diets and the related chronic diseases were for a long time no more than a 'secondary priority' for the EU, often mixed with food safety issues.[1452] It is not before the years 2000s that nutrition started to be dealt with in its own right, with obesity as the main focus.[1453]

The first push for a stronger EU engagement in nutrition matters originated from Member States, under the influence of international NGOs and organisations such as the WHO.[1454] In a first resolution adopted in 1990, the Council acknowledged that 'the Community ha[d] dealt on various occasions with nutritional problems and related measures in sectoral contexts, […] but ha[d] not given overall consideration to aspects of nutritional education and consumer information taken as a whole with the aim of promoting eating habits in keeping with individual needs'.[1455] It invited the Commission to submit a proposal for an action programme on nutrition and health and proposed to make 1994 the European Nutrition Year.[1456] This call for action was repeated by the Council on multiple occasions, singling out obesity as the main cause for concern.[1457]

Little came out of it.[1458] In the 2000 White Paper on Food Safety, the Commission signalled its intention to develop 'a comprehensive and coherent nutritional policy',[1459] which however would take a number of years to come of age. In the meantime, the Commission established a number of forums aimed at facilitating exchange and cooperation between stakeholders: the Network on Nutrition and Physical Activity in 2003,[1460] the European Platform for Action on Diet, Physical Activity and Health in 2005 (see Chapter 6, Section 4.4) and the High Level

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[1451] See the General Food Law Regulation.
[1452] See also MacMaoláin, *EU Food Law: Protecting Consumers and Health in a Common Market* (n 32) 221-222.
[1453] Paulette Kurzer and Alice Cooper, 'Hold the Croissant! The European Union Declares War on Obesity' (2011) 21 Journal of European Social Policy 107, 107–108. See also Tim Lang and Geof Rayner, 'Obesity: A Growing Issue for European Policy?' (2005) 15 Journal of European Social Policy 301; Paulette Kurzer, 'Non-communicable diseases: The EU declares war on "fat"', in Greer and Kurzer (n 37).
[1454] Kurzer and Cooper (n 1453); Kurzer, 'Non-communicable diseases: The EU declares war on "fat"' (n 1453) 157.
[1455] Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council of 3 December 1990 concerning an action programme on nutrition and health [1990] OJ C329/1, 1. See also Council of the European Union, Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council on 15 May 1992 on nutrition and health [1992] OJ C148/2.
[1456] Council of the European Union, Resolution concerning an action programme on nutrition and health, 2-3.
[1457] Council of the European Union, Council Resolution of 14 December 2000 on health and nutrition [2001] OJ C20/1; Council of the European Union, Council Conclusions of 2 December 2002 on obesity [2003] OJ C11/3; Council of the European Union, Council Conclusions on obesity, nutrition and physical activity [2005].
[1458] See Lang and Rayner (n 1453) 319.
[1459] European Commission, 'White Paper on food safety' COM (1999) 719 final, 33. See European Commission, 'Status report on the European Commission's work in the field of nutrition in Europe' (2002).
[1460] The Network on Nutrition and Physical Activity gathered representatives of the Commission, the WHO, Member States and civil society organisation. See the mandate adopted on 15 September 2003 <http://ec.europa.eu/health/ph_determinants/life_style/nutrition/documents/ev_20030630_rd02_en.pdf> accessed 11/05/2023.

Group on Nutrition and Physical Activity in 2007.[1461] In 2003, the Commission put forward its proposal for a Regulation on nutrition and health claims made on foods (Claims Regulation),[1462] adopted in 2006,[1463] arguably the first piece of EU legislation putting food quality at its core.

The first building brick of a 'comprehensive and coherent nutritional policy' came with the publication in 2005 of the Commission Green Paper on healthy diets and physical activity,[1464] followed two years after by the adoption of the White Paper 'A Strategy for Europe on Nutrition, Overweight and Obesity related health issues' (the EU Nutrition Strategy).[1465] In this White Paper, which remains to this date the only comprehensive strategy document adopted by the EU on the matter, the Commission lays down the foundations of 'an integrated EU approach to contribute to reducing ill health due to poor nutrition, overweight and obesity'.[1466] Although the focus is clearly on overweight and obesity, actions undertaken target 'all risks associated with poor diet and limited physical activity including, but not limited to, that associated with excess weight'.[1467] According to the Commission,

> Any public action, including those possibly undertaken at [Union] level, in this field should take into account three factors. Firstly, *the individual is ultimately responsible for his lifestyle*, and that of his children, *while recognising the importance and the influence of the environment on his behaviour*. Secondly, *only a well-informed consumer is able to make rational decisions*. Finally, an optimal response in this field will be achieved by promoting both the complementarity and integration of the different relevant policy areas (horizontal approach), and of the different levels of action (vertical approach).[1468]

As can be read from this excerpt, the perspective adopted is highly centred on the individual. The Commission draws inspiration from the Court of Justice's free movement case-law, whereby rational and diligent consumers make food choices on the basis of the information received. Quite logically, measures on food information occupy a central place in the EU Nutrition Strategy, aiming to give consumers 'access to clear, consistent and evidence-based information when deciding which foods to buy and […] [to regulate] the wider information environment which is in turn shaped by cultural factors, such as advertising and other

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[1461] Led by the Commission and gathering representative from EU Member States and EFTA States, this group is a network devoted to the sharing of evidence, data and best practice, working in cooperation with the EU Platform.
[1462] European Commission, Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (Claims Regulation Proposal) COM (2003) 424.
[1463] Regulation 1924/2006.
[1464] European Commission, 'Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases' Green Paper COM (2005) 637 final. See also European Parliament, European Parliament Resolution on 'Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases' [2007] OJ C250/93.
[1465] European Commission, EU Nutrition Strategy (n 218). See the reaction of the Council and the European Parliament to this strategy: Council of the European Union, Council Conclusions on Putting an EU strategy on Nutrition, Overweight and Obesity related Health Issues into operation [2007] 15612/07; European Parliament, European Parliament Resolution of 25 September 2008 on the White Paper on nutrition, overweight and obesity-related health issues [2007] OJ C8/97.
[1466] European Commission, EU Nutrition Strategy (n 218) 2.
[1467] ibid 3.
[1468] ibid.

media'.[1469] Among the options put on the table by the Commission were the introduction of a mandatory nutrition declaration on foodstuffs, which would be effective with the adoption of Regulation 1169/2011 on food information to consumers (Food Information Regulation), and the adoption of restrictions on harmful advertising and other promotional practises (see Chapter 6).[1470]

In reaction to the steep rise in overweight and obesity witnessed in this segment of the population, and as 'childhood is an important period to instil a preference for healthy behaviours and to learn the life skills necessary to maintain a healthy lifestyle',[1471] the EU Nutrition Strategy makes children a priority target of Union action. This was later confirmed with the adoption of an EU Action Plan on Childhood Obesity in 2014,[1472] whose 'overarching goal […] [was] to contribute to halting the rise in overweight and obesity in children and young people (0-18 years) by 2020'.[1473] The EU Strategy on the rights of the child, adopted in 2021, also contains nutrition-related commitments.[1474] In many ways, the approach taken in the Action Plan on Childhood Obesity is similar to the one adopted in the EU Nutrition Strategy, yet with a stronger focus on the environmental causes of obesity and less emphasis on individual responsibility.[1475] Information-based interventions are of course less relevant to an age group that does not necessarily possess fully developed cognitive capacities and is especially likely to fall prey to promotional techniques.

Nutrition remains a public health priority for the Commission,[1476] which increasingly tries to address the issue in conjunction with the environmental aspects of food consumption. The Commission's Farm to Fork Strategy 'for a fair, healthy and environmentally-friendly food system', presented in 2020, observes in that regard that 'current food consumption patterns are *unsustainable from both health and environmental points of view'*, due in particular to excessive 'average intakes of energy, red meat, sugars, salt and fats' and insufficient

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[1469] ibid 5.
[1470] ibid 5-6.
[1471] ibid 8.
[1472] European Commission, 'EU Action Plan on Childhood Obesity 2014-2020' (2014). See also Council of the European Union, Council Conclusions to contribute towards halting the rise in Childhood Overweight and Obesity [2017] OJ C205/46; Council of the European Union, Council Conclusions on the promotion of motor skills, physical and sport activities for children [2015] OJ C417/51; Council of the European Union, Council Conclusions - Healthy Nutrition for Children: The Healthy Future of Europe [2018] OJ C232/1.
[1473] European Commission, 'EU Action Plan on Childhood Obesity' (n 1472) 8.
[1474] European Commission, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'EU strategy on the rights of the child' COM (2021) 142 final.
[1475] ibid, 3-5. Eight key areas for action are laid down: support a healthy start in life, promote healthier environments, especially in schools and pre-schools, make the healthy option the easier option, restrict marketing and advertising to children, inform and empower families, encourage physical activity, monitor and evaluate, increase research. See ibid 11.
[1476] See Council of the European Union, Council Conclusions on nutrition and physical activity; Council of the European Union, Council Conclusions on food product improvement [2016] OJ C269/21; Council of the European Union, Council Conclusions of 8 June 2010 on action to reduce population salt intake for better health [2010] OJ C305/3.

'consumption of whole-grain cereals, fruit and vegetables, legumes and nuts'.[1477] According to the Commission, 'moving to a more plant-based diet with less red and processed meat and with more fruits and vegetables will reduce not only risks of life-threatening diseases, but also the environmental impact of the food system'.[1478] Neither the Form to Fork Strategy, however, nor the Beating Cancer Plan, deviate from the approach taken until now to favour information-based interventions or interventions that limit, weakly, as we shall see, the possibility for companies to promote unhealthy foodstuffs.[1479]

Save for minor exceptions, food business operators face few constraints as to the kind of food that can be placed on the market and advertised for. The conclusion drawn in the EU Nutrition Strategy evaluation report, conducted in 2013, still holds true today:

> [I]t is worth highlighting that most of the action taken in Europe to date (both at the EU and at the national levels) has been of a relatively *soft nature*, and has relied primarily (although the extent varies by country) *on information provision and education*, limited interventions in specific environments (such as schools), and voluntary actions by the food industry and other private actors, so as to generate an impact via a series of relatively subtle changes.[1480]

As part of its action to prevent overweight and obesity, the EU has also taken some initiatives aimed at promoting physical activity in the population,[1481] albeit on a much smaller scale. According to the EU Nutrition Strategy:

> Physical activity embraces a range of activities from organised sports to "active commuting" or outdoor activities. The Commission believes that the Member States and the EU must take pro-active steps to *reverse the decline in physical activity* levels in recent decades brought about by numerous factors.
>
> *The individual's attempt to find ways to increase physical activity in daily life should be supported by the development of a physical and social environment that is conducive to such activity*.[1482]

To tackle the decline in physical activity levels across society, public action should not only focus on physical activity as a leisure but must be targeted at the general environment surrounding individuals. That is why the EU has taken initiative in the fields of sports[1483] but

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[1477] European Commission, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' COM (2020) 381 final, 13, emphasis added.
[1478] ibid.
[1479] ibid. See also European Commission, 'Europe's Beating Cancer Plan' (n 23) 10.
[1480] European Commission, 'Evaluation of the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues' (2013) Final Report, 162, emphasis added. See also European Commission, 'Supporting the mid-term evaluation of the EU Action Plan on Childhood Obesity 2014-2020: The Childhood Obesity Study' (2018) 7-9, <https://op.europa.eu/en/publication-detail/-/publication/7e0320dc-ee18-11e8-b690-01aa75ed71a1> accessed 11/05/2023.
[1481] See Council of the European Union, Conclusions of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 27 November 2012 on promoting health-enhancing physical activity (HEPA) [2012] OJ C393/22; Council of the European Union, Council conclusions on the promotion of motor skills, physical and sport activities for children [2015] OJ C417/46; European Commission, 'Tartu Call for a Healthy Lifestyle' (n 1386).
[1482] European Commission, EU Nutrition Strategy (n 218) 7.
[1483] For more details, see Garde, *EU Law and Obesity Prevention* (n 32) 315-321.

also as regards health and safety at work[1484] and transport.[1485] The main horizontal instrument adopted by the EU in the field is the 2013 Council Recommendation on promoting health-enhancing physical activity across sectors,[1486] in which Member States are invited to develop cross-sectoral strategies and policies to promote health-enhancing physical activity (HEPA)[1487] in the population. A monitoring framework is set up with the help of the Commission so that Member States can report on their HEPA levels and HEPA policies to facilitate the exchange of information and good practices.[1488] EU Physical Activity guidelines were adopted in 2008,[1489] providing advice to Member States for the formulation and adoption of their own policy. The Guidelines cover a wide range of areas such as sports, education, transport, urban planning or work environment.

Regarding sports, EU action covers various dimensions, from the organisation of sports competition and their integrity to health aspects. One of the priorities contained in the 2007 White Paper on Sports was to enhance public health through physical activity:

> As a tool for health-enhancing physical activity, the sport movement has a greater influence than any other social movement. Sport is attractive to people and has a positive image. However, the recognised potential of the sport movement to foster health-enhancing physical activity often remains under-utilised and needs to be developed.[1490]

Since 2011, four European Union Work Plans for Sport have been adopted, with the 'promotion of participation in sport and health-enhancing physical activity' as a priority area.[1491] Action mostly concerns awareness raising, knowledge building and best-practice exchange.

2.4. Reducing the harmful consumption of alcohol

[1484] See ibid 321-326.
[1485] See ibid 326-334.
[1486] Council Recommendation on promoting health-enhancing physical activity across sectors.
[1487] The term health-enhancing physical activity has gained in popularity in policy circles to refer more specifically to the health benefits arising from physical activity. As such it can be used interchangeably with physical activity.
[1488] The first and only implementation review of the Recommendation, spanning from 2014 to 2016, showed several positive developments, including the adoption of new policies and action plans at national level and an improvement in monitoring and cross-border cooperation: European Commission, 'Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the Council Recommendation on promoting health-enhancing physical activity across sectors', COM (2016) 768 final.
[1489] European Union, 'EU Physical Activity Guidelines: Recommended Policy Actions in Support of Health-Enhancing Physical Activity' (2008), < https://ec.europa.eu/assets/eac/sport/library/policy_documents/eu-physical-activity-guidelines-2008_en.pdf> accessed 11/05/2023.
[1490] ibid 3-4.
[1491] Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, on a European Union Work Plan for Sport for 2011-2014 [2011] OJ C162/1; Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 21 May 2014 on the European Union Work Plan for Sport (2014-2017) [2014] OJ C183/12; Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, on the European Union Work Plan for Sport (1 July 2017-31 December 2020) [2017] OJ C189/5; Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States meeting within the Council on the European Union Work Plan for Sport (1 January 2021-30 June 2024) [2020] OJ C419/1.

From being treated as any other commodity, subject to the requirements of free movement rules and early food legislation, and, for agricultural products like wine, to those of the CAP, alcoholic beverages have slowly emerged as a relevant topic of EU health policy.[1492] In that sense, the EU's approach towards alcohol has developed in a way similar to nutrition and diets, although for a widely different outcome, as we shall see.

It is important to clarify at this stage that alcoholic beverages are 'foods' under EU law. Under the General Food Law Regulation, a 'food' is 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans',[1493] whether liquid or not or containing alcohol or not. This may lead to confusion, as alcoholic beverages tend not to be referred to as 'foods' in the common language, a distinction which has also been followed in this thesis. This distinction will be kept and the term 'food' should only be understood as including alcoholic drinks where it is used in relation to general food law instruments, such as the General Food Law Regulation, the Food Information Regulation or the Claims Regulation. In these instruments, separate provisions tend in any way to apply to alcoholic beverages.

The first signs of EU involvement with the health aspects of alcohol consumption coincided with the development of its cancer policy, started in the mid-80s. The Resolution of the Council and Member States on alcohol abuse,[1494] adopted a couple of weeks before the 1986 Action programme against cancer, recognised that 'in many countries the increase in alcohol abuse […] is causing serious concern for public health and social welfare'.[1495] It invited the Commission 'to *weigh carefully* the interests involved in the production, distribution and promotion of alcoholic beverages, and public health interests and to conduct a *balanced* policy to this end'.[1496] This cautious approach set the tone for what EU alcoholic policy would become in the following decades. It is telling that, although the first action plan against cancer recognised that alcohol consumption was the second most important cancer risk factor in Europe after tobacco, it contained virtually no proposal on the matter.[1497] Throughout the 1990s, alcohol remained absent from the EU's early public health efforts.

The accession of Finland and Sweden to the Union in 1995 brought visible changes to this state of play. The two countries, acting as 'policy entrepreneurs' through their Council presidencies, in 1999 and 2000 respectively, sought to put alcohol back on the agenda.[1498] This resulted in the adoption in 2001 of the Council Recommendation on the drinking of alcohol by young

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[1492] For a more detailed account of the early period, see Jenny Cisneros Örnberg, 'Alcohol Policy in the European Union', in Greer and Kurzer (n 37).
[1493] General Food Law Regulation, art 2
[1494] Council of the European Union, Resolution on a programme of action against cancer.
[1495] Council of the European Union, Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 29 May 1986, on alcohol abuse [1986] OJ C184/3.
[1496] ibid, emphasis added.
[1497] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (n 1373) 15-18.
[1498] Ugland, 'Promoting Policy Consistency and Continuity in the EU through the Trio' (n 1285) 520–522. See also Örnberg, 'The Europeanization of Swedish Alcohol Policy' (n 1342).

people,[1499] adopted by unanimity and endorsed by the European Parliament with a wide majority,[1500] and, the same year, of the Council Conclusions on a Community strategy to reduce alcohol-related harm.[1501] The latter invited the Commission to adopt a comprehensive strategy on alcohol.

The first, and ever, EU Alcohol Strategy was presented in 2006 in the form of a Commission communication. The overall approach is laid down as follows:

> [The Strategy] focuses on preventing and cutting back *heavy and extreme* drinking patterns, as well as under-age drinking, and some of their *most harmful* consequences such as alcohol-related road accidents and Foetal Alcohol Syndrome. *The Communication therefore is not a reflection on alcohol use as such, but on misuse and its harmful consequences*. The Communication recognises that there are *different cultural habits* related to alcohol consumption in the various Member States. *There is no intention to substitute Community action to national policies*, which have already been put in place in most of the Member States and relate to national competences in accordance with the *principle of subsidiarity* and Article 152 of the EC Treaty. In particular, the Commission *does not intend as a consequence of this Communication to propose the development of harmonised legislation* in the field of the prevention of alcohol-related harm.[1502]

With this Strategy, it is not alcohol consumption per se which is targeted but only 'heavy' and 'extreme' patterns. The objective of EU alcohol policy appears thus plainly different from that followed for tobacco, although, as should be stressed once again, 'moderate' alcohol consumption is no less hazardous than 'moderate' tobacco consumption, whatever this term may mean. The mention of the 'different cultural habits' existing between Member States appears on several occasions in the entire text, the Commission insisting on the variations in 'drinking patterns and cultures [existing] across the EU'[1503] as well as the particular context on which 'measures adopted by Member States to reduce alcohol-related harm with a view to protecting public health are based'.[1504] Although the reference made to subsidiarity in this context is rather obscure – we will come back to this question in Chapter 7 – it is undeniable that types and patterns of alcohol consumption differ widely between Member States, which could warrant a hands-off approach from the EU. Yet, while the same thing could be said of dietary habits and, to a lesser extent, of tobacco consumption, no reference to cultural diversity and subsidiarity is made in the EU Nutrition Strategy, or any other document related to tobacco for that matter.

[1499] Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents [2001] OJ L161/38.
[1500] Jenny Cisneros Örnberg, 'Escaping Deadlock – Alcohol Policy-Making in the EU' (2009) 16 Journal of European Public Policy 755, 760.
[1501] Council of the European Union, Council Conclusions of 5 June 2001 on a Community strategy to reduce alcohol-related harm [2001] OJ C175/1.
[1502] European Commission, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'An EU strategy to support Member States in reducing alcohol related harm' (EU Alcohol Strategy), COM (2006) 625 final, 1, emphasis added.
[1503] ibid 4.
[1504] ibid 13.

The EU Alcohol Strategy is essentially a mapping of good practices implemented at national level in a number of priority areas.[1505] The only mention of a possible harmonisation at the EU level concerns consumer information, '[s]uch reflections [being] particularly important as some Member States are planning to introduce warning labels (e.g. on alcohol and pregnancy), and as more generally there is an ongoing discussion about best practice in consumer education'.[1506] The Strategy was received with disappointment within the public health community.[1507] The predominant feeling was that 'the European Commission ha[d] correctly diagnosed the alcoholic disease ravaging Europe and announced its determination to keep the patient under close observation from now on, but perversely insist[ed] that no treatment [was] called for at this time'.[1508] According to some, the EU's lack of ambition results, at least in part, from the heavy opposition of the alcohol industry towards stronger regulatory action.[1509]

The Strategy expired in 2012, prompting the European Parliament and the Council to call for the adoption of a new strategy covering the years 2016-2022.[1510] Thus doing, both institutions did not intend to depart from the general orientation of EU alcohol policy, continuing to stress the need to respect national policy and the important cultural aspect of alcohol, and focusing on excessive drinking rather than drinking in general.[1511] The European Parliament stressed in particular that 'a clear distinction between responsible and harmful alcohol consumption [was] needed [because] *responsible alcohol consumption is compatible with a healthy way of living*',[1512] oblivious to the fact that alcohol can never be 'healthy'. Intensive lobbying efforts have been reported, to ensure that no new strategy entailing a stronger response on alcohol-

[1505] There are five of them: (i) protecting young people, children and the unborn child; (ii) reducing injuries and deaths from alcohol-related road traffic accidents; (iii) preventing alcohol-related harm among adults and reducing the negative impact on the workplace; (iv) informing, educating and raising awareness on the impact of harmful and hazardous alcohol consumption and on appropriate consumption patterns; and (v) developing, supporting and maintaining a common evidence base.

[1506] EU Alcohol Strategy (n 1502) 13.

[1507] See Jonathan Gornall, 'Europe under the Influence' (2014) 348 British Medical Journal 1166. A report evaluating the impact of the EU Alcohol Strategy was published in 2012. While not being able to draw any conclusion on the precise impact that the Strategy had had on alcohol consumption patterns, the report recognised that its aims had not been fully reached. It concluded nonetheless that the Strategy had helped in coordinating Member States' responses, provided guidance and support for further policy developments and contributed to a 'convergence of Member State policies [and] greater consensus'. See COWI Consortium, 'Assessment of the added value of the EU strategy to support Member States in reducing alcohol-related harm' (2012) Final report to the European Commission, 27.

[1508] Ben Baumberg and Peter Anderson, 'The European Strategy on Alcohol: A Landmark and a Lesson' (2007) 42 Alcohol and Alcoholism 1, 1.

[1509] Baumberg and Anderson (n 1508); Gornall (n 1507).

[1510] European Parliament, European Parliament Resolution of 29 April 2015 on Alcohol Strategy [2016] OJ C346/32; Council of the European Union, Council Conclusions on an EU strategy on the reduction of alcohol-related harm [2015] OJ C418/6; Council of the European Union, Council Conclusions on cross-border aspects in alcohol policy — tackling the harmful use of alcohol [2017] OJ C441/3. See also Council of the European Union, Council Conclusions of 1 December 2009 on alcohol and health [2009] OJ C302/15.

[1511] See European Parliament Resolution of 29 April 2015 on Alcohol Strategy (n 1510) 33. See also European Parliament, European Parliament Resolution of 5 September 2007 on a European Union strategy to support Member States in reducing alcohol-related harm [2008] OJ C187/160.

[1512] European Parliament Resolution of 29 April 2015 on Alcohol Strategy (n 1510) 34.

related harm would be put on the table.[1513] Since then, EU alcohol policy has come 'close to deadlock'.[1514] The Beating Cancer Plan may represent a new impetus, although the objective laid down as regards alcohol is modest if compared to the 'smoke-free' approach adopted for tobacco, with a goal of a relative reduction of at least 10% in the harmful use of alcohol by 2025.[1515] For that purpose, the Commission announced that it would work on new proposals in the area of taxation, commercial communications and labelling.[1516]

Due to the EU's lack of ambition in the field, there is a near absence of binding alcohol control legislation adopted at the EU level, as will appear from the developments contained later in the chapter and in the next one. The contrast is particularly strong with tobacco and related products, which are not only subject to far more restrictive rules but also governed by two specific legislative instruments, the Tobacco Products Directive and the Tobacco Advertising Directive. No such piece of legislation exists for alcoholic beverages, for which rules are scattered across different instruments.[1517]

This lack of ambition may be regretted as such, although it is not what is most questionable in the EU's approach towards alcohol-related harm. A first serious problem is the reliance on vague terms such as 'appropriate', 'reasonable' and 'responsible' consumption, on the one hand, and 'harmful', 'excessive' or 'heavy' drinking, on the other. These terms lack any proper scientific basis. The entire EU alcohol policy is based on concepts which are never defined and perpetuate the idea that alcohol is safe under a certain threshold of consumption, that only a minority of users will be confronted to harm in their lifetime. A second problem is the heavy emphasis laid on the diversity of habits and preferences as a justification for the absence of meaningful action. No one denies that alcohol presents an important cultural aspect, but the same can be said of other lifestyle risk factors too.

The promotion of responsible drinking is actually the approach championed by the industry, whose usual response to measures aiming at effectively reduce overall alcohol consumption is to frame the issue as concerning a minority of heavy alcohol users and to shift focus away from the majority of drinkers.[1518] As it happens, the alcohol industry is actually heavily reliant on episodes of intense drinking for its sales, which means that a policy that would effectively eliminate heavy drinking while leaving moderate patterns of consumption untouched would be, ironically enough, bad news for these companies.[1519]

[1513] Gornall (n 1507).
[1514] Pieter de Coninck and Ian Gilmore, 'Long Overdue: A Fresh Start for EU Policy on Alcohol and Health' (2020) 395 The Lancet 10, 10.
[1515] European Commission, 'Europe's Beating Cancer Plan' (n 23) 9.
[1516] ibid 9-10.
[1517] See De Coninck and Gilmore (n 1514) 10.
[1518] Pham Viet Cuong and others, 'Cross-country Comparison of Proportion of Alcohol Consumed in Harmful Drinking Occasions Using the International Alcohol Control Study' (2018) 37 Drug and Alcohol Review 45, 46.
[1519] Pham Viet Cuong and others (n 1518). This study establishes that around half or more of the total of absolute alcohol consumed across ten countries, mixing high- and middle-income countries, is consumed during harmful drinking occasions. This finding appears even more telling if one considers that the level of harmful drinking used in this analysis is considerably higher than the definition of heavy episodic drinking used by the WHO, meaning

This lack of engagement with alcohol-related harm is not a specificity of the EU.[1520] Global action in this field remains limited.[1521] Unlike for tobacco and illicit drugs, no international convention on alcohol exists, although the burden of alcohol worldwide, in terms of deaths and disabilities, far exceeds the one attributable to illicit drugs and is comparable to the one of tobacco. Conceptualising alcohol as a global challenge is not only warranted because countries experience similar alcohol-related problems and harm, but because of the global nature of the alcohol industry and its products, in terms of market concentration, trade and cross-border marketing.[1522] This is why a number of voices have been calling for the adoption of a comprehensive international legal instrument similar to the FCTC, a Framework Convention on Alcohol Control.[1523]

2.5. The criminalisation of illicit drug trafficking

The deepening of the internal market as an area without internal frontiers and the signature of the Schengen Agreement of 1985, which paved the way for the abolition of EU internal borders, put the question of cross-border crime and drug trafficking on the EU agenda.[1524] After the entry into force of the Maastricht Treaty, the EU was granted with formal powers in the field of criminal law, under the previous Justice and Home Affairs 'third pillar', subsequently narrowed to Police and Judicial Cooperation in Criminal Matters after the Treaty of Amsterdam.[1525] This allowed the EU to adopt substantive measures on drug trafficking, laying down minimum rules concerning the definition of criminal offences and sanctions. By their very illicit nature, drugs are an outlier in EU lifestyle risks regulation. As illicit sales cannot be regulated, most of the interventions used for other risk factors are not available. There cannot be any pricing policy, labelling requirement or regulation of commercial communications.

Aside from these criminal law aspects, Article 168(1) gives to the Union a direct mandate to 'complement the Member States' action in reducing drugs-related health damage, including information and prevention'. For this purpose, the EU has adopted since the 1990s a number

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that an effective reduction of alcohol consumption to moderate levels would effectively deplete the alcohol industry of most of its revenues.

[1520] See Jan van Amsterdam and Wim van den Brink, 'The High Harm Score of Alcohol. Time for Drug Policy to Be Revisited?' (2013) 27 Journal of Psychopharmacology (Oxford, England) 248.

[1521] See Sally Casswell, 'Will Alcohol Harm Get the Global Response It Deserves?' (2019) 394 The Lancet 1396; Paula O'Brien, 'Public Health and the Global Governance of Alcohol' (2021) 12 European Journal of Risk Regulation 415; Room (n 18).

[1522] O'Brien (n 1520) 416.

[1523] The Lancet, 'A Framework Convention on Alcohol Control' (2007) 370 The Lancet 1102. For recent discussions on what an international convention would bring and how it would go about in reality, see Robin Room and Jenny Cisneros Örnberg, 'A Framework Convention on Alcohol Control: Getting Concrete about Its Contents' (2021) 12 European Journal of Risk Regulation 433; Burci (n 1423); Suzanne Zhou, 'What Difference Would a Binding International Legal Instrument on Alcohol Control Make? Lessons from the World Health Organization Framework Convention on Tobacco Control's Impact on Domestic Litigation' (2021) 12 European Journal of Risk Regulation 514.

[1524] Mitsilegas (n 503) 5–9.

[1525] See Title VI of the Treaty on European Union, before and after the Amsterdam revision. For an introduction to third pillar law, see Mitsilegas (n 503) 9–23.

of strategies and action plans.[1526] Under the EU Drugs Strategies of 2005-2012 and 2013-2020, Union action was organised around five pillars: two main policy areas, drug demand reduction and drug supply reduction, and three cross-cutting themes, (i) coordination, (ii) international cooperation, and (iii) research, information, monitoring and evaluation. Drug demand reduction involved measures on 'prevention (environmental, universal, selective and indicated), early detection and intervention, risk and harm reduction, treatment, rehabilitation, social reintegration and recovery'.[1527]

The evaluation of the 2013-2020 Drugs Strategy, published in 2020, found that Union action had played 'an important role in bringing attention to a wide array of areas and needs related to drug demand and drug supply, and […] sparked a considerable amount of progress aimed at enhancing coordination, strengthening international cooperation, and contributing to better dissemination of monitoring, research and evaluation results in the drugs field'.[1528] It concluded however that the Strategy had failed to yield concrete results in reducing drug demand and supply, its two main objectives, and failed to meet its overall goal to ensure a high level of human health protection, social stability and security.[1529] Since 2013, prevalence of drug, drug-related deaths and drug availability and purity have increased across most types of drugs and across most Member States.[1530]

New policy orientations were set with the adoption of the EU Agenda and Action Plan on Drugs 2021-2025,[1531] which aims at tackling drugs' 'impact on individuals in terms of lives lost, deteriorated health and potential unrealised' and more generally, to address 'the considerable indirect negative impact the drug market has through links with wider criminal activities, the disruption of the legal economy, violence in communities, damage to the environment, and by acting as a significant driver for corruption that can undermine good

[1526] Council of the European Union, European Plan to Combat Drugs (1990) 10234/1/90; Council of the European Union, European Action Plan on drugs (1992) 10589/92; European Commission, Communication from the Commission to the Council and the European Parliament on a European Union action plan to combat drugs (1995-1999), COM (94) 234 final; Council of the European Union, European Union Drugs Strategy (2000-2004) 12555/3/99; European Commission, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the European Union action plan to combat drugs (2000-2004), COM (99) 239 final; Note from the Council of 22 November 2004 on the EU Drugs Strategy for the period 2005-2012, 15074/04; EU Drugs Action Plan for 2005-2008 [2005] OJ C168/1; EU Drugs Action Plan for 2009-2012 [2008] OJ C326/7; Council Recommendation, EU Drugs Strategy (2013-20) [2012] OJ C402/1; EU Action Plan on Drugs 2013-2016 [2013] OJ C351/1; EU Action Plan on Drugs 2017-2020 [2017] OJ C215/21.

[1527] EU Drugs Strategy 2013-20 (n 1526), para 17.

[1528] European Commission, 'Evaluation of the EU Drugs Strategy 2013-2020 and EU Action Plan on Drugs 2017-2020' (Staff Working Document) SWD (2020) 150 final, 39.

[1529] ibid 38.

[1530] ibid 20-28.

[1531] European Commission, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, 'EU Agenda and Action Plan on Drugs 2021-2025', COM (2020) 606 final.

governance'.[1532] The shortcomings of the previous strategy are acknowledged and a 'paradigm-shift in drugs policy' is proposed.[1533]

According to this new strategy, EU measures should 'have a substantive and measurable impact on the security and health issues arising from drug use and the operations of the drug market', while addressing 'both the direct and indirect consequences arising from this problem including links to violence and other forms of serious crime, related health and societal problems, environmental damage, while raising public and policy awareness on these issues.'[1534] In essence, drug supply and demand reduction remain at the heart of the EU's approach with some changes in priorities.[1535] In particular, a more prominent place is given to harm reduction. To promote 'healthy lifestyle choices' in the population, particularly amongst young people, children, and vulnerable groups, the Commission is set to adopt EU-wide campaigns targeted at parents, teachers and local decision makers.[1536]

On 12 January 2022, the European Commission presented a legislative proposal to revise the mandate of the European Monitoring Centre for Drugs and Drug Addiction, transforming it into a European Union Drugs Agency.[1537] The EMCDDA's main role is to provide 'factual, objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences'.[1538] It was felt that there was an increasing mismatch between the complexity of the drug phenomenon and the Centre's mandate.[1539] A targeted revision of that mandate is proposed, to ensure that the future Agency can 'react effectively to new challenges, provide better support to Member States, and contribute to developments at the international level'.[1540]

In spite of the global efforts of the last fifty years to eradicate it, illicit drugs consumption and trafficking endures. In the EU, this is especially true of cannabis, which is widely consumed and available, reflecting particular social norms of acceptance. A debate surrounding the 'war on drugs' is growing worldwide, putting into question the effectiveness of prohibition and repression strategies to reduce consumption and harm, with disastrous consequences in terms

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[1532] ibid 1.
[1533] ibid 2.
[1534] ibid 4.
[1535] The EU Agenda and Action Plan on Drugs 2021-2025 sets out eight strategic priorities under three main strands: (i) disrupting drug markets, (ii) prevention and awareness raising of the adverse effects of drugs and (iii) addressing drug-related harms.
[1536] Annexes to the EU Agenda and Action Plan on Drugs 2021-2025 (n 1531) 8.
[1537] European Commission, Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency COM (2022) 18 final.
[1538] Regulation 1920/2006, art 1(2). See above n 251.
[1539] Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency (n 1537), Explanatory Memorandum 1.
[1540] ibid. 'Notably, the proposal aims to expressly cover poly-substance, i.e. other substance-based addictions when these substances are taken together with illicit drugs; to strengthen monitoring and threat assessment capabilities; to establish a laboratory to ensure that all forensic and toxicological information is available to the Agency; to reinforce the position of national focal points to ensure that they are able to provide relevant data; to establish the competence of the Agency to develop EU-level prevention and awareness raising campaigns as well as issue alerts in case particularly dangerous substances are available on the market.' : ibid.

of crime and respect of fundamental human rights.[1541] As expressed by the United Nations Commissioner for Human Rights:

> Data and experience accumulated by UN experts have shown that the "war on drugs" *undermines health and social wellbeing and wastes public resources while failing to eradicate the demand for illegal drugs and the illegal drug market*. Worse, this "war" has engendered narco-economies at the local, national and regional levels in several instances to the detriment of national development. *Such policies have far-reaching negative implications for the widest range of human rights*, including the right to personal liberty, freedom from forced labour, from ill-treatment and torture, fair trial rights, the rights to health, including palliative treatment and care, right to adequate housing, freedom from discrimination, right to clean and healthy environment, right to culture and freedoms of expression, religion, assembly and association and the right to equal treatment before the law.[1542]

As an organisation putting the protection of fundamental rights at its core, the EU, although it is not directly responsible for the enforcement of drug policies and for most of the negative consequences described above, cannot avoid some soul-searching on the issue.[1543] Member States at the national level may wish to take this into their hands and adopt drug policy reforms towards legalisation, which, as we shall see later, raise a number of questions as regard their compatibility with EU law (see Section 3.1.2).

2.6. The neglected public health aspect of gambling

Although gambling is a hazardous lifestyle in its own right, the public health aspect of this activity is largely neglected by the EU. Gambling is nowhere mentioned in the policy documents analysed thus far. One may therefore consider that games of chances are not part of EU lifestyle risks policy.[1544] Gambling is more generally only weakly regulated at the EU level, even as an economic activity.[1545] Not only has no sectoral legislation been adopted in the field,

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[1541] Robin Room and Peter Reuter, 'How Well Do International Drug Conventions Protect Public Health?' (2012) 379 The Lancet 84; Fiona Godlee and Richard Hurley, 'The War on Drugs Has Failed: Doctors Should Lead Calls for Drug Policy Reform' (2016) 355 British Medical Journal 6067.

[1542] Office of the United Nations High Commissioner for Human Rights, 'End "War on Drugs" and Promote Policies Rooted in Human Rights: UN Experts' (2022), <https://www.ohchr.org/en/statements/2022/06/end-war-drugs-and-promote-policies-rooted-human-rights-un-experts> accessed 11/05/2023, emphasis added.

[1543] See in this regard: Council Conclusions on alternatives to coercive sanctions for drug using offenders [2018] 6931/18; Council conclusions on human rights-based approach in drug policies [2022] 15818/22.

[1544] It is interesting to note that in the ALICE-RAP (Addiction and Lifestyles in Contemporary Europe Reframing Addictions) project, a five year European research project (2011-2016) 'aimed to strengthen scientific evidence to inform the public and political dialogue and to stimulate a broad and productive debate on current and alternative approaches to addictions', and co-financed by the European Commission, gambling was addressed alongside other lifestyles and that a number of scientific findings regarding gambling disorder were made. See the 'ALICE RAP Science Findings', available at <http://www.alicerap.eu/about-alice-rap.html> accessed 11/05/2023.

[1545] The adoption of sectoral legislation seems to have been contemplated by the Commission. That option was abandoned in the 1990s: see European Council, Edinburgh 11-12 December 1992, Conclusions of the Presidency [1992] 456/1/92, 28.

but gambling is also excluded from some of the main internal market secondary law instruments, such as the Services Directive[1546] and the E-commerce Directive.[1547] Gambling remains mostly governed by the free movement provisions contained in the TFEU, as interpreted by the Court of Justice, analysed in Chapter 3 and 4.[1548] Member States may therefore freely set policy objectives on games of chance, organise the market in the way they see fit and decide of the level of protection regarding consumer protection and public health, in compliance with free movement law.

The EU has nonetheless not been completely inactive as regards gambling, online gambling in particular. Some initiatives have been taken to strengthen the level of consumer protection in the EU, as regards health and problem gambling, crime and money laundering,[1549] and match-fixing.[1550] The Commission presented in 2011 a Green Paper on online gambling,[1551] followed a year after by the publication of a Communication on a European framework for online gambling.[1552] According to the Commission, technological developments have made the gambling offer more abundant and diverse, online especially, which exposes consumers to greater risks.[1553] While excluding the adoption of any legislation in the field, the Communication establishes four priorities for EU action on consumer protection: (i) drawing consumers away from unregulated and potentially harmful offers, (ii) protecting minors from accessing gambling facilities, (ii) protecting other vulnerable groups and (iv) preventing the development of gambling related disorders.[1554]

An expert group on gambling, composed of representatives of Member States' gambling authorities, was established in 2012 in order to share experience and good practices and to provide advice and expertise on the preparation of EU initiatives.[1555] The Commission also

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[1546] Directive 2006/123, art 2(2)(h) and recital 25.
[1547] Directive 2000/31, art 1(5)(d) and recital 16.
[1548] Various secondary law instruments may incidentally apply to gambling services and contain provisions that are relevant to the prevention of gambling disorder: see Sibony and Michail (n 1249) 41-47. See in particular Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive) [2005] OJ L149/22. As regards commercial communications for gambling services, see below Chapter 6, Section 2.3.
[1549] See European Commission, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, 'Towards a comprehensive European framework for online gambling', COM (2012) 596 final, 13-14; Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing [2015] OJ L141/73, recital 21 in particular.
[1550] See European Commission, 'Towards a comprehensive European framework for online gambling' (n 1549) 14-16. For further elements see <https://ec.europa.eu/sport/policy/integrity/match-fixing_en> accessed 11/05/2023.
[1551] European Commission, 'Green Paper on online gambling in the Internal Market' COM (2011) 128 final.
[1552] European Commission, 'Towards a comprehensive European framework for online gambling' (n 1549).
[1553] ibid 3.
[1554] ibid 10.
[1555] ibid 5, see Commission Decision of 5 December 2012 setting up the group of experts on gambling services C(2012) 8795.

announced that same year that it would prepare a recommendation on responsible gambling advertising, 'to ensure that operators authorised in a given Member State advertise gambling in a socially responsible manner and provide key information to consumers',[1556] and a recommendation on the common protection of consumers.[1557] Only the latter recommendation would finally be adopted in 2014.[1558]

In December 2017, the European Commission decided to close all open infringement procedures in the field of gambling and to stop the treatment of complaints.[1559] Gambling has altogether ceased to be a priority for the Commission, which stresses in that regard 'the broader political legitimacy of the public interest objectives that Member States are pursuing when regulating gambling services' and recognises 'Member States' efforts to modernise their online gambling legal frameworks, channel citizens' demand for gambling from unregulated offer to authorised and supervised websites, and ensure that operators pay taxes'.[1560] Following this, the Commission also announced that the mandate of the Expert group on gambling would not be renewed beyond its term,[1561] set on 31 December 2018.[1562] It has so far resisted calls from national regulators and gambling operators to reinstall it.[1563]

Because of the clear cross-border elements involved and the limits to what Member States can achieve alone in this field, as regards online activities especially, stronger EU involvement in gambling appears desirable to ensure a minimum degree of protection for consumers across the EU. The gambling market is as Europeanised as markets for unhealthy commodities, there is therefore no obvious reason why gambling should, per se, be more of a Member State responsibility.[1564] In that sense, the Commission follows an approach similar to that of the Court of Justice regarding national restrictions to free movement, carving out a specific area of autonomy for Member States in an arbitrary way.

2.7. Interim conclusion

[1556] European Commission, 'Towards a comprehensive European framework for online gambling' (n 1549) 11.
[1557] ibid 11. See also European Parliament Resolution of 10 September 2013 on online gambling in the internal market [2016] OJ C93/42.
[1558] Gambling Recommendation.
[1559] European Commission, 'Commission closes infringement procedures and complaints in the gambling sector' (2017) Press release, <https://ec.europa.eu/commission/presscorner/detail/en/IP_17_5109> accessed 11/05/2023.
[1560] ibid.
[1561] European Commission, 'Minutes of the Meeting of the Expert Group on Gambling Services', 2 March 2018, 1. All minutes are available at <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=2868> accessed 11/05/2023.
[1562] Commission Decision of 9 December 2015 amending the Commission Decision of 5 December 2012 setting up the group of experts on gambling services as regards its applicability C(2015) 8643 final.
[1563] Nosa Omoigui, 'European Commission rejects calls to bring back Expert Group on Gambling' (2021) IGamingBusiness, <https://igamingbusiness.com/european-commission-rejects-calls-to-bring-back-expert-group-on-gambling/> accessed 11/05/2023.
[1564] See Alain-Laurent Verbeke, 'Gambling Regulation in Europe: Moving beyond Ambiguity and Hypocrisy' in Alan Littler and others (eds), *In the Shadow of Luxembourg: EU and National Developments in the Regulation of Gambling* (Brill 2011); Philippe Vlaemminck, 'Is There a Future for a Comprehensive EU Gambling Services Policy?' in Littler and others (n 1564).

Changing peoples' lifestyle behaviours to reduce the associated health risks has remained a cornerstone of EU health policy, both to combat the harmful consequences falling on individuals and society and to help reducing the financial burden on health systems. A number of harmonisation measures have been adopted that prescribe the conditions under which unhealthy products may be marketed in the European Union, if at all, to which the remainder of this chapter and the next chapter are devoted. Among the various programmes, strategies or action plans on health that have been devised in the last forty years, continuous reference is made to tobacco, diets, alcohol and, to a lesser extent, illicit drugs.

The reason for a focus of the EU on lifestyle health promotion may be twofold. From a purely health perspective, there are all reasons to tackle the burden of chronic non-communicable diseases and their causes, as these now constitute the main cause of mortality and morbidity in the EU. From a legal perspective, the exercise of EU *regulatory* power, 'influencing people by establishing rules on how they should live', compensates for the lack of EU *spending* power, 'influencing people through resources and the distribution of money', which is so crucial as regards health and the welfare state.[1565] Lifestyle risks are also an area where the EU can easily act, thanks to its broad internal market harmonisation powers, and where action may appear, precisely because of this internal market aspect, less objectionable. In that regard, it appears that, over the years, EU lifestyle risks policy has progressively emancipated itself from its internal market 'tag'. This is not so much the case legally, measures adopted remain internal market measures, but substantively. EU interventions have less and less to do with ensuring free movement and more and more with controlling the goods and services that are put in free circulation.

As we have seen, a heavy emphasis is laid on individual choices and one's responsibility to adopt a healthier lifestyle, an approach which must be questioned, considering the complexity of the root causes of unhealthy behaviours and their largely collective aspect. This approach corresponded, for a time, with the adoption of measures aiming primarily at informing consumers of the characteristic of products and the risks incurred with their consumption. This has nonetheless not prevented the EU from enacting rules which go way beyond the simple dissemination of information.

Although the different lifestyle risk factors are considered jointly at the policy level, gambling excluded, this does not result in them being subject to the same regulatory regime. On the one hand, the EU embraces the 'endgame' approach, under which tobacco products, for smoking especially, need to be phased out entirely. The same is true for illicit drugs whose consumption, by definition, ought not take place. This ideal of a 'smoke-free' and 'drug-free' world reflects the view that the risks entailed by the consumption of those products is deemed to outweigh possible benefits, bringing an overall negative contribution to human lives and society. For

[1565] Mark Dawson and Floris de Witte, *EU Law and Governance* (Cambridge University Press 2022) 73. See also Greer, 'Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union' (n 485).

alcohol, on the other hand, in spite of harm levels comparable to that of tobacco, and much higher than that of illicit drugs, a much more hands-off approach is taken.

3. Restricting choice: bans and composition requirements

The most direct way to orient behaviours is to restrict or eliminate choice, by removing products from the market or prescribing the content thereof, so that products or substances deemed to pose too great of a risk to people's health are no longer accessible. For that purpose, the EU has enacted a number of bans and composition requirements across the different lifestyle risk factors.

The EU's most forceful type of intervention is without doubt the general ban on the commerce of illicit drugs, the violation of which constitutes a criminal offence and must attract appropriate criminal penalties. Two other bans, of a different nature, apply to two categories of tobacco products: tobacco for oral use and tobacco products containing characterising flavours. As to the composition of products, the EU has few rules in place. These concern mostly tobacco products and, to a smaller extent, foods and alcoholic beverages.

Overall, to the notable exception of illicit drugs, economic operators remain free to place unhealthy and hazardous products on the market, without suffering much constraint. This may be explained, in part, by the ethical and practical implications of enacting and enforcing bans. The fact remains that the EU, by refusing to directly regulate most of the hazardous supply put on the market, leaves unharnessed one of the most powerful drives behind the development of unhealthy behaviours.

3.1. The prohibition of illicit drug trafficking

3.1.1. Illicit drugs under EU law

Regarding the definition of illicit drugs and drug precursors, the Union legal framework directly refers to the three relevant UN conventions: the Single Convention, the Convention on Psychotropic Substances and the Convention against Illicit Traffic (see Chapter 1, Section 4.4). Council Framework Decision 2004/757/JHA (the Framework Decision on Illicit Drug Trafficking) is the main EU legal instrument applicable to the matter.[1566] Under this Framework Decision, 'drugs' mean any of the substances covered by the Single Convention or the Convention on Psychotropic Substances or any of the substances listed in the Annex to the

[1566] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (Framework Decision on Illicit Drugs) [2004] OJ L335/8. According to Article 34(2)(b) TEU (Amsterdam version), framework decisions 'shall be binding upon the Member States as to the result to be achieved but shall leave to the national authorities the choice of form and methods' and 'shall not entail direct effect'. Framework decisions were used in the 'third pillar' law under the post-Maastricht Treaty framework. These instruments are similar to directives but do not have direct effect. With the Lisbon revision and the disappearance of the pillar structure, framework decisions no longer constitute acts of the Union and minimum rules in criminal matters are adopted through directives. Previous framework decisions continue to exist.

Framework Decision.[1567] The Annex, added in 2017, contains a list of new psychoactive substances.[1568] A 'new psychoactive substance' is 'a substance in pure form or in a preparation that is not covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances but may pose health or social risks similar to those posed by the substances covered by those Conventions'.[1569] 'Precursors' are 'any substance scheduled in the Community legislation giving effect to the obligations deriving from Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 20 December 1988'.[1570]

Article 1a of the Framework Decision lays down the procedure for including new psychoactive substances in the Annex, bringing them within the 'illicit drugs' category. Based on a risk assessment made by the EMCDDA, the Commission adopts delegated acts amending the Annex.[1571] To do so, the Commission must take into account a number of factors: (i) 'whether the extent or patterns of use of the new psychoactive substance and its availability and potential for diffusion within the Union are significant', (ii) whether the harm to health caused by the consumption of the new psychoactive substance is 'life-threatening', meaning if the new psychoactive substance is 'likely to cause death or lethal injury, severe disease, severe physical or mental impairment or a significant spread of diseases', and (iii) 'whether the social harm caused by the new psychoactive substance to individuals and to society is severe'.[1572] Member States may maintain or introduce, without prejudice to their obligations under the Framework Decision, national control measures on new psychoactive substances.[1573]

The international and EU frameworks for illicit drugs control are based on a system of scheduling, meaning that it is the placing of a given substance on different lists that matters, rather than its characteristics or its psychoactive effects. Determining whether a substance belongs to one of these lists may however not always be a straightforward exercise, as shown by the ruling of the Court of Justice in the *CBD* case.[1574]

In this case, the Court had to decide whether CBD, cannabidiol, constituted an 'illicit drug' under EU law. Schedule I of the UN Single Convention, to which the Framework Decision on

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[1567] ibid, art 1.
[1568] See Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA [2017] OJ L305/12. This Directive was adopted to include substances, 'which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading rapidly in the Union': see Directive 2017/2103, recital 4.
[1569] Framework Decision on Illicit Drugs, art 1(4).
[1570] ibid, art 1(2). See Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors [2005] OJ L22/1, Annex.
[1571] Framework Decision on Illicit Drugs, art 1a(1). This risk assessment is carried out pursuant to Regulation 1920/2006.
[1572] Framework Decision on Illicit Drugs, art 1a(2).
[1573] ibid, art 1(b).
[1574] *CBD* (n 650).

Illicit Drug Trafficking refers, includes 'cannabis, cannabis resin, extracts and tinctures of cannabis',[1575] where 'cannabis' is defined as 'the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated' and where 'cannabis plant' means 'any plant of the genus Cannabis'.[1576]

As CBD is extracted from cannabis, a literal interpretation of these provisions would lead to the conclusion that CBD constitutes an illicit drug.[1577] The Court preferred however to follow a teleological interpretation based on the objective of the UN Single Convention, which is to protect human health and welfare.[1578] According to the Court, the inclusion of cannabis in the Single Convention is 'intrinsically linked' to its harmfulness for human health.[1579] CBD, however, 'does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data'.[1580] Including CBD under the definition of 'drugs' within the meaning of that convention would therefore, for the Court, be contrary to its purpose and general spirit, which follows that CBD does not constitute a drug under the Single Convention and hence under EU law.[1581]

This ruling has had profound effects on the market for CBD and CBD products, paving the way for their free commercialisation in the EU, where certain Member States had adopted a repressive approach until now. Market developments are currently putting the existing national and EU regulatory frameworks under strain and uncertainty.[1582] Although one can be satisfied with the outcome reached in that judgement, allowing a product with no known harmful effects on health to be placed on the market, the Court's interpretation of the UN Single Convention is not without raising questions. By focusing on the effects of a substance to determine whether it should be classified as an illicit drug, rather than its placing under the relevant schedule, the Court goes against the very spirit of international and European drug classification. It also underlines the fact that other substances which are as harmful as, or even more harmful to human health than certain illicit drugs, escape any kind of control of this sort.

3.1.2. Rules on criminal offences and sanctions for illicit drug trafficking

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[1575] The UN Conventions schedules are available at: <https://www.unodc.org/unodc/en/commissions/CND/conventions.html> accessed 11/05/2023.
[1576] Single Convention on Narcotic Drugs, arts 1(b) and (c).
[1577] *CBD* (n 650), para 71.
[1578] ibid, para 73.
[1579] ibid, para 74.
[1580] ibid, para 72.
[1581] ibid, paras 75-76. Advocate General Tanchev comes to the same conclusion with a different, less convincing, reasoning, based on Article 28(2) of the Single Convention and the Commentary to the Single Convention. He reads from these provisions that 'cultivation of the hemp plant is not subject to control where it is not for the purpose of producing a narcotic drug'. He also mentions the fact that the WHO recommended an amendment to Schedule I of the Single Convention, in order to clarify that CBD is not a narcotic drug. See Case C-663/18, *CBD* [2020] EU:C:2020:383, Opinion of Advocate General Tanchev, paras 74 -75.
[1582] Brendan Hughes and others, 'Regulatory Approaches to Cannabidiol in the European Union: Are Market Developments Sowing the Seeds of Confusion?' (2022) 117 Addiction 3.

The EU adopted its first instrument on illicit drugs in 1996, the Joint Action 96/750/JHA on drug addiction and illegal drug trafficking,[1583] which contained a general call upon Member States to 'cooperate fully in the fight against drug addiction', to make their laws 'mutually compatible to the extent necessary to prevent and combat illegal drug trafficking in the Union',[1584] and to 'ensure that under their legal systems the penalties imposed for serious drug trafficking are among the most severe penalties available for crimes of comparable gravity'.[1585]

This legal framework was considerably strengthened with the adoption of the Framework Decision on Illicit Drug Trafficking in 2004. Pursuant to its Article 2:

> 1. Each Member State shall take the necessary measures to ensure that the following intentional conduct *when committed without right* is punishable:
>
> (a) the production, manufacture, extraction, preparation, offering, offering for sale, distribution, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation or exportation of drugs;
>
> (b) the cultivation of opium poppy, coca bush or cannabis plant;
>
> (c) the possession or purchase of drugs with a view to conducting one of the activities listed in (a);
>
> (d) the manufacture, transport or distribution of precursors, knowing that they are to be used in or for the illicit production or manufacture of drugs.
>
> 2. The conduct described in paragraph 1 shall not be included in the scope of this Framework Decision when it is committed by its perpetrators exclusively for their own personal consumption as defined by national law.[1586]

Regarding Article 2 second paragraph, Recital 4 clarifies that the exclusion of conducts committed exclusively for one's personal consumption from the scope of the Framework Decision does not amount to a position taken on the legitimacy of such conducts and their position under national law, but is rather an expression of the principle of subsidiarity, EU action focusing on the 'the most serious types of drug offence'. Member States remain free to criminalise, or not, behaviours related to personal consumption, including personal consumption itself, but also purchase and cultivation. This is an important point from a public health perspective, as the criminalisation of drug use is one of the main obstacles preventing users from seeking help and consuming in a safer way.[1587]

Under Article 3 of the Framework Decision, Member States shall also make 'incitement to commit, aiding and abetting or attempting' one of the offences referred to in Article 2 a criminal offence.[1588] The offences defined in Articles 2 and 3 must be punishable by 'effective,

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[1583] Joint Action 96/750/JHA of 17 December 1996 adopted by the Council on the basis of Article K.3 of the Treaty on European Union concerning the approximation of the laws and practices of the Member States of the European Union to combat drug addiction and to prevent and combat illegal drug trafficking [1996] OJ L342/6.
[1584] ibid art 1.
[1585] ibid art 4. See also Council Resolution of 20 December 1996 on sentencing for serious illicit drug-trafficking [1997] OJ C10/3.
[1586] Emphasis added. These conducts are reproduced from Article 3(1)(a) of the UN Convention on Illicit Traffic.
[1587] See Room and Reuter (n 1541); Godlee and Hurley (n 1541).
[1588] Framework Decision on Illicit Drug Trafficking, art 3.

proportionate and dissuasive criminal penalties'.[1589] Articles 4 and 5 lay down a number of requirements as to the nature of the penalty – imprisonment – and the quantum of the punishment, depending on how serious the offence is and on the behaviour of the offender. The Framework Decision finally contains provisions on liability and sanctions for legal persons, jurisdiction and prosecution.[1590]

Originally, the Commission's proposal for the Framework Decision contained a formal definition of 'illicit drug trafficking'[1591] and simply required Member States 'to take the necessary measures to make illicit drug trafficking a criminal offence'.[1592] As the Commission was well aware, this constituted a bold step since, at that time, national legislations did not contain a legal definition of illicit drug trafficking but rather criminalised a set of more specific conducts.[1593] Member States ultimately preferred not to have their hands tied with a common definition on this highly sensitive topic and sticked to the logic of criminalising specific conducts linked to illicit drug trafficking.[1594]

Apart from the Framework Decision on Illicit Drug Trafficking, the Convention implementing the Schengen Agreement, incorporated into EU law in 1999, also contains provisions on illicit drug trafficking.[1595] Pursuant to its Article 71(1), the contracting parties shall 'undertake as regards the direct or indirect sale of narcotic drugs and psychotropic substances of whatever type, including cannabis, and the possession of such products and substances for sale or export, to adopt in accordance with the existing United Nations Conventions, *all necessary measures to prevent and punish the illicit trafficking in narcotic drugs and psychotropic substances*'.[1596] Under Article 71(2), the parties also undertake to prevent and punish the illegal export, sale, supply and handing over of narcotic drugs and psychotropic substances.[1597] That obligation is

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[1589] ibid, art 4.
[1590] ibid, arts 6, 7 and 8.
[1591] Proposal for a Council Framework Decision laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking [2001] OJ C304E/172. Under Article 1, illicit drug trafficking means 'the act, without authorisation, of selling and marketing as well as, for profit, of cultivating, producing, manufacturing, importing, exporting, distributing, offering, transporting or sending or, for the purpose of transferring for profit, of receiving, acquiring and possessing drugs'.
[1592] ibid, art 2.
[1593] ibid, Explanatory Memorandum. See also Emanuele Pitto, 'La lutte contre le trafic de drogue' (2006) 77 Revue Internationale de Droit Pénal 271, 273.
[1594] See Valsamis Mitsilegas, Jörg Monar, and Wyn Rees, *The European Union and Internal Security: Guardian of the People?* (Palgrave Macmillan 2003) 104.
[1595] Convention implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders [2000] OJ L239/19. This Convention, originally signed in 1990 by Belgium, France, Germany, Luxembourg and the Netherlands, is part of the 'Schengen acquis', incorporated into EU law by the Treaty of Amsterdam. See Council Decision of 20 May 1999 concerning the definition of the Schengen acquis for the purpose of determining, in conformity with the relevant provisions of the Treaty establishing the European Community and the Treaty on European Union, the legal basis for each of the provisions or decisions which constitute the acquis [1999] OJ L176/1.
[1596] Emphasis added.
[1597] Convention implementing the Schengen Agreement, art 71(2).

however subject to a reservation contained in a joint declaration from France, Germany and the Benelux countries:

> In so far as a Contracting Party departs from the principle referred to in Article 71(2) in connection with its national policy on the prevention and treatment of addiction to narcotic drugs and psychotropic substances, all Contracting Parties shall adopt the necessary administrative measures and penal measures to prevent and punish the illicit import and export of such products and substances, particularly towards the territories of the other Contracting Parties.[1598]

The margin of discretion that Member States enjoy under that reservation remains quite unclear. It seems however possible to construe it as an equivalent of Article 2(2) of the Framework Decision, authorising Member States to adopt divergent policies regarding conducts related to personal use.

The EU also has rules in place regarding trade in drug precursors, to ensure that these are not diverted from their legal purpose. This is meant to give effect to Article 12 of the UN Convention on Illicit Traffic, to which the EU is party, which requires that measures be taken to prevent diversion of drug precursors. Two regulations are in place, one for monitoring the trade in drug precursors between the EU and third countries[1599] and another applicable to trade between Member States.[1600] Both instruments set rules to ensure that no diversion of such substances take place.[1601] Rules are more stringent for external trade than they are for intra-EU trade, with a system of licences and import and export authorisation.[1602]

As debates on the adequacy of the global prohibitionist approach towards drugs grow, a number of EU Member States have proposed or adopted reforms aimed at decriminalising cannabis use and/or at legalising its commerce, fully or in part. Indeed, cannabis 'exhibits a considerable degree of normalisation' despite decades of prohibition and strict law enforcement.[1603] If national provisions on private cannabis production and use fall outside EU law's purview, this is not the case of provisions that would legalise the production and sale of the plant.

Since December 2021, Malta authorises adults to carry up to seven grams of cannabis and to grow at home a maximum of four plants per household, for personal use.[1604] The new 'Law on the Responsible Use of Cannabis' also provides 'for the possibility of creating a regularised and safe source from which a person can obtain cannabis and cannabis seeds in limited and

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[1598] ibid, Joint Declaration on Article 71(2).
[1599] Council Regulation 111/2005.
[1600] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [2004] OJ L47/1.
[1601] Article 1 of Regulation 111/2005 and Regulation 273/2004.
[1602] For more elements on this legislative framework, see European Commission, 'Report from the Commission to the European Parliament and the Council, Evaluation of the EU drug precursors regulations' COM (2020) 768 final.
[1603] Asbridge and others (n 349).
[1604] Government of Malta, 'Press Release - New Law on the Responsible Use of Cannabis Enters Into Force' (2021),<https://www.gov.mt/en/Government/DOI/Press%20Releases/Pages/2021/December/18/pr212248en.aspx#:~:text=Act%20LXVI%20of%202021%20(Chapter,our%20society%20perceives%20and%20treats> accessed 11/05/2023.

controlled amounts, under strict conditions', so-called cannabis-clubs.[1605] A bill is currently under discussion in Luxembourg that would also allow the cultivation of up to four cannabis plans per household, but would not decriminalise the possession and use of cannabis in the public space.[1606] The Luxemburgish and Maltese laws, which do not amount to a full-scale legalisation, appear to benefit from the exemption contained in Article 2(2) of the Framework Decision on Illicit Drug Trafficking, as the behaviours made licit only relate to personal consumption.

In 2021, Germany put forward a far bolder plan allowing the licensed cultivation of cannabis and the selling in specialised shops to persons over 18 years.[1607] This would have made Germany the first country in the EU to move towards a full legalisation of the product. The German government seemed first to believe that such legalisation could be made compliant with EU law. It considered in particular that the reference to a conduct 'committed without right' in Article 2(1) of the Framework Decision means that the obligations contained in that provision cease to apply from the moment that a Member State create a right for such conduct, as would be the case with the reform.[1608] This interpretation is however unconvincing, as it would amount to deprive Article 2 of the Framework Decision of its harmonisation effect, and hence of its purpose. Each Member State would be able to criminalise conduct related to drug trafficking or not.[1609] Due to serious doubts regarding the legality of such legalisation under EU law, Germany announced in 2023 a revision of its projected reform, significantly watering down its original plan. The proposal now only allows small-scale cultivation for personal use and controlled distribution via cannabis-clubs.[1610] The commercial distribution of cannabis will only be tested through regional model trials and scientifically monitored. Germany hopes that the outcome of these trials will inform a future reform of EU rules on cannabis, although support for such move remains low among Member States at the moment.[1611]

3.2. The prohibition of tobacco for oral use and flavoured tobacco

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[1605] ibid. See Mafalda Pardal and others, 'Mapping Cannabis Social Clubs in Europe' (2022) 19 European Journal of Criminology 1016.

[1606] Gouvernement du Luxembourg, 'Projet "Cannabis récréatif' (2021), <https://gouvernement.lu/fr/dossiers.gouv_mj%2Bfr%2Bdossiers%2B2021%2BCannabis.html> accessed 11/05/2023.

[1607] Robin Hofmann, 'Cannabis Legalization in Germany – The Final Blow to European Drug Prohibition?' (2022) European Law Blog, <https://europeanlawblog.eu/2022/01/11/cannabis-legalization-in-germany-the-final-blow-to-european-drug-prohibition/> accessed 11/05/2023.

[1608] ibid.

[1609] ibid.

[1610] Euractiv, 'Germany wants EU cannabis law changes, waters down own legalisation plans (2023), <https://www.euractiv.com/section/health-consumers/news/germany-wants-eu-cannabis-law-changes-waters-down-own-legalisation-plans/?utm_source=piano&utm_medium=email&utm_campaign=9447&pnespid=v6JjBj9MKLlFxfbdvjmvDJGdth_iWcdwJvCuwbIwsxpmD9X7I99oQMQmz7kaoC1ucOPgEsqT> accessed 11/05/2023.

[1611] ibid.

As part of its tobacco control policy, the EU prohibits the placing on the market of two categories of products: tobacco for oral use and tobacco with a characterising flavour.[1612] The EU justifies these two bans with the health risks involved and the possible gateway effect to the consumption of tobacco for smoking, for young people especially.

3.2.1. The prohibition of tobacco for oral use

Since 1992, the EU prohibits the placing on the market of tobacco for oral use,[1613] on grounds of the specific health risks associated with the consumption of this category of products, oral cancer in particular, and of its potential role as a gateway to the consumption of other, riskier forms of tobacco products.[1614] Consumption of tobacco for oral use was negligible in the EU when the ban was adopted, which made its prohibition possible and relatively uncontroversial. The only exception to the ban concerns Sweden, where tobacco for oral use, known as snus, is still widely consumed. Sweden secured an opt-out upon its accession to the EU in 1995,[1615] which is still in force today.[1616]

Under the TPD, tobacco for oral use belongs to the broader category of smokeless tobacco products, which also includes chewing tobacco and nasal tobacco.[1617] Although the consumption of chewing and nasal tobacco involves health risks and is also negligible in the

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[1612] Flavoured tobacco is considered as a separate category of product, distinct from non-flavoured tobacco. Hence restrictions on the use of flavours is treated here as a product ban and not a composition requirement. See Chapter 7, section 2.2.1.

[1613] Tobacco Products Directive, arts 1(c) and 17. The ban was first introduced by Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products [1992] OJ L158/30, art 1. Under the TPD, tobacco for oral use means 'all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets': art 2(8).

[1614] Council Directive 92/41/EEC, recitals.

[1615] Act concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded [1994] OJ C241/9, art 151.

[1616] Pursuant to Article 17 of the TPD, 'Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden'. The Swedish exception gives rise to difficulties in other Member States, with the development of an illegal trade in snus from Sweden into neighbouring countries and of cross-border sales in border regions : European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 97.

[1617] TPD, art 2(7). Chewing tobacco means 'a smokeless tobacco product exclusively intended for the purpose of chewing': art 2(6). Distinguishing tobacco for oral use from chewing tobacco can be difficult, as both products are consumed orally and may have a similar appearance. In *Günter Hartmann*, the Court of Justice provided some guidance as to how to differentiate between these two categories of products. According to the Court, chewing tobacco is essentially a sub-category from tobacco for oral use and its authorisation represents an exception to the general rule that tobacco for oral use is prohibited on the EU market. Hence, it must be understood strictly. Chewing tobacco includes products 'which can release their essential ingredients in the mouth only by chewing' whereas a product 'which, whilst also being able to be chewed, is essentially intended to be sucked, that is to say a product which it is sufficient to hold in the mouth for its essential ingredients to be released, cannot be classified as such' but must be classified as tobacco for oral use. See Case C-425/17 *Günter Hartmann Tabakvertrieb* [2018] EU:C:2018:830, paras 30-35.

EU, the placing on the market of these two products remains possible.[1618] The EU legislator justifies this difference in treatment by the, allegedly, stronger appeal of tobacco oral use in comparison to other STPs. Regarding the latter, 'strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use'.[1619]

The Court of Justice upheld this reasoning in the *Arnold André*, *Swedish Match* and *Swedish Match II* cases, ruling that, as regards tobacco for oral use and other STPs, no breach of the principle of equal treatment could be established.[1620] Apart from Sweden, tobacco for oral use was new to the markets of the Member States when the ban was first enacted, whereas tobacco for chewing, albeit little consumed, had had a history of traditional use.[1621] This feature, according to the Court, is enough to differentiate tobacco for oral use from any other tobacco product because, if allowed, tobacco for oral use 'would continue to be novel as compared with other smokeless tobacco products and tobacco products for smoking, including cigarettes, and would accordingly be attractive to young people'.[1622] Furthermore, whereas 'tobacco products for oral use have considerable potential for expansion', 'smokeless tobacco products other than those for oral use represent only niche markets which have limited potential for expansion, on account of, inter alia, their costly and in part small-scale production methods'.[1623]

As regards the scientific justification for the ban on tobacco for oral use, uncertainty remains. In its 2008 opinion on the matter, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded that smokeless tobacco products were addictive products and involved health risks, of cancer and cardiovascular diseases especially, although it was not established that tobacco for oral use specifically entailed a higher risk of oral cancer.[1624] The SCENIHR found no evidence regarding the overall effectiveness of smokeless tobacco products as cessation aids and their relative effectiveness compared to other established therapies.[1625] It could also not take a definitive stance on the existence of a gateway effect to the consumption of other tobacco products, further observing that the 'marked social, cultural and product differences between North America and Europe suggest caution in translating

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[1618] There has been attempts from manufacturers to circumvent the ban on tobacco for oral use by marketing their products as chewing tobacco, even if in reality intended for oral use: European Commission, 'Report on the application of Directive 2014/40/EU' (n 1429) 16; European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 98. For this reason, some Member States have made use of the possibility granted under Article 24(3) TPD to prohibit chewing and/or nasal tobacco products in their domestic market. See below Chapter 7, Section 3.3.2.
[1619] Tobacco Products Directive, recital 32.
[1620] *Arnold André* (n 975), para 69; *Swedish Match* (n 975), para 71; Case C-151/17 *Swedish Match AB v Secretary of State for Health* (*Swedish Match II*) [2018] EU:C:2018:938, para 28. The Court also examined other alleged grounds of invalidity, see Chapter 7.
[1621] *Arnold André* (n 975), para 69; *Swedish Match* (n 975), para 71. See also *Swedish Match II* (n 1620), para 24 and Council Directive 92/41/EEC, recitals.
[1622] *Swedish Match II* (n 1620), para 26.
[1623] ibid, para 27.
[1624] SCENIHR (n 166) 119-121. The SCENIHR was the predecessor of the SCHEER, see n 177.
[1625] ibid 121.

findings across countries, also within Europe'.[1626] The report concluded that it was not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco if that product were to be reintroduced in the EU, because 'the association between patterns of smokeless tobacco use and smoking cessation differs from one population to the other and is likely to be affected by cultural and societal factors'.[1627]

The EU ban on tobacco for oral use remains controversial. A number of voices have called for a removal of the ban, so as to help reducing the prevalence of smoking, taking the Swedish case as an example.[1628] While it cannot be denied that the use of snus has had a protective effect on the Swedish population, it is hard to predict what would result from the reintroduction of tobacco for oral use in other EU markets, where it has been banned for more than three decades and is largely unknown to the population, and whether a significant number of smokers would fully switch to tobacco for oral use, thereby effectively lowering their risk.

3.2.2. The prohibition of tobacco products with a characterising flavour

One of the main changes brought by the TPD was the prohibition on the placing on the market of tobacco products with a characterising flavour, contained in Article 7.[1629] A characterising flavour is defined as 'a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, […] which is noticeable before or during the consumption of the tobacco product'.[1630] Flavours include, but are not limited to, 'fruit, spice, herbs, alcohol, candy, menthol or vanilla'.[1631]

The prohibition currently applies to cigarettes and roll-your-own (RYO) tobacco only,[1632] as these are the products mostly consumed by young people, the primary target of this measure.[1633] Indeed, the EU legislator considered that characterising flavours, which mask the

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[1626] ibid.
[1627] ibid 122.
[1628] Clive Bates and others, 'European Union Policy on Smokeless Tobacco: A Statement in Favour of Evidence Based Regulation for Public Health' (2003) 12 Tobacco Control 360; Fagerström and Schildt (n 173); Lynn T Kozlowski, Richard J O'Connor and Beth Quinio Edwards, 'Some Practical Points on Harm Reduction: What to Tell Your Lawmaker and What to Tell Your Brother about Swedish Snus' (2003) 12 Tobacco Control 372; Clarke and others (n 170); Farsalinos (n 171); Ramström (n 171). See also European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 96.
[1629] Tobacco Products Directive, arts 7(1) and (7). While Article 7(1) only prohibits 'the placing on the market of tobacco products with a characterising flavour', Article 7(7) also prohibits 'the placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity'. As to the determination of whether a tobacco product contains a characterising flavour, see Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour [2016] OJ L131/48; Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour [2016] OJ L131/79.
[1630] Tobacco Products Directive, art 2(25).
[1631] ibid.
[1632] ibid, art 7(12).
[1633] ibid, recital 19.

taste and smell of tobacco and may reinforce the appeal of tobacco products, could 'facilitate initiation of tobacco consumption or affect consumption patterns'.[1634] For products whose Union-wide sales volumes represented 3 % or more in a particular product category, such as menthol cigarettes, the prohibition has only been applying since 20 May 2020.[1635] On 29 June 2022, the European Commission adopted a delegated directive extending the prohibition on the use of characterising flavours to heated tobacco products, applicable from 23 October 2023.[1636]

The ban on characterising flavours was unsuccessfully challenged before the Court on three occasions.[1637] In *Poland v Parliament and Council*, the Court considered that 'tobacco products containing a characterising flavour, whether that is menthol or another flavouring, have certain similar, objective characteristics and similar effects as regards initiating tobacco consumption and sustaining tobacco use'.[1638] It rejected Poland's plea that mentholated tobacco products should be treated differently from other products with a characterising flavour, on grounds of their long-standing presence on the European market, of an alleged lesser attractiveness to young people and a lesser ability to eliminate the taste and smell of tobacco.[1639] In *Planta Tabak*, the Court rejected the argument made that the lack of specification in Article 7 TPD of which products were those whose EU-wide sales volumes represented 3% or more in a product

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[1634] ibid, recital 16. For evidence of this, see James C Hersey and others, 'Are Menthol Cigarettes a Starter Product for Youth?' (2006) 8 Nicotine & Tobacco Research 403; Kim Klausner, 'Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective' (2011) 20 Tobacco Control 12; James Nonnemaker and others, 'Initiation with Menthol Cigarettes and Youth Smoking Uptake' (2013) 108 Addiction 171; Cristine D Delnevo and others, 'The Influence of Menthol, e-Cigarettes and Other Tobacco Products on Young Adults' Self-Reported Changes in Past Year Smoking' (2016) 25 Tobacco control 571.

[1635] Tobacco Products Directive, art 7(14), as interpreted by the Court in Case C-220/17 *Planta Tabak* [2019] EU:C:2019:76, paras 60-67.

[1636] Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products [2022] OJ L283/4, art 1. Under Article 7(12) TPD, the Commission shall adopt delegated acts 'to withdraw that exemption [the prohibition on the use characterising flavours] for a particular product category, if there is a substantial change of circumstances as established in a Commission report'. The delegated directive follows the publication of a report establishing such a change of circumstances for HTPs: European Commission, 'Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU' COM (2022) 279 final. The definition of a 'substantial change of circumstances' is given at Article 2(28) TPD. HTPs, which gained ground on the EU market after the TPD was adopted, are not defined under the Directive and are considered as 'novel tobacco products'. A novel tobacco product is a tobacco product that does not fall within any of the categories currently regulated under the TPD and is placed on the market after 19 May 2014: Tobacco Products Directive, art 2(14). Delegated Directive 2022/2100 introduces a definition of HTPs within the TPD: 'a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking': art 1. It is noteworthy that the device used for heating HTPs falls outside this definition, and out of the TPD's reach altogether. There has therefore been calls for HTPs and their devices to be properly addressed as a separate category in the future revision of the TPD: European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 111.

[1637] *Poland v European Parliament and Council* (n 587); *Philip Morris* (n 28); *Planta Tabak* (n 1635). A thorough analysis of these judgements is made in Chapter 7.

[1638] *Poland v European Parliament and Council* (n 587), para 48.

[1639] ibid, paras 49-55.

category, and the absence of a specific procedure to determine which product fell in that category, constituted a breach of legal certainty.[1640] It also rejected the argument that the distinction between tobacco products containing a characterising flavour according to sales volumes infringed the principle of equal treatment and proportionality.[1641]

The prohibition of flavoured tobacco was expected to result in a decrease in cigarette consumption in the European Union of 0.5 to 0.8% over a five-year period.[1642] A 2020 study from the EUREST-PLUS Consortium, whose data were collected before the ban on menthol entered into force, invites to a certain degree of caution as to its effectiveness.[1643] It shows that a majority of smokers using flavoured cigarettes switched to unflavoured ones and that users of flavoured tobacco did not quit in greater numbers if compared to smokers of unflavoured tobacco. This should not, however, be interpreted as a failure of the measure. The main objective behind the ban on flavours was to reduce the appeal and the uptake of smoking, for young people especially, rather than providing an incentive to quit smoking. Further, it is still too early to measure the effect of the ban on menthol cigarettes, by far the most popular category of flavoured tobacco products – more than twice as many smokers used menthol compared to other flavours prior to the TPD – which is likely to have the most effect on consumption patterns.[1644]

Consumers and manufacturers may also have taken advantage of some loopholes in the legislation. As it stands, the prohibition not only leaves aside a range of other tobacco products but also fails to cover flavoured products intended to change the taste of tobacco but *sold separately*, 'such as cigarette paper tubes with characterising flavour, liquid to flavour roll-your own tobacco, aroma capsules, menthol sticks to insert into cigarettes, and flavoured filters or flavoured cards put inside a cigarette packet'.[1645] Consumers may have reverted to these alternatives to counteract the effects of the prohibition. These market developments and the overall effect of the prohibition on characterising flavours should therefore be carefully monitored in the coming years.

[1640] ibid, paras 30-34.
[1641] ibid, paras 35-58.
[1642] European Commission, 'Impact assessment accompanying the document: Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member states concerning the manufacture, presentation and sale of tobacco and Related products' (TPD impact assessment) (Staff Working Document) SWD (2012) 452 final, part 1, 114. See also *Poland v European Parliament and Council* (n 587), para 101.
[1643] Mateusz Zatoński and others, 'Cessation Behaviours among Smokers of Menthol and Flavoured Cigarettes Following the Implementation of the EU Tobacco Products Directive: Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health 34, 36. The EUREST-PLUS Consortium is an EU-funded scientific project aimed at monitoring and evaluating the impact of the TPD at the EU level. For more information, see <http://ensp.network/eurest-plus/> accessed 11/05/2023.
[1644] Mateusz Zatoński and others, 'Characterising Smokers of Menthol and Flavoured Cigarettes, Their Attitudes towards Tobacco Regulation, and the Anticipated Impact of the Tobacco Products Directive on Their Smoking and Quitting Behaviours: The EUREST-PLUS ITC Europe Surveys' (2018) 16 Tobacco Induced Diseases 1.
[1645] European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 61-62. See Anne-Line Brink, Andrea Stadil Glahn and Niels Them Kjaer, 'Tobacco Companies' Exploitation of Loopholes in the EU Ban on Menthol Cigarettes: A Case Study from Denmark' (2022) Tobacco Control, Online First <https://tobaccocontrol.bmj.com/content/early/2022/03/20/tobaccocontrol-2021-057213> accessed 11/05/2023 11 October 2022.

3.3. Product composition: ingredients, emissions and others

For a number of products that can legally be sold in the EU, Union rules set specific requirements as to their composition, so as to limit the health risks incurred. More precisely, these composition requirements follow two different but complementary objectives: preventing the intake of substances which are intrinsically harmful and preventing the use of substances which, even if per se innocuous, are susceptible to mislead consumers and alter their perception of the risks, thereby contributing to a greater consumption of the products in question.

3.3.1. Tobacco products

The TPD contains provisions on ingredients and emissions, applicable to tobacco products and electronic cigarettes, with a view to limit the attractiveness of tobacco products and the health risks associated with it. These are contained in Articles 3 to 7 for tobacco products and Article 20 for e-cigarettes.

Article 3 lays down maximum emission levels from cigarettes for tar, nicotine, carbon monoxide and other substances (TNCO emissions). These are set at 10 mg of tar, 1 mg of nicotine and 10 mg of carbon monoxide per cigarette.[1646] The Commission may, by means of delegated acts, decrease these maximum emission levels or adopt supplementary maximum levels, applicable to other products or other types of emissions. [1647] Member States may also adopt supplementary maximum emission levels.[1648] Article 4 sets methods for the measurement of emissions, which must be verified by approved laboratories that are not directly or indirectly controlled by the tobacco industry.[1649]

Article 7 regulates ingredients present in tobacco products. Apart from the ban on characterising flavours, it prohibits the use of a number of additives: (i) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks, (ii) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality, (iii) additives having colouring properties for emissions, (iv) additives that facilitate inhalation or nicotine uptake in tobacco products for smoking and (v) additives that have carcinogenic, mutagenic or reprotoxic (CMR) properties in unburnt form.[1650] Tobacco products containing additives in quantities 'that increase the toxic

[1646] Tobacco Products Directive, art 3(1).
[1647] ibid, arts 3(2) and (4).
[1648] ibid, art 3(3).
[1649] The list of approved laboratories is available at <https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf> accessed 11/05/2023. Regarding existing concerns as to the methods currently in use for the measurement of TNCO and their independence from the industry, see European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 33-39. Regarding the interpretation and validity of Article 4 TPD, see Case C-160/20 *Stichting Rookpreventie Jeugd and Others* [2022] EU:C:2022:101.
[1650] Tobacco Products Directive, art 7(6).

or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree' are also prohibited.[1651]

Regulating ingredients and emissions requires to gather information, to assess the attractiveness, addictiveness and toxicity of tobacco products and the health risks associated with their consumption.[1652] Articles 5 and 6 lay down a number of reporting obligations applicable to manufacturers and importers. These must submit information to Member States' competent authorities regarding the ingredients used in the manufacture of their products and their quantities, and regarding emission levels.[1653] Enhanced reporting obligations apply to certain additives contained in cigarettes and RYO tobacco, figuring on a list adopted by the Commission.[1654] These additives are those most commonly used and those for which certain evidence exists suggesting that they (i) contribute to the toxicity or addictiveness of the products concerned, (ii) result in a characterising flavour, (iii) facilitate inhalation or nicotine uptake or (iv) lead to the formation of substances that have CMR properties.[1655]

In order to monitor market developments, Article 19 lays down specific obligations regarding novel tobacco products. Manufacturers and importers are required to submit a notification to the competent authorities of the Member State where they intend to place such product on the market, six months before the intended introduction of the product.[1656] The notification must be accompanied by a detailed description of the product and a number of information regarding its use, ingredients and emissions, as well as available scientific studies regarding its effects on health and tobacco consumption.[1657] Member States may introduce a system for the authorisation of novel tobacco products.[1658] Article 22 also lays down obligations regarding the reporting of ingredients used in herbal products for smoking.

E-cigarettes and their refill containers are subject to an entirely distinct set of provisions in the TPD, contained in Article 20.[1659] It must be borne in mind that the Directive does not apply to e-cigarettes and refill containers regulated as medicinal products or medical devices, thus coming within the scope of Directive 2001/83 and Regulation 2017/745 (former Directive

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[1651] ibid, art 7(9).
[1652] ibid, recital 13.
[1653] ibid, art 5(1). See Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products [2015] OJ L312/5.
[1654] Tobacco Products Directive, art 6(1). See Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations [2016] OJ L131/88.
[1655] Tobacco Products Directive, arts 6(1) and (2).
[1656] Tobacco Products Directive, 19(1).
[1657] ibid.
[1658] ibid, art 19(3).
[1659] Electronic cigarette and refill container are defined at Articles 2(16) and (17) of the TPD as, respectively, 'a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank' and 'a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette'. In Case C-477/14 *Pillbox 38 (UK) Ltd v Secretary of State for Health* [2016] EU:C:2016:324, the Court ruled that Article 20 was valid, in light among other things of the principle of proportionality, subsidiarity and equal treatment. See further Chapter 7.

93/42).[1660] Nicotine-containing liquid used for e-cigarettes must be stored in refill containers not exceeding a volume of 10 ml or in e-cigarettes tanks and single use cartridges that do not exceed a volume of 2 ml.[1661] The liquid itself must not exceed the threshold of 20 mg of nicotine per millilitre and must be manufactured only with ingredients of high purity that do not pose a risk to human health.[1662] The use of additives prohibited under Article 7(6) TPD related to tobacco products is also prohibited for the nicotine-containing liquid.[1663] E-cigarettes must deliver the nicotine doses at consistent levels.[1664] E-cigarettes and containers must also be child- and tamper-proof, and prevent any breakage and leakage.[1665]

Article 20 does not regulate the use of flavours in e-cigarettes, which is left to the discretion of Member States.[1666] As of May 2021, only three EU Member States – Finland, Estonia and Hungary – had implemented a full ban on e-cigarette flavours.[1667] As for tobacco products, flavours could constitute a gateway to the consumption of e-cigarettes and attract new users, especially youngsters, even more so considering that flavours in cigarettes and RYO tobacco are banned.[1668] To ensure consistency across the range of products regulated by the TPD, the Commission is currently considering introducing a full ban on flavours in the next revision of the Directive.[1669]

As for tobacco products, the TPD also lays down monitoring and reporting obligations for e-cigarettes. A notification to Member States' authorities must be made six months prior to the intended placing on the market of e-cigarettes and containers, and for each substantial modification of the product.[1670] Manufacturers and importers of e-cigarettes and containers are

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[1660] TPD, art 20(1). See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169/1; Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L117/1.

[1661] Tobacco Products Directive, art 20(3)(a).

[1662] ibid, arts 20(3)(b), (d) and (e). The Court clarified in *Pillbox 38* (n 1662), paras 94-95, that electronic cigarettes whose liquid contains more than 20 mg/ml of nicotine are not prohibited under EU law. Pursuant to Article 20(1), read in the light of Recital 36 the TPD, such products may be placed on the market under the conditions laid down by Directive 2001/83/EC and Regulation 2017/745. This is meant to take account of the need for some consumers, based on their state of dependence or their habits, to use electronic cigarettes with a higher nicotine strength as an aid to quit smoking.

[1663] Tobacco Products Directive, art 20(3)(c).

[1664] ibid, art 20(3)(f).

[1665] ibid, art 20(3)(g). See Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes [2016] OJ L101/15.

[1666] See ibid, recital 47.

[1667] European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 117.

[1668] ibid 117-118.

[1669] European Commission, 'Europe's Beating Cancer Plan' (n 23) 9.

[1670] Tobacco Products Directive, art 20(2). See Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers [2015] OJ L309/15. The notification must include a number of information, including ingredients and emissions, toxicological data and nicotine doses and uptake: TPD, arts 20(2)(a)-(g). This information is made publicly

required to annually submit various commercial data, including their sales volumes and information on consumer preferences,[1671] and to collect information about the suspected adverse effects on human health of these products.[1672] In case of safety, quality or conformity concerns, corrective action must be taken to remove the affected product from the market, in which case the authorities of other Member States where the product is intended to be marketed must be informed.[1673] Similarly, if a competent national authority considers that some specific products or types of products present a serious risk to human health, it may take appropriate provisional measures, under the control of the Commission, in which case other Member States must be informed as well.[1674]

A last provision applicable to tobacco products should be mentioned, although it is not a composition requirement per se. Article 14 sets a minimum content for unit packets of cigarettes and RYO tobacco at, respectively, 20 cigarettes and no less than 30 gram of tobacco.[1675] This rule aims at increasing the upfront cost of tobacco so as to deter its purchase, for young people especially.[1676] As explained by the Court in *Philip Morris*, 'smaller sales units are more of an inducement to start smoking because the consumer is inclined to think that they are cheaper, less of a constraint and psychologically more acceptable'.[1677] The EU does not set a maximum number of cigarettes per unit packet. An interesting debate exists on these minimum and maximum thresholds, some authors claiming that a cap, set for instance at 20 cigarettes, could be beneficial, since evidence suggests that greater cigarette pack size is associated with higher cigarette consumption.[1678] Others think that a cap is unlikely to bring benefits, rather favouring a dramatic scale-up of the minimum content of packets, for instance with a sale of cigarettes in boxes of 100 units,[1679] so as to deter buyers even more.

3.3.2. Foods and alcoholic beverages

If a wide range of general or product-specific instruments govern the composition of foods and alcoholic beverages placed on the EU market,[1680] these are usually enacted for free movement

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available on a website: ibid, art 20(8). As clarified by the Court in *Pillbox 38*, this procedure must be construed as a notification scheme rather than an authorisation scheme: *Pillbox 38* (n 1662), para 70.

[1671] ibid, art 20(7).

[1672] ibid, art 20(9).

[1673] ibid.

[1674] ibid, art 20(11).

[1675] Tobacco Products Directive, art 14(1).

[1676] See European Commission, '10 key changes for tobacco products sold in the EU' (n 1431); Anna KM Blackwell and others, 'Should Cigarette Pack Sizes Be Capped?' (2020) 115 Addiction 802.

[1677] *Philip Morris* (n 28), para 197.

[1678] Blackwell and others (n 1676). See also European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 66.

[1679] See Kenneth M Cummings, 'What's in a Number?' (2020) 115 Addiction 814.

[1680] See e.g. Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts [1999] OJ L66/26; Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption [2000] OJ L197/19; Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products

and consumer protection purposes, ensuring the homogeneity of foods marketed under a certain name or protecting the use of certain denominations.[1681] Nutrition and health concerns tend to be absent from that legal framework,[1682] although some provisions, taken in isolation, may contribute to improve the nutritional quality of certain products.[1683] Save for some notable exceptions, the EU's powers to set the composition of foods and alcoholic beverages remain vastly underused. This may be regretted, as a recent study has shown that, despite some progress made in certain food categories, the amounts of sugars, saturated fat and salt contained in products sold in Europe remains too high from a public health perspective.[1684]

The regulation of trans fatty acids, also called trans fats or TFAs,[1685] is the EU's strongest legislative effort to date regarding the nutritional composition of food products. TFAs are a particular type of unsaturated fatty acids that can be produced industrially or be naturally present in food.[1686] High TFAs intake is a risk factor for coronary heart disease,[1687] the single leading cause of mortality in the EU.[1688] Intake of TFAs is not required in human diet and should therefore ideally be entirely avoided.[1689] TFAs are however contained in fats and oils, which represent important sources of essential fatty acids and nutrients, and can therefore not be completely eliminated from human diet without risking to compromise appropriate intake of these essential fatty acids and nutrients.[1690] EFSA therefore recommends 'that trans fatty acids intake should be as low as is possible within the context of a nutritionally adequate diet'.[1691]

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intended for human consumption [2002] OJ L10/58. Regarding these 'recipe laws', see MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 196-206.

[1681] Recipe laws are thus a direct outcome to the food cases referred to in Chapter 4, Section 3.1.2, where Member States tried to prevent foreign products sold under a certain name to enter their markets. Regarding EU quality schemes, see above n 402.

[1682] It is for instance remarkable that health is nowhere mentioned in Directive 2000/36 on cocoa and chocolate.

[1683] Such would be the case for instance of the prohibition of added sugars in fruit juices contained in Directive 2001/112, annex I. This rule is in force since 2012 and the adoption of Directive 2012/12/EU of the European Parliament and of the Council of 19 April 2012 amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption [2012] OJ L115/1.

[1684] Maria Alice Moz-Christofoletti and Jan Wollgast, 'Sugars, Salt, Saturated Fat and Fibre Purchased through Packaged Food and Soft Drinks in Europe 2015–2018: Are We Making Progress?' (2021) 13 Nutrients 2416.

[1685] TFAs are defined as 'fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration': Food Information Regulation, annex 1 art 4.

[1686] European Commission, 'Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population', COM (2015) 619 final, 3.

[1687] ibid 4; EFSA, 'Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol' (2010) 8 EFSA Journal 1461, 1465; EFSA, 'Scientific and technical assistance on trans fatty acids' (2018) Technical report.

[1688] European Commission, Executive summary of the impact assessment of the initiative to limit industrial trans fats intakes in the EU (Staff Working Document) SWD (2019) 161 final, 1.

[1689] EFSA, 'Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol' (n 1687) 5; EFSA, 'Scientific and technical assistance on trans fatty acids' (n 1687).

[1690] EFSA, 'Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol' (n 1687) 5

[1691] ibid.

A 2015 Commission report established that although TFAs' intake had been decreasing in the EU population and was on average below the 1% of total daily energy intake threshold recommended by the WHO,[1692] some population groups were at risk of exceeding this threshold, such as low-income citizens or young people between the age of 18 and 30.[1693] The report also established that consumer knowledge of TFAs and their effects on health was low[1694] and that information about TFAs had little impact on consumers' ability to identify the healthier product when confronted to a complex but realistic choice situation, whereby a product is for instance high in TFAs and low in saturated fatty acids, salt and sugars, or vice versa.[1695] The report therefore expressed doubts as to the effectiveness of using TFAs labelling as a regulatory option to decrease consumption.

On this basis, the Commission considered that placing a limit on the TFAs content of food was the most effective option to achieve the objective of reducing intake to a minimum,[1696] which resulted in the adoption in 2019 of Commission Regulation 2019/649.[1697] Save for TFAs naturally present in fat of animal origin, the Regulation sets an upper limit of 2 grams of TFAs per 100 grams of fat, for food intended for the final consumer and food intended for supply to retail.[1698] This limit corresponds to the WHO limit of 1% TFAs in the daily energy intake.[1699] The Regulation is fully applicable since 1 April 2021.[1700] The Regulation also mandates food business operators that do not supply directly to the consumer to inform their customers if the foods they sell exceed this limit.[1701]

A number of other provisions on food composition are contained in instruments applicable to specific category of products. Regulation 609/2013 on food for specific groups regulates foods that are vital for the management of certain conditions or essential to satisfy the nutritional requirements of certain vulnerable population groups, such as infants and young children, and foods that are used as diet replacement for weight control.[1702] It covers the following categories

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[1692] European Commission, 'Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population' (n 1686) 8. This report was submitted pursuant to Article 30(7) of the Food Information Regulation.
[1693] ibid 9.
[1694] ibid 9. See also TNS European Behaviour Studies Consortium (n 309) 63.
[1695] European Commission, Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population (n 1686) 9. See also TNS European Behaviour Studies Consortium (n 309) 14-16.
[1696] European Commission, Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population (n 1686) 13-14.
[1697] Commission Regulation (EU) 2019/649 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin [2019] OJ L 110/17.
[1698] ibid, art 1.
[1699] European Commission, Factsheet, 'Trans fats in foods a new regulation for EU consumers' (2019).
[1700] ibid, art 4.
[1701] Commission Regulation 2019/649, art 2.
[1702] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and

of food: (i) infant formula and follow-on formula, (ii) processed cereal-based food and baby food, (iii) food for special medical purposes and (iv) total diet replacement for weight control.[1703] The Regulation lays down general requirements applicable to these various categories and a number of specific requirements, some of which adopted by means of delegated acts.[1704] It requires, as a general rule, that any product regulated under that instrument 'is appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended, in accordance with generally accepted scientific data'[1705] and does 'not contain any substance in such quantity as to endanger the health of the persons for whom it is intended'.[1706] The delegated regulations on infant formulae and food for diet control lay down more specific composition requirements.[1707] Delegated Regulation 2017/1798 requires for instance that the energy provided by a daily ration of total diet replacement for weight control products is no less than 600 kcal and no more than 1 200 kcal.[1708]

Directive 2002/46 on food supplements and Regulation 1925/2006 on fortified foods include provisions regarding the maximum amounts of vitamins and minerals contained in these two categories products.[1709] Food supplements are 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form'.[1710] Fortified foods are foods to which vitamins and minerals have been added, in order to correct a deficiency in the population, or specific population groups, and to improve its nutritional status.[1711] Regulation 1925/2006 prohibits the addition of vitamins and minerals to beverages containing more than 1,2% vol of alcohol,[1712] on the ground that foods to which vitamins and minerals are added are often promoted by manufacturers and may be perceived by consumers

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2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 [2013] OJ L181/35.

[1703] ibid, art 1. See art 2 for the definitions.

[1704] ibid, art 11.

[1705] ibid, art 9(1).

[1706] ibid, art 9(2).

[1707] Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control [2017] OJ L259/2, art 3; Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding [2016] OJ L25/1, arts 2-4.

[1708] Delegated Regulation 2017/1798, annex I.

[1709] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [2002] OJ L183/51, art 5; Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods [2006] OJ L404/26, art 6.

[1710] Directive 2002/46, art 2(a). Only vitamins and minerals listed in the Directive can be used as food supplements: ibid, art 4(1), annexes I and II.

[1711] Regulation 1925/2006, art 3, annexes I and II.

[1712] ibid, art 4(b). A very narrow exception exists, see points (i) to (iii).

as having a health advantage over products that do not contain such nutrients.[1713] Alcoholic beverages should therefore not benefit from such a promotional effect.

4. Guide choice through disincentives: the EU's under-used taxation powers

As discussed in Chapter 1, measures affecting price and disincentivising the purchase of unhealthy commodities are widely seen as the most effective type of lifestyle risks control measures. Evidence is particularly robust as regards tobacco products and alcoholic beverages, two categories of lifestyle products over which the EU has exercised its taxation powers. No rules have been adopted on the taxation of unhealthy foodstuffs, something that may change with the new Beating Cancer Plan.[1714]

Under Article 113 TFEU, the EU may adopt harmonisation measures in the field of indirect taxation, as regards turnover taxes and excise duties in particular. EU rules applicable to the taxation of alcohol and tobacco belong to three sets of instruments of fiscal policy: excise duties, value added tax (VAT) and customs duties. Excise duties are indirect taxes levied on the sale or use of specific products. In the EU, rules on excise duties apply to tobacco, alcohol, and energy products. The VAT is a general tax applying to most of the sales of goods and provisions of services. While excise duties are characterised by a 'selectivity in coverage [and] discrimination in intent',[1715] the VAT 'is generally levied to raise revenue [and] not to pursue other public policy objectives'.[1716] Customs duties, finally, are levies imposed on goods imported from third countries when entering the EU internal market.

Within this framework, three kinds of rules are of specific interest from a public health perspective. First, fiscal provisions stricto sensu, dealing with the structure and the rates of excise duty for tobacco and alcohol. These are contained in instruments specific to these two categories of products. Second, rules that govern the cross-border acquisitions of products by individuals within the EU internal market. Third, rules governing the imports of tobacco and alcoholic products originating from third countries, and the possible exemptions from the payment of excise duties, VAT and customs duties applying to them. The second and third type of rules are contained in instruments applying both to tobacco and alcoholic beverages, as well as a range of other products.

Similarly to Article 114 TFEU, Article 113 TFEU is primarily geared towards ensuring the establishment and the functioning of the internal market and avoiding distortions of competition. Differences in tax rates between Member States creates distortions of competition

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[1713] ibid, recital 12.
[1714] See European Commission, 'Europe's Beating Cancer Plan' (n 23) 11: 'Taxation measures can also help with health promotion. The Commission's proposal on VAT rates allows Member States to make more targeted use of rates, for instance to support the availability and affordability of healthy and nutritious food. In addition, in 2022, the Commission will publish a study mapping fiscal measures and pricing policies on sugars, soft drinks and alcoholic beverages. Following this, the Commission will look into the feasibility of proposing new tax measures on sugars and soft drinks.'
[1715] Alemanno and Carreño, '"Fat Taxes" in Europe – A Legal and Policy Analysis under EU and WTO Law' (n 781) 103.
[1716] ibid.

and diverging rules as regards chargeability may create obstacles to the free movement of goods or people. Yet, as is the case with Article 114 TFEU, nothing prevents the EU from using its taxation powers to better protect public health, setting rates at a sufficiently high level or ensuring that taxation is not circumvented by cross-border movements. As we shall see, though, it is not the orientation chosen by the EU so far. Rules on excise duties and other indirect forms of taxation remain primarily concerned with the proper functioning of the EU internal market. Worse, on some occasions, these are even detrimental to public health, undermining the effectiveness of Member State fiscal policies. There is a growing awareness of the potential borne by that legal framework for the purpose of lifestyle health promotion, yet not fully tapped into. This may change in the coming years. The European Commission, as part of the EU Beating Cancer Plan, expressed its intention to review existing rules on excise duty to take better account of the public health dimension, both regarding the rate and structure of duties and the cross-border acquisitions of individuals.[1717]

In the following developments, the rules governing the general arrangements for excise duties and the specific rules applicable to the rate and structure of excise duty on tobacco and alcohol are covered first. Rules addressing specific situations linked to the cross-border movement of goods and people, both internal and external to the EU internal market, are then presented. Finally, the section addresses the issue of illicit trade in tobacco products, one of the main obstacles to the effective payment of excise duties and other dues.

4.1. Excise duties: general rules, structure and rate

Excise duties for tobacco and alcohol are governed by a general framework and by specific instruments applicable to each of the two categories of products.[1718] The general arrangements applicable to excise duties are contained in Directive 2020/262 (the General Excise Duties Directive),[1719] former Directive 2008/118.[1720]

4.1.1. General arrangements

The General Excise Duties Directive is primarily an internal market instrument whose provisions seek to unify the concept of excise duty and the conditions for its chargeability, by making clear when excise goods are released for consumption and who is liable to pay the

[1717] European Commission, 'Europe's Beating Cancer Plan' (n 23) 9. See also European Commission, Communication from the Commission to the European Parliament and the Council, 'An action plan for fair and simple taxation supporting the recovery strategy', COM (2020) 312 final, 2-3.
[1718] According to the Court in *Commission v France*, the various directives on excise duties 'are essentially confined to classifying products on the basis of objective factors, connected in particular with the production methods employed, to defining the conditions governing chargeability to excise duty, to organising a system for circulation of the products subject to excise duty, to determining the tax base of the excise duties and to fixing minimum rates': Case C-434/97 *Commission v France* [2000] EU:C:2000:98, para 17.
[1719] Council Directive (EU) 2020/262 of 19 December 2019 laying down the general arrangements for excise duty (recast) (General Excise Duties Directive) [2020] OJ L58/4.
[1720] Council Directive 2008/118/EC of 16 December 2008 concerning the general arrangements for excise duty and repealing Directive 92/12/EEC [2009] OJ L9/12.

excise duty.[1721] The Directive applies to energy products and electricity, alcohol and alcoholic beverages, and manufactured tobacco.[1722]

Importantly, from the point of view of Member State autonomy and health, Article 1 of the Directive lays down the conditions under which Member States may continue to conduct on independent taxation policy. For the three categories of excise goods to which the Directive applies, Article 1(2) of the Directive allows Member States to levy other indirect taxes 'for specific purposes', meaning that the objective of the tax must be other than budgetary.[1723] In *Commission v France*, the Court confirmed that 'a contribution levied on tobacco and alcoholic beverages on the ground of the health risks involved in immoderate use of those products' follows a specific purpose and can thus lawfully be enacted by Member States.[1724] These are therefore not deprived of this health tool.[1725]

Article 1(3) makes clear that Member States are free to impose taxes on products other than excise goods and on the supply of services. As regards services, this possibility includes taxes 'relating to excise goods, which cannot be characterised as turnover taxes'.[1726] In *Hermann*, the Court clarified that a tax applicable to the consumption of alcoholic beverages in the catering sector constituted a tax on the supply of services within the meaning of Article 1(3).[1727] When imposing taxes on non-excised goods or services, Member States need not put forward a specific purpose[1728] and need not comply with Union tax rules, but must simply ensure that these taxes do not, 'in trade between Member States, give rise to formalities connected with the crossing of frontiers'.[1729] Since the requirement of Article 1(3) – not giving rise to formalities connected with the crossing of frontiers – is less strict than that of Article 1(2) – complying with Union tax rules – it is important to distinguish between additional taxes on excise goods, caught by the latter article, and taxes on the supply of a service relating to excise goods, caught by the former article.

[1721] ibid, recitals 2 and 7.
[1722] ibid, art 1(1).
[1723] *Commission v France* (n 1718), para 19; Case C-437/97 *EKW and Wein & Co.* [2000] EU:C:2000:110, para 31; Case C-491/03 *Hermann* [2005] EU:C:2005:157, para 16.
[1724] *Commission v France* (n 1718), para 19. For an unsuccessful reliance on public health as the specific purpose of a tax on alcoholic beverages, see *EKW and Wein & Co.* (n 1723), para 37.
[1725] The possibility to enact other indirect taxes on excise goods is however subject to the condition that those taxes comply with Union tax rules applicable to excise duty or VAT, 'as far as determination of the tax base, calculation of the tax, chargeability and monitoring of the tax are concerned, but not including the provisions on exemptions': General Excise Duties Directive, art 1(2). In *Commission v France* (n 1718), para 27, the Court clarified that Article 1(2) 'does not require Member States to comply with all rules applicable for excise duty or VAT purposes as far as determination of the tax base, calculation of the tax, and chargeability and monitoring of the tax are concerned. It is sufficient that the indirect taxes pursuing specific objectives should, on these points, accord with the general scheme of one or other of these taxation techniques as structured by the Community legislation'. See also *EKW and Wein & Co.* (n 1723), para 47.
[1726] General Excise Duties Directive, art 1(3).
[1727] *Hermann* (n 1723), paras 23-30.
[1728] ibid, para 33.
[1729] General Excise Duties Directive, art 1(3).

Although not having a clear link to public health, other provisions of the Directive have been found to potentially constrain Member States in their public health policy. Article 6(2) of the Directive provides that excise duty becomes chargeable at the time and in the Member State, of release for consumption. Article 8(1) provides that the chargeability conditions and rate of excise duty to be applied are to be those in force in that Member State on the date on which the duty becomes chargeable. In *Commission v Portugal*,[1730] (see, as regards proportionality, Chapter 4, Section 3.1.3) Portugal had a rule in place prohibiting the marketing and sales of packets of cigarettes after March of the year following that in which they were released for consumption. The measure's aim was to remove incentives for economic operators to release excessive quantities of tobacco products in anticipation of a future increase of excise duty, thus pursuing a public health objective. The Court considered that Article 8(1) did not prevent Portugal to adopt such a rule, provided it complies with the principle of proportionality.[1731] The Court found that it was an appropriate measure to reach the objectives of combating tax evasion, tax avoidance and the protection of public health,[1732] and that the disadvantages caused to operators were not disproportionate to the objectives pursued.[1733] The Court did found however that a less restrictive measure could be put in place, namely to apply the measure only in the case of an increase in the rate of excise duty on cigarettes.[1734] Indeed, '[i]n the absence of any increase, the incentive for economic operators to release excessive quantities of cigarettes for consumption, in order to avoid paying higher excise duties is non-existent'.[1735]

4.1.2. Specific rules on structure and rate

The specific rules governing the structure and rate of excise duty are contained in Directive 2011/64 (the 'Tobacco Excise Duties Directive')[1736] and two directives on alcohol, one applicable to the structure of alcohol excise duties, Directive 92/83 (the 'Alcohol Excise Duties Structure Directive'),[1737] and one applicable to the rates of alcohol excise duties, Directive 92/84 (the 'Alcohol Excise Duties Rates Directive')[1738].

[1730] *Commission v Portugal* (n 1181).
[1731] ibid, paras 61-62.
[1732] ibid, paras 66-67.
[1733] ibid, paras 81-90.
[1734] ibid, para 80.
[1735] ibid, para 79.
[1736] See also the two previous directives: Council Directive 72/464/EEC of 19 December 1972 on taxes other than turnover taxes which affect the consumption of manufactured tobacco [1972] OJ L303/1; Council Directive 95/59/EC of 27 November 1995 on taxes other than turnover taxes which affect the consumption of manufactured tobacco [1995] OJ L291/40.
[1737] Council Directive 92/83/EEC of 19 October 1992 on the harmonization of the structures of excise duties on alcohol and alcoholic beverages (Alcohol Excise Duties Structure Directive) [1992] OJ L316/21.
[1738] Council Directive 92/84/EEC of 19 October 1992 on the approximation of the rates of excise duty on alcohol and alcoholic beverages (Alcohol Excise Duties Rates Directive) [1992] OJ L316/29.

The Tobacco Excise Duties Directive applies to cigarettes, cigars and cigarillos and smoking tobacco, including fine-cut tobacco for the rolling of cigarettes.[1739] Cigarettes are subject to a set of specific provisions[1740] distinct from those applicable to other tobacco products.[1741] The minimum rate of excise duty for cigarettes consists of a specific component and an *ad valorem* component. The overall excise rate should be of at least 90 euros per 1000 cigarettes and represent 60% of the weighted average retail selling price of cigarettes.

The Tobacco Excise Duties Directive pursues a dual objective of ensuring the proper functioning of the internal market while providing for a high level of health protection,[1742] recognising that 'the level of taxation is a major factor in the price of tobacco products, which in turn influences consumers' smoking habits'.[1743] This represents an improvement if compared to the two previous directives on tobacco excise duties, where the only mention of health referred to the need of preserving a 'healthy competition' in the single market.[1744] Though, as it stands, the Directive does little for health.

The Directive provides for minimum rates and structures to be applied to tobacco products, in the hope that these lead to a convergence of the tax levels applied by Member States, reducing fraud and smuggling within the Union and benefiting public health.[1745] The 2020 evaluation report of the Directive showed however that most Member States had reached by then the prescribed minimum tax levels, 'so the current provisions have become of little relevance for the way forward',[1746] making the revision foreseen in the EU Cancer Plan all the more necessary. Since the Directive does not set maximum tax rates, the attempted convergence did not materialise, quite the contrary. As a result of some Member States conducting a strong tobacco control policy, the gap between 'high-tax' and 'low-tax' countries slightly expanded between 2010 and 2017.[1747] As will be further explored below, this provides a powerful incentive for illicit trade and unrecorded tobacco consumption.[1748] The report concluded that 'EU minimum rates have mainly supported public health related impact in only a minority of Member States in Eastern Europe'.[1749]

Not only does the Tobacco Excise Duties Directive little for public health itself, but it also prevents Member States from adopting some useful fiscal measures. In order to prevent the

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[1739] ibid, art 2(1). See the precise definitions contained in arts 3 to 5. On these definitions, see Case C-638/15 *Eko-Tabak* [2017] EU:C:2017:277; Case C-638/17 *Skonis ir kvapas* [2019] EU:C:2019:316; Case C-674/19 *Skonis ir kvapas* [2020] EU:C:2020:710.
[1740] Tobacco Excise Duties Directive, arts 7 to 12.
[1741] ibid, arts 13 and 14.
[1742] ibid, recital 2.
[1743] ibid, recital 16.
[1744] Directive 72/464/EEC, recital 1; Directive 95/59/EC, recital 2.
[1745] ibid, recitals 15 and 16.
[1746] European Commission, 'Evaluation of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco' (Staff Working Document) SWD (2020) 32 final, 51.
[1747] ibid 20.
[1748] Unrecorded tobacco consumption comprises non-domestic (EU) legal products, illegal products and external legal products: see ibid 26.
[1749] ibid 34.

level of taxation of the cheapest cigarettes from being too low, the Directive permits Member States to levy a minimum excise duty.[1750] In *Yesmoke*, the Italian legislation at issue provided that the minimum excise duty for cigarettes sold cheaper than the most popular price category was to represent115% of the minimum excise duty applicable to the cigarettes in the most popular price category, so as to ensure that the price of the cheapest cigarettes reached a certain level.[1751] The Court ruled that the minimum excise duty provided for in the Directive had to be applied to all cigarettes, irrespective of their characteristics or price,[1752] which precluded the adoption of such legislation.[1753] As public health was an objective already taken into account in the Directive, that measure could not be validly defended on grounds of public health.[1754]

Another problem is the impossibility for Member States to enact minimum price measures. Under the Tobacco Excise Duties Directive, national authorities may apply higher rates of excise duty but are not allowed to directly set prices. According to Recital 10 of the Directive, '*the imperative needs of competition* imply a system of freely formed prices for all groups of manufactured tobacco',[1755] which explains why Article 15(1) provides that manufacturers and importers of tobacco shall be free to determine the maximum retail selling price for each of their products in each Member State.

In a series of cases, the Court judged that Member State rules imposing a minimum retail selling price for cigarettes were contrary to Article 15(1) and could not be justified on ground of public health. According to the Court, 'the setting of a minimum selling price by public authorities inevitably has the effect of limiting the freedom of producers and importers to determine their maximum retail selling prices since, in any event, such prices cannot be any lower than the compulsory minimum price'.[1756] Such legislation is therefore 'capable of undermining competition by preventing some of those producers or importers from taking advantage of lower cost prices so as to offer more attractive retail selling prices'.[1757] As previously discussed in Chapter 4 (see Section 3.1.2), the Court wrongly concluded that minimum price measures did not represent a more effective alternative to excise duties to ensure that all products sold on the market reach a sufficient price, thus depriving Member States of a useful public health tool, complementing indirect taxation.[1758]

[1750] Tobacco Excise Duties Directive, art 8(6). See Case C-428/13 *Yesmoke* [2014] EU:C:2014:2263, para 30.
[1751] *Yesmoke* (n 1750).
[1752] ibid, para 28. See also *Commission v France* (n 731), para 20.
[1753] *Yesmoke* (n 1750), paras 30-34.
[1754] ibid, paras 35-37.
[1755] Emphasis added.
[1756] *Commission v Greece* (n 1141), para 21, *Commission v France* (n 731), para 15. See also Case *Commission v France* (n 1087), para 37; *Commission v Ireland* (n 1441), para 40; *Commission v Italy* (n 1441), para 39.
[1757] *Commission v France* (n n 1087), para 37; *Commission v Ireland* (n 1441), para 40; *Commission v Italy* (n 1441), para 39. See also *Commission v Austria* (n 1441), para 33.
[1758] As discussed in Chapter 3, Section 3.1, such Member State rules are in any way likely to constitute measures having equivalent effect to quantitative restrictions within the meaning of Article 34 TFEU, in which case they may be upheld if justified and proportionate. We have seen in Chapter 4, Section 3.1.2, that the Court is not ready to accept such measures, on grounds of their disproportionate effect on free movement if compared to taxation measures.

In *Commission v France* and *Commission v Ireland*, the Court rejected both countries' argument that the adoption of a national minimum price measure was made necessary by Article 6(2) of the FCTC, which call on Parties to 'implement[…] tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption'.[1759] According to the Court, the FCTC 'imposes no actual obligation on the Contracting Parties with regard to price policies for tobacco products, and merely describes possible approaches […]', and 'provides only that the Contracting Parties are to adopt or maintain measures which "may include" implementing tax policies and, "where appropriate", price policies, concerning tobacco products'.[1760]

Member States are however not fully deprived of their ability to directly regulate price. In *Colruyt*, the Court ruled that Article 15(1) did not preclude a national legislation prohibiting retailers from selling tobacco products at a unit price lower than the price indicated by the manufacturer or importer on the revenue stamp affixed to those products, since such a rule did not affect their freedom to determine the maximum retail selling price for each of their products as guaranteed by this provision.[1761] In the *JTI* case, Advocate General Øe, considered that Article 15(1) did not preclude national legislation providing that manufacturers and importers can determine a single retail selling price for each of their manufactured tobacco products of a particular brand and type, which cannot be modulated according to the quantity contained in the unit packets.[1762] The reference for a preliminary ruling was subsequently withdrawn, so the Court did not have the opportunity to rule on the issue.[1763]

As regards alcohol, finally, the applicable rules do not seem at any point to consider the requirement of a high level of public health protection. The Alcohol Excise Duties Structure Directive sets out the structures of excise duties on alcohol and alcoholic beverages, the categories of products to which these apply and how they should be calculated.[1764] Five categories of products are covered: (i) beer;[1765] (ii) wine;[1766] (iii) fermented beverages other than beer and wine;[1767] (iv) 'ethyl alcohol', including spirits[1768] and (v) other alcoholic beverages with an alcoholic volume comprised between 1,2 % vol and 22 %, called intermediate products.[1769] The Alcohol Excise Duties Rates Directive lays down the rates applicable to alcohol products, which have not been modified since 1992. These are set at 0.748

[1759] FCTC, art 6(2).
[1760] *Commission v France* (n 1087), para 45; *Commission v Ireland* (n 1441), para 46.
[1761] *Colruyt* (n 691), paras 19-31. See also *INNO v ATAB* (n 686), paras 63-64.
[1762] Case C-596/17 *Japan Tobacco International* [2018] EU:C:2018:996, Opinion of Advocate General Saugmansgaard Øe.
[1763] Order of the Court in Case C-596/17 *Japan Tobacco International* [2019] EU:C:2019:131.
[1764] Reduced rate may be applied to products from independent small breweries and distilleries, and to certain products and geographical regions, such as rum produced in France's overseas territory or Greece's aniseed flavoured spirit drinks: Alcohol Excise Duties Structure Directive, arts 4, 22 and 23.
[1765] ibid, arts 1-6.
[1766] ibid, arts 7-10.
[1767] ibid, arts 11-15.
[1768] ibid, arts 19-23.
[1769] ibid, arts 16- 18.

or 1.87 euros per hectolitre for beer, depending on how the quantity is calculated, at 0 euro per hectolitre for wine and other fermented beverages, at 45 euros per hectolitre for intermediate products and at 550 euros per hectolitre of pure alcohol for spirits.[1770]

Contrary to the Tobacco Excise Duties Directive, the two alcohol directives make no reference to the contribution of alcohol taxation to public health. The 2016 evaluation report on the Alcohol Excise Duties Structure Directive confirmed this, stating that '[i]n practice, only a few Member States mentioned health policy objectives in connection with the overall relevance of the provisions [of the Directive]' and that 'accordingly, no definitive conclusions can be drawn in this area'.[1771] It added that public health considerations would need to be included in any future revision process. The near absence of health policy objectives in that area can easily be seen from the absence of any minimum tax rate for wine and other fermented beverages and the outdated character of the rates more generally, which are now three decades old.

Some first steps towards a better inclusion of public health concerns in the alcohol taxation framework have been taken with the adoption of Directive 2020/1151, which brought some amendments to the Alcohol Excise Duties Structure Directive and whose provisions are applicable since 1 January 2022.[1772] In order to encourage the development of low-strength beer, the alcohol content under which a reduced rate may be applied to beer is increased from 2,8 to 3,5% vol.[1773] The Commission is also required to submit a report on the implementation of the Alcohol Excise Duties Structure Directive every five years, taking account, inter alia, the impact of its provisions on public health.[1774]

4.2. Internal movement: cross-border acquisition and distance sales

While existing rules on the structure and rates of excise duties appear insufficient and even counter-productive from a public health perspective, these are not the most problematic aspect of the tobacco and alcohol taxation framework. In an internal market such as that of the EU, which guarantees the free movement of goods and people, consumers can take advantage of free movement to acquire excised goods cross-border, where lower taxation rates are applicable. Divergent excise duties rates between Member States provide a powerful incentive

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[1770] Alcohol Excise Duties Rates Directive, arts 3 to 6. Exemptions and reduced rate exist for some regions in Greece, in Italy and the Portuguese regions of Madeira and Azores: art 7. In *Socridis*, the difference in the excise duty applicable to wine and beer was challenged for being contrary to Article 110(2) TFEU, as wine could be exempted from all excise duties and not beer. The Court considered that the Directive let sufficient margin for Member States to ensure that no unlawful taxation in the meaning of 110(2) was put in place between the two beverages: Case C-166/98 *Socridis* [1999] EU:C:1999:316, para 20.

[1771] European Commission, Report from the Commission to the Council on the evaluation of Council Directive 92/83/EEC on the structures of excise duties on alcohol and alcoholic beverages, COM (2016) 676 final, 8.

[1772] Council Directive (EU) 2020/1151 of 29 July 2020 amending Directive 92/83/EEC on the harmonization of the structures of excise duties on alcohol and alcoholic beverages [2020] OJ L256/1, art 2. The main change introduced is the extension of the possibility of applying a reduced rate to independent small producers other than breweries and distilleries: Alcohol Excise Duties Structure Directive, arts 9a, 13a and 18a.

[1773] Alcohol Excise Duties Structure Directive, art 5(1). See also Directive 2020/1151, recital 4.

[1774] Alcohol Excise Duties Structure Directive, art 28b.

for such cross-border movements,[1775] potentially undermining Member State public health policies. Two situations must be distinguished: individuals may make the journey themselves to acquire goods in another country or may purchase such goods at a distance. In the first case, current EU rules entirely fail to discourage cross-border acquisitions made with the goal to escape domestic taxes. As regards distance sales, the situation is much more satisfactory.

The general rule for excise duty is that it becomes chargeable at the time and in the Member State of release for consumption.[1776] Where goods have been released for consumption in one Member State and are subsequently moved to another to be delivered there for commercial purposes, the goods are subjected to excise duty in the Member State of destination.[1777] The idea is that products consumed in one Member State are subject to the rate that is applicable in that Member State, for its benefit.

That system, however, does not apply to private individuals. Pursuant to Article 32(1) of the General Excise Duties Directive,

> [E]xcise duty on excise goods *acquired by a private individual for his or her own use*, and transported from the territory of one Member State to the territory of another Member State by this private individual, shall be charged only *in the Member State in which the excise goods are acquired*.[1778]

This means that individuals may in principle freely purchase excised goods while travelling without having to pay the excise duty applicable in the place where the goods are consumed. Such exception makes sense from the perspective of free movement. If individuals had to go through a lengthy and complicated procedure to correct the payment of the excise duty every time they exercised their rights to free movement, this would disincentivise cross-border movement and shopping.

At the same time, as clearly expressed in Recital 41 of the Directive, such a rule creates a number of risks:

> Excise duty levels for tobacco products and alcoholic beverages applied by Member States vary due to a number of factors, such as fiscal and public health policy and such divergences in some cases are significant. In this context, Member States should be able to contain risks, which are facilitating tax fraud, avoidance or abuse, threatening or undermining public policy or *protection of health and life of humans*.[1779]

As the Court of Justice recognised itself, there is a financial incentive to purchase goods on which lower excise duties have been paid and import them into a Member State where excise duties are higher.[1780] This threatens the effectiveness of a public health policy of high tax rates on tobacco or alcohol, especially in border regions. A risk also exists that commercial entities disguise their imports as private acquisitions, to circumvent the rule that goods moved to

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[1775] See Pete Driezen and others, 'Cross-Border Purchasing of Cigarettes among Smokers in Six Countries of the EUREST-PLUS ITC Europe Surveys' (2019) 16 Tobacco Induced Diseases 13.
[1776] General Excise Duties Directive, art 6(2).
[1777] ibid, art 33(1).
[1778] ibid, art 32(1).
[1779] Emphasis added.
[1780] Case C-315/12 *Metro Cash and Carry Denmark* [2013] EU:C:2013:503, para 12.

another Member States for commercial purposes are subject to excise duties in the Member States of destination and not that of origin.

The General Excise Duties Directive partially seeks to address these problems. Article 32(2) lays down criteria that Member States shall take into account for the purpose of assessing whether the movement of goods crossing a border is meant for an individual's personal use or for commercial purposes: '(a) the commercial status of the holder of the excise goods and the reasons for holding them; (b) the place where the excise goods are located or, if appropriate, the mode of transport used; (c) any document relating to the excise goods; (d) the nature of the excise goods; (e) the quantity of the excise goods'.[1781]

Regarding that latter criterion, quantity, Article 32(3) allows Member States to lay down guide levels, which are quantitative thresholds over which a shipment may be presumed of being of a commercial nature. These guide levels may not be set at a level lower than that provided for in the Directive: as regards tobacco products, 800 cigarettes, 400 cigarillos, 200 cigars and 1 kilo of smoking tobacco; as regards alcoholic beverages, 10 litres of spirit drinks, 20 litres of intermediate products,[1782] 90 litres of wines, including a maximum of 60 litres of sparkling wines, and 110 litres of beer. These lower limits were set in Directive 92/12/EEC,[1783] which came into force on 1 January 1993, and have not been changed ever since.

In *Commission v France*, the Court made clear that the provisions of Article 32 do not permit Member States 'to determine that products are held for commercial purposes *solely on the basis of a purely quantitative threshold* for products held'[1784] and that the lower limits cannot be aggregated but apply for each distinct categories of products.[1785] This means, for instance, that a private person coming back to its Member State of origin with eleven litres of spirit drinks purchased abroad cannot automatically be considered as acting commercially, and be required to pay the excise duties in that Member State. Further, a private person transporting nine litres of spirit drinks and 109 litres of beer must be considered as falling below the threshold. Relatedly, the Court also held in that judgement that lower limits should be applied per person and not per vehicle.[1786]

Regarding the definition of 'own use', contained in Article 32(1) of the General Excise Duties Directive, Member States diverge in their interpretation. Some consider that the entirety of the goods must be consumed by the private individual making the purchase and transporting it, while some form of collective consumption is allowed for others.[1787] Most Member States'

[1781] Directive 2020/262, art 32(2).
[1782] For the definition of intermediate products, see the preceding section
[1783] Council Directive 92/12/EEC of 25 February 1992 on the general arrangements for products subject to excise duty and on the holding, movement and monitoring of such products [1992] OJ L 76/1.
[1784] Case C-216/11 *Commission v France* [2011] EU:C:2013:162, para 17.
[1785] ibid, para 22.
[1786] ibid, para 23.
[1787] European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC concerning the general arrangements for excise duty' (2020) Final Report 51, <https://op.europa.eu/en/publication-detail/-

legislation is silent on the matter. In *Joustra*, the Court considered that products acquired for the use of other individuals, in this case the other members of a wine tasting circle, could not come within the scope of Article 32, as the products would then cease to be used 'for strictly personal purposes'.[1788]

Regarding the transport of the goods, the Court has made clear that 'for excise duty to be payable in the country of purchase, transportation must be effected personally by the purchaser of the products subject to duty'.[1789] Article 32 of the Directive is not applicable where the purchase and/or transportation of the goods is carried out by another person or company on behalf of a private individual.[1790] Had the Court ruled otherwise, this would have allowed individuals to order goods abroad and have them delivered domestically, rendering the distinction made between personal and commercial purposes devoid of any meaning.

In *Metro Cash and Carry Denmark*, the Court clarified that a business whose customers are undertakings is not required to control whether customers from other Member States intend to import products subject to excise duty in another Member State and whether they intend to use these products for private or commercial purposes.[1791] The circumstance that such products are bought in one of these shops, supposedly for companies, does not automatically mean that customers cannot benefit from the conditions of Article 32. It is for Member States to verify, on a case-by-case basis, if such purchases fall under Article 32 of the Directive.[1792]

Regarding frequency, finally, Article 32 offers no indication as to whether the threshold apply per trip or per a certain duration of time, for instance per day, or whether individuals are allowed to cross the border several times a day. Most Member States do not specify this in their own legislation.[1793]

A large study commissioned by the European Commission and published in 2020 shows that Article 32 is deficient from a public heath point of view,[1794] and has been unable, if such was ever its purpose, to stem the development of cross-border acquisitions of tobacco and alcohol by individuals. What this study establishes first is the importance of the phenomenon. Over the previous twelve months before it was made, around 14% of the total EU adult population purchased alcohol products in another Member State and 12% purchased tobacco products.[1795] This amounts to 1.4 billion litres of alcoholic beverages and around 15 thousand tonnes of tobacco products per year, which represents approximately 5% of per capita alcohol

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/publication/4dffa2d3-a92e-11ea-bb7a-01aa75ed71a1/language-en> accessed 11/05/2023. Purchases for the benefit of immediate family or for weddings and birthdays are for instance explicitly allowed in Sweden.

[1788] Case C-5/05 *Joustra* [2006] EU:C:2006:733, paras 35-36.

[1789] Case C-296/95 *EMU Tabac* [1998] EU:C:1998:152, para 33.

[1790] ibid, para 37. See also *Joustra* (n 1788), para 41.

[1791] *Metro Cash and Carry Denmark* (n 1780), para 38.

[1792] ibid, para 48.

[1793] European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787) 52. Denmark specifies for instance that only one movement within 24 hours can be considered occasional.

[1794] European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787).

[1795] ibid 57.

consumption and 2,8% of cigarette consumption in the EU.[1796] This varies significantly between Member States and within Member States, and across the different segments of the population.[1797] Countries with high excise duties and prices and border regions are concerned to a greater extent. Unsurprisingly, Member States with particularly stringent tobacco or alcohol control policies, such as France, Sweden or Finland, have the highest per capita cross-border purchases of cigarettes and alcohol.[1798]

Guide levels are undoubtedly the main issue. The lower limits contained in Article 32(3) of the Directive are set at astronomical levels if compared to the average consumption of tobacco and alcohol in the European population. After controlling for those that do not drink, the limits are still set around 4 litres of pure alcohol higher than the annual consumption of the populations that drink the most in the EU, in Lithuania, Czechia and Bulgaria.[1799] This is all the more telling when considering that the guide levels apply per trip and not per year. The situation is slightly better for tobacco, the limits equating for instance to around one and a half months of average consumption in Greece and two and a half months in the Netherlands.[1800] Yet, this still means that a smoker only needs to make a handful of trips abroad every year to source all its consumption from a country where taxes are lower.

Overall evidence of the negative impact of cross-border personal acquisition of alcohol and tobacco on public health is limited, but nonetheless exists for countries that are most severely hit by the phenomenon, the Nordic countries as regards alcohol and France as regards tobacco.[1801] For Finland, Sweden, Denmark and Estonia, 'evidence consistently supports the notion that cross-border purchases have had a net effect on alcohol consumption; that increased access to alcohol through the internal market has contributed to a higher total alcohol consumption than otherwise would be the case'.[1802] Finland and Denmark have significantly lowered their taxes after EU rules on traveller's allowances fully entered into application after accession.[1803] In Finland, domestic prices were further reduced after Estonia's accession to the EU, as a consequence of its inability to block imports of cheap drinks from this country.[1804]

[1796] ibid 58.
[1797] ibid 57-58.
[1798] ibid 58.
[1799] ibid 65.
[1800] ibid 66.
[1801] The study concludes the following: 'While it is difficult to measure the extent to which cross-border shopping undermines national health policies, the above analysis indicates that consumers in all Member States consume, on average, more alcohol and tobacco as a result of the availability of these products in the internal market. While not particularly significant at the EU level, for certain Member States, and products, this has a more substantial impact on consumption levels.' See ibid 90.
[1802] ibid 71. For Finland, see also Karlsson (n 1359) 47.
[1803] Jenny Cisneros Örnberg, 'Sweden, the EU and the Alcohol Traveller's Allowances' (2010) 37 Contemporary Drug Problems 3, 16; Karlsson (n 1359) 45.
[1804] McKee, Hervey and Gilmore (n 1405) 235.

This resulted in 'a steep rise in alcohol related deaths'.[1805] In France, one in five smokers report getting their supply often or almost always from purchases abroad.[1806]

The study suggests to introduce a number of changes to remedy this problem: reduce the minimum guide levels to better reflect the average consumption of private individuals, add a frequency to the guide levels or replace the guide levels with binding thresholds.[1807] The most effective way would probably be to allow Member States to derogate from the provisions of Article 32, where justified on grounds of their specific situation and subject to the requirements of proportionality.[1808] A compromise must be found between the interests of free movement and that of public health as regards cross-border acquisitions by individuals. The rule providing that excise duties for such acquisitions are paid in the country of purchase should be preserved and amended to make sure that it is less abusively used.

As regards distance sales, applicable rules do not create nearly as many problems. The principle set by Article 44(1) of the General Excise Duties Directive is that excise goods already released for consumption in the territory of one Member State and sold and delivered to a person in another Member State, who does not carry an independent economic activity, are subject to excise duty in the Member State of destination. There is hence no financial incentive for individuals to buy tobacco products or alcoholic beverages at a distance, as far as the level of excise duties is concerned.

A possible problem with distance selling could be the circumvention of age checks for the purchase of tobacco and alcohol. As regards tobacco products, Article 18 of the TPD provides Member States with the possibility to prohibit cross-border distance sales.[1809] Where such sales are not prohibited, retail outlets must register with their Member State of establishment and the Member States where their consumers are located.[1810] The list of these outlets is made available to consumers.[1811] Retail outlets engaged in distance sales must also operate an age verification

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[1805] Anna Koski and others, 'Alcohol Tax Cuts and Increase in Alcohol-Positive Sudden Deaths-a Time-Series Intervention Analysis' (2007) 102 Addiction 362.
[1806] European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787) 72.
[1807] ibid 106.
[1808] France actually decided to take this course of action and to decrease the guides levels contained in its legislation as regards tobacco. These are currently set at 200 cigarettes, 100 cigarillos, 50 cigars and 250 g of smoking tobacco: see Code général des impôts, art 575 I. This move was clearly motivated by public health concerns, as the growing disparity between French prices and that of its neighbours led to increased cross-border acquisition of tobacco. France acknowledged that this was done in breach of Article 32 of the General Excise Duties Directive but defended its amendment as a way to spark a debate on the further harmonisation of excise duty rates at the European level. See Amendement n°2468 au PLFR pour 2020, <http://www.assemblee-nationale.fr/dyn/15/amendements/3074/AN/2468> accessed 11/05/2023 ; Assemblée nationale, Compte rendu intégral de la deuxième séance du mercredi 8 juillet 2020, <http://www.assemblee-nationale.fr/15/cri/2019-2020-extra/20201008.asp#P2147358> accessed 11/05/2023.
[1809] Tobacco Products Directive, art 18(1). Under the TPD, cross-border distance sales are defined as 'distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established': art 2(34). Pursuant to art 20(6), art 18 also applies to e-cigarettes.
[1810] ibid.
[1811] ibid, art 18(2).

system to ensure that buyers comply with the minimum age requirements in force in the Member State of destination.[1812] In May 2021, nineteen Member States had prohibited tobacco distance sales and no conclusive evidence exists as to whether the pattern of such sales had changed since the introduction of the TPD.[1813] Enforcement of the ban gave rise to difficulties and most retailers across different Member States seem to rely only on weak self-reporting age checks, which do not correctly prevent underaged shoppers to access tobacco products.[1814] Regarding alcoholic beverages, most Member States have consumer age verification measures in place and do not report any significant impact of alcohol distance selling on public health.[1815]

Where these are not prohibited, rules governing cross-border distance sales, which give a certain leeway to Member States, result in a high administrative burden for companies.[1816] In the present configuration, tax differences are neutralised and the incentive for individuals to purchase goods abroad is limited. The balance found as regards distance sales is the opposite as that found for cross-border acquisitions: public health is better protected at the expense of free movement. The difference in treatment between the two situations may probably be explained by the fact that cross-border acquisitions require individuals to undertake a journey, providing a physical limit to the development of the phenomenon. Conversely, were the excise duties for cross-border distance sales to be paid in the country of purchase, consumers in highly taxed country could, regardless of their location, easily source their entire consumption from abroad, with disastrous effect on Member State health policies.

4.3. External movement: exemption from VAT, excise duty and customs duty

Similar questions arise as regards movement originating from third countries and the taxation of products that enter the EU internal market. In order to facilitate free movement, the EU adopted rules exempting certain goods from the payment of value added tax, excise duty or customs duties. Interestingly enough, rules applicable to external cross-border movements of tobacco and alcohol appear more protective of health than those applicable to internal movements. In return, free movement within the EU internal market is better protected.

In order to prevent double taxation, Directive 2007/74 lays down a framework for the exemption from value added tax and excise duty of non-commercial imports of goods transported in the personal luggage of travellers coming from third countries.[1817] The Directive

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[1812] ibid, art 18(4).
[1813] European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 99.
[1814] ibid. For more details, see 99-105.
[1815] European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787) 171.
[1816] See ibid 174, 178.
[1817] Council Directive 2007/74/EC of 20 December 2007 on the exemption from value added tax and excise duty of goods imported by persons travelling from third countries [2007] OJ L346/6. Formerly Council Directive 69/169/EEC.

applies to good transported by travellers from a third country or a country where EU provisions on VAT and excise duties do not apply.[1818] Goods imported in the personal luggage of travellers are exempted from VAT and excise duty, on the basis of either monetary thresholds or quantitative limits, and provided that the imports are of a non-commercial character.[1819] Imports are regarded as being of a non-commercial character if they take place occasionally and consist exclusively of goods for personal or family use, or goods intended as presents.[1820] The nature or quantity of the goods cannot be relied on as an indicator that these are being imported for commercial reasons.[1821] Monetary thresholds apply to benefit from the exemption. The total value of imports of goods must not exceed 300 euros per person for land travel and 430 euros for air and sea travel.[1822]

As it is the case for cross-border acquisitions by individuals within the EU territory, such an exemption provides an incentive for consumers residing in border regions to purchase tobacco products and alcoholic beverages in neighbouring countries where prices are lower, potentially undermining national taxation and public health policies. To alleviate this concern, the Directive sets specific rules for tobacco and alcohol.[1823] The general monetary thresholds do not apply to these products and are replaced by quantitative thresholds.[1824] For tobacco, Member States must apply the following higher or lower quantitative limits: 200 cigarettes or 40 cigarettes, 100 cigarillos or 20 cigarillos, 50 cigars or 10 cigars, 250 g smoking tobacco or 50 g smoking tobacco.[1825] The choice of the low or high quantitative limit is left to the discretion of each Member State, a possibility that explicitly derives from 'the need to promote a high level of human health protection for EU citizens'.[1826] Because cross-border shopping is easier for land and sea travel than for air travel, the Directive also allows Member States to exclude air travellers from the lower tobacco limits.[1827] For alcohol, the Directive only lays down single limits: 1 litre of alcohol and alcoholic beverages of an alcoholic strength exceeding 22 % vol;[1828] 2 litres of alcohol and alcoholic beverages of an alcoholic strength not exceeding 22 % vol; 4 litres of still wine and 16 litres of beer.[1829]

[1818] Directive 2007/74/EC, art 1.
[1819] ibid, art 4; see article 5 for the definition of 'personal luggage'.
[1820] ibid, art 6.
[1821] ibid.
[1822] ibid, art 7(1). See also recital 5 : 'The ease of shopping abroad could cause problems to Member States which share land-borders with third countries with significantly lower prices. It is justifiable, therefore, to set a lower monetary threshold for forms of travel other than air and sea travel.'
[1823] See ibid, recitals 8 and 9.
[1824] ibid, art 12.
[1825] ibid, art 8(1).
[1826] ibid, recital 9.
[1827] ibid, art 8(2) and recital 5.
[1828] '[O]r undenatured ethyl alcohol of 80 % vol and over': ibid, art 9(1).
[1829] ibid, art 9(1) and (3). The beer limit did not exist under Directive 69/169. In *Commission v Denmark* and *Commission v Ireland*, both Member States were found to have breached that Directive after having introduced a limit of respectively 10 and 12 litres for beer: Case C-208/88 *Commission v Denmark* [1990] EU:C:1990:442; Case C-367/88 *Commission v Ireland* [1990] EU:C:1990:443. Both countries argued 'that it was necessary to establish that [limit] on account of the numerous abuses by travellers who imported large quantities of beer free

The limits set for tobacco and alcohol products can be combined within each of these two categories but cannot be cumulated, apart from those for wine and beer that apply separately.[1830] Each individual threshold represents 100% of the total allowance. This means, if taking the higher limits for tobacco, that a person may for instance import at once 100 cigarettes (50% of 200), 20 cigarillos (20 % of 100) and 15 cigars (30% of 50 cigars). The exemptions from the payment of VAT and excise duties do not apply for travellers under 17 years of age, here again explicitly on grounds of public health protection.[1831] Member States may lower the quantitative limits for certain categories of travellers, including persons resident in a frontier zone and frontier-zone workers.[1832]

This last point alone illustrates how much more protective of public health this framework is if compared to that applicable to intra-EU cross-border acquisitions. The quantitative limits are not indicative but are binding on Member States and hence on travellers. They are set at a much lower level and, unlike under the General Excise Duties Directive, are not cumulative, reducing the total amount of tobacco and alcohol that can be brought back after a trip. A limit of 40 cigarettes, as provided under Directive 2007/74, means that a heavy smoker needs to travel at least every other day in order to source its consumption from a third country. Underaged travellers are also protected, and finally, Member States are provided with the possibility of lowering the limits for categories of travellers that are more 'at risk'.

Moreover, the Court ruled in *Heinonen*, that Directive 2007/74 does not prevent Member States from laying down stricter rules prohibiting or restricting the importation of certain products, provided that these rules comply with Article 36 TFEU.[1833] The Finish rule at stake prohibited

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of duty […] for subsequent retail sale and of the resultant difficulty of checking case by case, in an entirely objective manner and in conditions of legal certainty, whether or not each importation had a commercial character': *Commission v Denmark* (ibid), para 5; see also *Commission v Ireland* (ibid), para 5. The two countries were subsequently granted a derogation enabling them to use limits for beer, a situation later extended to all Member States with the adoption of Directive 2007/74: see Council Directive 91/191/EEC of 27 March 1991 amending Directive 69/169/EEC on tax-paid allowances in intra-Community travel and as regards a derogation granted to the Kingdom of Denmark and to Ireland relating to the rules governing travellers' allowances on imports [1991] OJ L94/24.

[1830] Directive 2007/74/EC, arts 8(4) and 9(2).

[1831] ibid, art 10 and recital 8.

[1832] ibid, arts 13(1)(a) and (b), see arts 3(5) and (6) for the definitions of these two categories.

[1833] *Heinonen* (n 501), para 27. The judgement was rendered under the previous directive, Directive 69/169. It applies to Directive 2007/74 by analogy. The solution found in this judgement may appear as contradicting the one adopted in *Commission v Ireland*, where the Court found that Ireland had failed to fulfil its obligation under EU law by adopting a similar rule limiting the tax exemptions to travellers arriving at its borders after a minimal period of 48 hours outside its territory: Case 158/88 *Commission v Ireland* [1990] EU:C:1990:242, para 12. For Advocate General Saggio, the difference in outcome stems from the fact that the Irish government defended its measure on pure economic grounds, relying on the 'serious damage to the Irish economy' done by the multiplication of single day journeys abroad with the sole purpose of taking advantage of the lower VAT rates, while the Finish government was relying on public order and public health concerns: Case C-394/97 *Heinonen*, Opinion of Advocate General Saggio (n 1354), paras 6 and 18-19. The ruling in *Heinonen* also begs the question as to whether the solutions adopted in *Commission v Denmark* (n 1829) and *Commission v Ireland* (n 1829) regarding the setting of thresholds for products not contained in the Directive, beer at the time, still holds. It could be that the two governments also relied primarily on economic arguments in these two cases, although the two judgements are silent in this regard.

the import of alcoholic drinks for Finish residents travelling back from a third country after a journey of less than 20 hours, in order to limit trips made for the sole purpose of buying cheaper alcohol.

For customs duties, finally, Regulation 1186/2009 lays down a Union system of reliefs applicable in circumstances where the application of the Common Customs Tariff is rendered unnecessary, because 'the usual need to protect the economy is absent': [1834] goods imported on the occasion of a marriage, property acquired by inheritance, consignments of negligible value, etc. As regards the importation of tobacco products and alcoholic beverages, this instrument is probably the most protective of public health.

First of all, the exemption of customs duty is almost never granted to alcoholic and tobacco products.[1835] It only occurs for consignments sent by one private individual to another when such importations are not of a commercial nature.[1836] Imports are considered not being of a commercial nature if they are occasional, free of any payment and 'contain goods exclusively for the personal use of the consignee or his family, which do not, by their nature or quantity, reflect any commercial intent'.[1837] Second, the relief is subject to low monetary and quantitative limits: 45 euros per consignment and a maximum of 50 cigarettes, 25 cigarillos, 10 cigars, 50 grams of smoking tobacco, or a proportional assortment thereof, for tobacco products, and a maximum of two litres of still wines and one litre of various other drinks, including sparkling wines or spirits. [1838] Further, Recital 9 of the Directive clearly states that the application by Member States of further restrictions on import or export is not precluded, provided these are justified under the grounds contained in Article 36 TFEU, including public morality, public policy or public security.[1839]

The difference in treatment between cross-border acquisitions on the basis of their intra or extra-EU origin finds no justification from a public health perspective, as these movements are equally damaging for national taxation policies. What differs, however, and may explain why applicable rules are stricter regarding extra-EU movements of goods than regarding intra-EU movement, is both the type of cross-border flows that are impacted and the relevance of the taxation revenue for the EU. The EU is probably more reticent to adopt rules that affect intra-EU movement of people and keener on preserving Member State's tax revenue where those, as is the case for VAT and customs duties, directly contribute to the EU budget.

4.4. Traceability and security: the fight against illicit trade in tobacco products

[1834] Council Regulation (EC) No 1186/2009 of 16 November 2009 setting up a Community system of reliefs from customs duty [2009] OJ L324/23, see recital 3.
[1835] ibid, arts 14, 18, 24, 62, 83 and 94.
[1836] ibid, art 25(1).
[1837] ibid, art 25(2).
[1838] ibid, arts 26-27.
[1839] See also *Heinonen* (n 501), para 26.

Illicit trade in tobacco products is recognised internationally as one of the main challenges to effective tobacco control, allowing for products to be placed on the market in violation of fiscal rules and other requirements.[1840] It does not only lead to foregone revenues for governments – the loss was estimated in 2013 at over 10 billion euros in the budgets of the European Union and its Member States – but fuels the shadow economy and organised crime, and undermines tobacco control policies.[1841] To address and ultimately eliminate the phenomenon, the parties to the FCTC adopted a specific Protocol on illicit trade in tobacco products, which entered into force in 2018.[1842]

Addressing illicit trade in tobacco products has been on the EU's agenda for over a decade. The European Commission adopted a dedicated strategy and a first action plan in 2013,[1843] laying down a number of measures aimed at decreasing the incentives to fraud, securing the supply chain, and strengthening enforcement and sanctions.[1844] As regards securement of the supply chain, the FCTC Protocol obliges parties to adopt a tracking and tracing system of tobacco products, which was introduced at the EU level with the adoption of the TPD.

Articles 15 and 16 TPD set up a system of traceability and security features for tobacco products.[1845] All unit packets of tobacco products must be marked with a unique identifier allowing for several elements to be determined, regarding the manufacturing process and the movement of the product through the supply chain.[1846] To ensure traceability, operators involved in the trade of tobacco products must keep a record of all the movement of unit packets and transactions, information which they must store in an independent data storage facility.[1847] In addition to the unique identifier, all unit packets of tobacco products must carry a tamper proof security feature, which must be 'irremovably printed or affixed, indelible and not hidden

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[1840] Illicit tobacco products 'is understood to include different types of (international) smuggling of both genuine and counterfeit tobacco products (mainly cigarettes), as well as illicit internal EU production and distribution': European Commission, Communication from the Commission to the Council and the European Parliament, 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy', COM (2013) 324 final, 4.

[1841] ibid 4.

[1842] WHO, 'Protocol to eliminate illicit trade in tobacco products, WHO Framework Convention on Tobacco Control' (2013), <https://apps.who.int/iris/bitstream/handle/10665/80873/9789241505246_eng.pdf> accessed 11/05/2023.

[1843] European Commission, 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy' (n 1840); European Commission, 'Anti-smuggling Action Plan' (Staff Working Document) SWD (2013) 193 final. See also European Commission, Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, '2nd Action Plan to fight the illicit tobacco trade 2018-2022', COM (2018) 846 final, 1.

[1844] European Commission, 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy' (n 1840) 14-21.

[1845] See Tobacco Products Directive, recital 29.

[1846] Tobacco Products Directive, arts 15(1)-(4).

[1847] Tobacco Products Directive, arts 15(5)-(9) and recitals 30 and 31. See Commission Delegated Regulation (EU) 2018/573 of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products [2018] OJ L96/1 and Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products [2018] OJ L96/7.

or interrupted in any form'.[1848] Obligations regarding traceability and security have been applicable to cigarettes and RYO tobacco since 20 May 2019 and will apply to tobacco products other than cigarettes and RYO tobacco from 20 May 2024.[1849]

Given the tobacco industry's historical involvement with the smuggling of tobacco products,[1850] Article 8 of the FCTC Protocol provides for the exclusion of tobacco interests from the operation of tracking and tracing systems. This requirement also features in the Union traceability system,[1851] although a recent study revealed that the EU fell short of the Protocol's requirement and had failed to keep the tobacco industry at bay. It found that 'the tobacco industry has succeeded in undermining the independence of the EU's track and trace system', which 'delegates key responsibilities to the industry and associated third-parties, raising serious concerns about its compliance with the [FCTC Protocol]'.[1852] This reveals once again the enduring incapacity of the EU to limit the involvement of the industry in the design and implementation of its tobacco control policy.

5. Conclusion

One of the key objectives of EU health policy is to reduce the burden of lifestyle-related mortality and morbidity by addressing key lifestyle risk factors. The use and trade in harmful products or services is increasingly framed as a public health issue and regulated accordingly, rather than envisaged from a purely economic and free movement point of view. To this general objective, however, does not correspond similar degrees of engagement across the different risk factors. Although subjected to an entirely different legal regime, illicit drugs and tobacco products are considered as undesirable. The ultimate objective is to eradicate consumption for both these categories of products. For foods and alcohol, however, the idea is to promote 'responsible' consumption, i.e. limited intake in a balanced diet. This difference in treatment, as should be clear by now, cannot be explained by purely 'risk' concerns.

Looking in details at two categories of measures situated at the higher end of the intervention ladder, it appears that their use by the EU legislator is overall limited. Most unhealthy commodities may be marketed freely and at a price freely set by business operators, as far as EU law is concerned. Bans on products or categories of products are little used by the EU legislator. This is not altogether surprising, considering the widespread use of lifestyle products and their importance for individuals and societies, notwithstanding their harmfulness. Leaving illicit drugs aside, the two products that have been prohibited by the EU are specific tobacco

[1848] Tobacco Products Directive, art 16(1), see Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products [2018] OJ L 96/57.
[1849] Tobacco Products Directive, arts 15(13) and 16(3).
[1850] Anna B Gilmore, Allen WA Gallagher and Andy Rowell, 'Tobacco Industry's Elaborate Attempts to Control a Global Track and Trace System and Fundamentally Undermine the Illicit Trade Protocol' (2019) 28 Tobacco Control 127; Allen William Andrew Gallagher, Anna B Gilmore and Michael Eads, 'Tracking and Tracing the Tobacco Industry: Potential Tobacco Industry Influence over the EU's System for Tobacco Traceability and Security Features' (2020) 29 Tobacco Control e56.
[1851] Commission Implementing Regulation 2018/574, art 35.
[1852] Gallagher, Gilmore and Eads (n 1850) 60.

products which are not consumed, or perhaps even known, by most of the population. As regards regulation on the composition of products, the lack of EU engagement appears more regrettable, considering especially that food supply is a major driver of the rise in unhealthy diets and obesity. TFAs provide a good example of unhealthy component which is placed in food unbeknownst to consumers and whose use can be restricted without raising significant opposition.

Rules on the taxation of tobacco and alcohol are one of the most complex aspect of the EU lifestyle risk regulatory framework, both in terms of the number of applicable instruments and their content. Taxation is an area where the intertwining of health and internal market concerns is particularly obvious because the rules adopted have an immediate impact on the free movement of goods or persons, as consumers take advantage of their free movement rights to acquire cheaper products inside or outside the EU. Overall, EU rules on the taxation of unhealthy commodities remain mostly dominated by internal market concerns, failing to support Member States in their fiscal policies and even undermining them at times.

Chapter 6

EU promotion of healthy lifestyles: rules on commercial communications, information requirements and non-binding measures

1. Introduction

In Chapter 6 are presented a second series of regulatory tools used by the EU to promote healthier lifestyles, situated at the lower end of the intervention ladder. The chapter addresses rules restricting or prohibiting commercial communications, advertising and sponsorship in particular, and rules regulating the information environment, as well as non-binding measures. Similar to the interventions described in Chapter 5, the analysis reveals a great deal of diversity across risk factors. A general conclusion on both chapters is then drawn.

2. Enabling choice: the EU's contrasted regulation of commercial communications

This section covers rules on advertising and other forms of commercial communications,[1853] focusing on instruments and provisions that directly address the promotion of unhealthy products in order to limit the appeal of these products.[1854] As the subsequent developments will show, the regulation of commercial communications is an area where the contrast between risk factors appears particularly stark. The large body of rules adopted on tobacco results in a quasi-general ban on cross-border commercial communications for these products. Conversely, operators of the food and drink industry face minor constraints and remain able to massively advertise for their products, as far as EU law is concerned. The same is true for gambling.

2.1. The wide ban on tobacco advertising and promotion

Commercial communications for tobacco and related products are highly regulated under EU law, which prohibits all forms of tobacco advertising and sponsorship with a cross-border

[1853] Under the AVMS Directive, 'audiovisual commercial communication' means 'images with or without sound which are designed to promote, directly or indirectly, the goods, services or image of a natural or legal person pursuing an economic activity' and include 'inter alia, television advertising, sponsorship, teleshopping and product placement': AVMS Directive, art 1(1)(h). The term 'commercial communication' will be used in this section as an umbrella term covering not only advertising but also a range of other promotional techniques, such as sponsorship and product placement, in an audiovisual form or not. The term 'marketing' is often used to refer to companies' promotional activities: see e.g. Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns' (n 34); David Jernigan and others, 'Alcohol Marketing and Youth Alcohol Consumption: A Systematic Review of Longitudinal Studies Published since 2008: Alcohol Marketing and Youth Drinking' (2017) 112 Addiction 7; Amandine Garde, 'Harmful Commercial Marketing and Children's Rights: For a Better Use of EU Powers' (2020) 11 European Journal of Risk Regulation 841. The choice has been made not to use the term 'marketing' as it may be confused with the concept of 'placing on the market', used in many EU law instruments.

[1854] Directive 2006/114 on misleading and comparative advertising, which aims primarily at protecting traders, is for instance not covered: see Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (codified version) [2006] OJ L 376/21, art 1.

dimension. Most other forms of 'static' commercial communications for tobacco are prohibited at the national level.[1855]

As early as 1989, the Television Without Frontiers Directive prohibited all forms of television advertising for tobacco products.[1856] The TWF Directive was later repealed by the Audiovisual Media Services Directive, which currently prohibits all forms of audiovisual commercial communications for tobacco products, electronic cigarettes, and refill containers.[1857] The AVMSD also prohibits the sponsorship of audiovisual services or programmes by undertakings whose principal activity is the manufacture or sale of tobacco products, e-cigarettes and containers,[1858] and prohibits the product placement of such products, as well as any other product placement from undertakings whose principal activity is the manufacture or sale of these products.[1859]

For commercial communications outside the audiovisual sphere, a first specific directive on tobacco products was adopted in 1998.[1860] Directive 98/43 banned all forms of advertising and sponsorship for tobacco products.[1861] The Directive was however annulled by the Court of Justice in *Tobacco Advertising*, considering that the Union lacked competence to enact a general prohibition of these activities. In particular, if advertising with a cross-border dimension, in periodicals, magazines and newspapers, could lawfully be prohibited under EU law,[1862] this was not the case for static forms of advertising such as 'advertising on posters, parasols, ashtrays and other articles used in hotels, restaurants and cafés, and […] advertising spots in cinemas'.[1863] The rationale underlying this judgement will be further analysed in Chapter 7.

A new directive was adopted in 2003, upheld this time by the Court, after Germany had filed another challenge.[1864] Directive 2003/33, the Tobacco Advertising Directive, prohibits the advertising of tobacco products in the press and other printed publications, in information

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[1855] Regarding action undertaken at the Member State level, see European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (2021) Final Report 40-41, <https://op.europa.eu/en/publication-detail/-/publication/68ce81fc-5d55-11ec-9c6c-01aa75ed71a1/language-en/format-PDF/source-search> accessed 11/05/2023.
[1856] TWF Directive, art 13. For the definition of 'television advertising', see art 1(1)(i) of the AVMS Directive.
[1857] AVMS Directive, art 9(1)(d). For the definition of 'audiovisual commercial communications', see above n 1853. The inclusion of electronic cigarettes and refill containers in the AVMSD framework was first made indirectly through a reference in the TPD and then directly with the 2018 revision of the AVMS. See Tobacco Products Directive, art 20(5); Directive 2018/1808, art 1.
[1858] ibid, art 10(2). For the definition of 'sponsorship', see art 1(1)(k).
[1859] ibid, art 11(4). For the definition of 'product placement', see art 1(1)(m).
[1860] For an account of the difficulties surrounding the negotiations of the directive, see Francesco Duina and Paulette Kurzer, 'Smoke in Your Eyes: The Struggle over Tobacco Control in the European Union' (2004) 11 Journal of European Public Policy 57.
[1861] Directive 98/43, art 3(1).
[1862] *Tobacco Advertising* (n 25), paras 97-98.
[1863] ibid, paras 99-100.
[1864] *Tobacco Advertising II* (n 26).

society services and on radio.[1865] Advertising for tobacco products may still be used in publications 'intended exclusively for professionals in the tobacco trade and to publications which are printed and published in third countries, where those publications are not principally intended for the [Union] market'.[1866] Sponsorship by undertakings whose principal activity is the manufacture or sale of tobacco products is prohibited for radio programmes.[1867] The sponsorship of events or activities involving or taking place in several Member States or having cross-border effects is also prohibited, including via the free distribution of tobacco products.[1868] This is for instance the case for sports events with a European wide audience. These may no longer be sponsored by tobacco companies, as it had often been the case in the past for football, Formula 1 and other sports.[1869] As strange as it may seem today, it is only after the Los Angeles edition of 1984 that the Olympic Games ceased to have an official cigarette sponsor. The TPD extends the various prohibitions contained in the TAD to e-cigarettes and refill containers.[1870]

Although it is prohibited in most media, European citizens remain exposed to tobacco advertising to a significant degree. According to the 2021 Eurobarometer 'Attitudes of Europeans towards tobacco and electronic cigarettes', more than a third of respondents had seen advertisements or promotions for e-cigarettes and smoking tobacco products in the last twelve months, a decreasing proportion since 2014.[1871] If looking in detail, exposure seems to come mostly from forms of advertising that are currently not regulated under EU law, static advertising such as advertising at sales point or on billboards and posters, and forms of advertising that are not clearly prohibited under EU law, such as advertisements on online social networks or blogs.[1872] The study notes that 'the most notable evolutions compared to 2014 are the increases in the proportions [of respondent] mentioning online social network or blogs (+10 percentage points), sales points (+7 pp), and retailers' websites and mobile phone

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[1865] Tobacco Advertising Directive, arts 3 and 4(1). Advertising is defined as 'any form of commercial communications with the aim or direct or indirect effect of promoting a tobacco product': art 2(b). For the definition of 'information society service', see Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services [2015] OJ L 241/1, art 1(1)(b). It must be observed that the definition of 'tobacco products' contained in the TAD differs from that contained in the TPD: Tobacco Advertising Directive, art 2(a). The narrower definition contained in the TAD has led to uncertainties as regards the coverage of HTPs in that instrument: see European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (n 1855) 40-41.

[1866] Tobacco Advertising Directive, art 3(1).

[1867] ibid, art 4(2). Sponsorship is defined as 'any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting a tobacco product': art 2(c).

[1868] ibid, art 5.

[1869] See John L Crompton, 'Sponsorship of Sport By Tobacco and Alcohol Companies: A Review of the Issues' (1993) 17 Journal of Sport and Social Issues 148; Alan Blum, 'Tobacco in Sport: An Endless Addiction?' (2005) 14 Tobacco Control 1.

[1870] Tobacco Products Directive, art 20(5).

[1871] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 172. See also European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (n 1855) 72-85.

[1872] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 184.

applications (both +5 pp)',[1873] which shows that the tobacco industry is ready to take advantage of any existing loophole in the current legislation.[1874] This is confirmed by further evidence from the EUREST-PLUS Consortium, revealing that exposure to commercial communications for e-cigarette declined on television and radio after the adoption of the TPD, but increased on some of the unregulated channels, especially those associated with youth use.[1875] The EU is aware of this problem and plans, as part of the Beating Cancer Plan, to strengthen its instruments so as to tackle 'tobacco advertising, promotion and sponsorship on the internet and social media'.[1876]

Treating e-cigarettes and refill containers equally to tobacco products as regards commercial communications may appear surprising considering the diverging risk profile between the two categories of products, with tobacco for smoking in particular. This is not the choice made for other aspects of EU tobacco control, regulation of characterising flavours or labelling obligations for instance, where e-cigarettes are subject to less stringent measures. The EU legislator's decision is grounded on the fact that 'electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and *normalize* the action of smoking'.[1877] More than the specific health risks associated with it, it is the alleged link between e-cigarettes and traditional tobacco consumption, the gateway effect, which is targeted. Proponents of harm reduction strategies are usually critical of total bans on e-cigarette advertising, considering that an equilibrium should be found between avoiding exposure of youth to such advertising, so as to prevent the take-up of any tobacco-related product, and ensuring that current smokers have an accurate perception of e-cigarettes, which remain far less harmful than traditional tobacco.[1878] Admittedly, this equilibrium may be difficult to find in practice, as it is hard, if not impossible, to ensure that promotional messages intended for adults are not viewed by children.[1879]

2.2. Limited rules on foods and alcoholic beverages

The EU's approach towards commercial communications for unhealthy foods and alcoholic beverages stands in stark contrast with that applicable to tobacco products. Such commercial communications are authorised on all media and economic operators are subject to few obligations. Rather than adopting binding measures limiting the reach of harmful commercial communications, the EU has preferred to rely on self-regulation through the use of codes of

[1873] ibid.
[1874] The extent to which the TAD applies to promotional activities made within private groups on social media remains for instance unclear: see European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (n 1855) 40-41.
[1875] Sarah Kahnert and others, 'Impact of the Tobacco Products Directive on Self-Reported Exposure to e-Cigarette Advertising, Promotion and Sponsorship in Smokers—Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health 55.
[1876] European Commission, 'Europe's Beating Cancer Plan' (n 23) 10.
[1877] Tobacco Products Directive, recital 43, emphasis added.
[1878] See Voigt (n 198) 1970.
[1879] ibid.

conduct. The relevant provisions are primarily contained in the AVMS Directive, save for some product-specific rules that will be addressed in Section 3.3.[1880]

Most of the applicable rules on commercial communications for food and alcohol concern minors and children, attempting at reducing exposure to harmful content for this category of the population. This is sensible from the perspective of habit formation. Children are less likely to make a difference between what constitutes truthful information and promotional messages. There is clear evidence that children are massively exposed to advertising for unhealthy foods, which yield influence on children's dietary habits.[1881] The vast majority of foods advertised during children's TV viewing hours can be considered as unhealthy,[1882] advertisements that are now also increasingly present on social media platforms.[1883] A study on the European market for foodstuffs, published in 2019, revealed that between 48% and 68% of the products surveyed should be ineligible for marketing to children, depending on the nutrient profiling system used.[1884] Research has also shown that young people who have greater exposure to alcohol marketing are more likely to initiate alcohol use and engage in binge and hazardous drinking.[1885]

Pursuant to Article 22 of the AVMS Directive, whose drafting has remained the same since the introduction of that provision in the TWF Directive,[1886]

> Television advertising and teleshopping for alcoholic beverages shall comply with the following criteria:
>
> (a) it may not be aimed *specifically at minors* or, in particular, depict minors consuming these beverages;
>
> (b) it shall not link the consumption of alcohol to enhanced physical performance or to driving;
>
> (c) it shall not create the impression that the consumption of alcohol contributes towards social or sexual success;
>
> (d) it shall not claim that alcohol has therapeutic qualities or that it is a stimulant, a sedative or a means of resolving personal conflicts
>
> (e) it shall not encourage *immoderate consumption of alcohol* or present abstinence or moderation in a negative light;
>
> (f) it shall not place emphasis on high alcoholic content as being a positive quality of the beverages.

The other main provision of the AVMSD applying to food and alcoholic beverages, Article 9, currently reads:

> '1. […]

[1880] See also Food Information Regulation, art 7(4)(a).
[1881] Emma Boyland and Mimi Tatlow-Golden, 'Exposure, Power and Impact of Food Marketing on Children: Evidence Supports Strong Restrictions' (2017) 8 European Journal of Risk Regulation 224.
[1882] ibid 225–226.
[1883] ibid 227-228.
[1884] Stefan Storcksdieck genannt Bonsmann and others, 'The Ineligibility of Food Products from across the EU for Marketing to Children According to Two EU-Level Nutrient Profile Models' (2019) 14 PLOS One 1, 9–10. Regarding nutrient profiling, see Chapter 6, Section 3.2.1.3.
[1885] Jernigan and others (n 1853).
[1886] TWF Directive, art 15.

(c) (iii) audiovisual commercial communications shall not encourage *behaviour prejudicial to health or safety*;

[…]

(e) audiovisual commercial communications for alcoholic beverages shall not be aimed *specifically* at minors and shall not encourage immoderate consumption of such beverages;

[…]

(g) audiovisual commercial communications shall not *cause physical, mental or moral detriment to minors*; therefore, they shall not *directly* exhort minors to buy or hire a product or service by exploiting their inexperience or credulity, *directly* encourage them to persuade their parents or others to purchase the goods or services being advertised […]

[…]

3. Member States shall encourage the use of co-regulation and the fostering of self-regulation through codes of conduct as provided for in Article 4a(1) regarding *inappropriate* audiovisual commercial communications for *alcoholic beverages*. Those codes shall aim to effectively reduce the exposure of minors to audiovisual commercial communications for alcoholic beverages.

4. Member States shall encourage the use of co-regulation and the fostering of self-regulation through codes of conduct as provided for in Article 4a(1) regarding *inappropriate* audiovisual commercial communications, *accompanying or included in children's programmes*, for foods and beverages containing nutrients and substances with a nutritional or physiological effect, *in particular fat, trans-fatty acids, salt or sodium and sugars*, of which excessive intakes in the overall diet are not recommended.

Those codes shall aim to effectively reduce the exposure of children to audiovisual commercial communications for such foods and beverages. They shall aim to provide that such audiovisual commercial communications do not emphasise the positive quality of the nutritional aspects of such foods and beverages.[1887]

There are two main differences between the provisions applicable to alcoholic beverages and unhealthy foods. While Article 22 contains rules regarding alcohol advertising and teleshopping for the whole population, the rules in Article 9 only apply to food audiovisual commercial communications insofar as these target minors or children. Further, although audiovisual commercial communications for alcoholic beverages may not target minors specifically, such is not the case for food. These can still accompany or be included in children's programme.[1888]

The EU favours the use of co- and self-regulation to limit the exposure of minors and children to harmful audiovisual commercial communications. It was felt upon the adoption of the AVMS Directive that '[m]easures aimed at achieving public interest objectives in the emerging audiovisual media services sector [would be] more effective if they [were] taken with the active

[1887] Emphasis added. See, under the previous legal framework: TWF Directive, arts 3*e*(2), 12(d) and 16. A similar provision to Article 9(1)(g) can be found in the Unfair Commercial Practices Directive, which prohibits the inclusion 'in an advertisement [of] a direct exhortation to children to buy advertised products or persuade their parents or other adults to buy advertised products for them': Unfair Commercial Practices Directive, art 5(5) and annex I.

[1888] To the exception of product placement for unhealthy foods in children's programmes, which is prohibited under Article 11(2) of the AVMSD.

support of the service providers themselves'.[1889] The 2018 revision of the AVMS Directive sought to strengthen the effectiveness of the codes of conducts. Apart from adding a second paragraph to Article 9(4), this revision introduced a new Article 4a laying down a number of requirements applicable to these codes,[1890] with Article 4a(2) allowing for the development of Union codes of conduct, a possibility that has not been used to date. The use of codes of conduct was also extended to video-sharing platform services,[1891] such as YouTube.

Despite having codes of conduct in place in almost all Member States,[1892] the number of self-regulatory initiatives adopted by operators remains limited. The third report on the application of the AVMS Directive, adopted in 2020, which covers the 2014-2019 period, confirmed this.[1893] The EU Pledge, a voluntary initiative from major food and beverage companies, launched in 2007,[1894] is the industry's main effort in the field of unhealthy food advertising and promotion. It consists of two main commitments. Members must, first, refrain from advertising their unhealthy products to children under the age of twelve on TV, print and internet and, second, abstain to communicate in primary schools, except where specifically requested by, or agreed with, the school administration, for educational purposes.[1895] These commitments are a first step but, regardless of their actual implementation by the EU Pledge signatories, remain largely insufficient 'in terms of products, companies, media and ages covered.'[1896] There is no valid reason to set the threshold at the age of 12, since teenagers are equally harmed by advertising for unhealthy foods. Further, the EU Pledge targets programmes with an audience threshold of 35% of children under 12 years, down from 50% originally. This leaves out many popular family programmes which are watched by a large number of adults but reach children nonetheless.[1897]

The weakness of this soft law approach is reinforced by several limitations arising from the definitions contained in the AVMS Directive and the terms chosen in its provisions. The scope of 'audiovisual commercial communications' is too narrow, leaving out many social media

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[1889] ibid, recital 44.
[1890] These codes must (i) 'be such that they are broadly accepted by the main stakeholders in the Member States concerned', (ii) 'clearly and unambiguously set out their objectives', (iii) 'provide for regular, transparent and independent monitoring and evaluation of the achievement of the objectives aimed at' and (iv) 'provide for effective enforcement including effective and proportionate sanctions': ibid, art 4a(1) .
[1891] ibid, art 28b(2).
[1892] European Commission, 'Defining a framework for the monitoring of advertising rules under the Audiovisual Media Services Directive' (2016) Final Report 128, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016PC0287&from=EN> accessed 11/05/2023.
[1893] European Commission, 'Reporting on the application of Directive 2010/13/EU "Audiovisual Media Services Directive" for the period 2014-2019' (Staff Working Document) SWD (2020) 228 final. See also European Commission, 'Ex-post REFIT evaluation of the Audiovisual Media Services Directive 2010/13/EU' (Staff Working Document) SWD (2016) 170 final, 53.
[1894] See <https://eu-pledge.eu/> accessed 11/05/2023.
[1895] ibid.
[1896] Amandine Garde, Bill Jeffery and Neville Rigby, 'Implementing the WHO Recommendations Whilst Avoiding Real, Perceived or Potential Conflicts of Interest' (2017) 8 European Journal of Risk Regulation 237, 245–248. See also Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns' (n 34) 506–507.
[1897] Garde, Jeffery and Rigby (n 1896) 246.

platforms[1898] and other promotional tools such as corporate websites.[1899] It also fails to address marketing techniques that are 'particularly powerful at influencing children [such as] the use of celebrities, the use of licensed or equity brand characters [or] the offer of free toys'.[1900] These weaknesses are even more regrettable since the EU Action Plan on Childhood Obesity recognised that 'efforts to restrict marketing and advertising to children and young people should include not only TV but all marketing elements, including in-store environments, promotional actions, internet presence and social media activities'.[1901]

As regards the formulations used in the relevant AVMSD provisions, these seem to be deliberately weak and vague. Article 9(1)(g) only refers to 'direct' exhortation or encouragement. This undermines its effectiveness since most advertising to children or minors operates in an indirect manner.[1902] Article 9(3) and (4) mention 'inappropriate' commercial communications, an unclear term that leaves companies with a broad margin of discretion.[1903] One could think that any communication promoting unhealthy foods or alcoholic beverages to children or minors is inappropriate per se. Article 9(4) also refers to 'children's programmes', a narrow reach which leaves out programmes that are not specifically aimed at children but are watched by many of them nonetheless. In 2018, the Commission proposed to replace it with the broader concept of 'programmes with a significant children's audience',[1904] a change ultimately rejected by the European Parliament, which considered that this category was insufficiently clear. [1905] Finally, as regards alcohol, other vague and undefined expressions are used, such as programmes 'not specifically aimed at minors' or 'immoderate' consumption.[1906]

Moreover, contrary to tobacco, there are no provisions restricting the sponsorship of programmes or events by alcohol of predominantly HFSS foods companies. The absence of such restrictions for events with a cross-border dimension can be particularly regretted, considering that such events, sports competition in particular, are susceptible to attract a large

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[1898] Directive (EU) 2018/1808 of the European Parliament and of the Council of 14 November 2018 amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) in view of changing market realities [2018] OJ L303/69, recital 5.
[1899] Oliver Bartlett and Amandine Garde, 'The EU's Failure to Support Member States in Their Implementation of the WHO Recommendations: How to Ignore the Elephant in the Room?' (2017) 8 European Journal of Risk Regulation 251, 254.
[1900] ibid.
[1901] European Commission, 'EU Action Plan on Childhood Obesity' (n 1472) 16.
[1902] Garde, *EU Law and Obesity Prevention* (n 32) 188.
[1903] Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns' (n 34) 506.
[1904] European Commission, Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services in view of changing market realities, COM (2016) 287 final, arts 1(11) and 11(13).
[1905] Bartlett and Garde, 'The EU's Failure to Support Member States in Their Implementation of the WHO Recommendations: How to Ignore the Elephant in the Room?' (n 1899) 257-259.
[1906] See Oliver Bartlett and Amandine Garde, 'EU Public Health Law and Policy – on the Rocks? A Few Sobering Thoughts on the Growing EU Alcohol Problem' in Hervey, Alasdair Young and Bishop (n 37) 389–390.

young audience. It is telling that the European cup of professional rugby clubs is still officially known as the Heineken Champions Cup.[1907] Available evidence shows a positive association between exposure to alcohol sponsorship and alcohol consumption,[1908] especially for young people that play sports,[1909] and shows that unhealthy food sports sponsorship achieves enormous population reach and exposure and contributes to increased brand awareness, preference and consumption of the sponsored products.[1910]

The EU's approach towards food and drink commercial communications remains largely insufficient,[1911] despite a growing international recognition of the need to better protect children from harmful commercial practices,[1912] including from a children's right perspective,[1913] and the existing evidence as to the effectiveness of mandatory restrictions.[1914] The ex-post evaluation of the AVMS Directive itself, conducted in view of the 2018 revision, raised doubts as to the effectiveness of co- and self-regulation strategies.[1915] A 2015 study commissioned by the European Commission revealed that minor's exposure to alcohol advertising remained high. It was estimated that, on average, a minor in the EU saw advertising spots for alcoholic drinks 200 times a year, compared to 450 for an adult, meaning that 1.8%

[1907] See the Heineken Champion's Cup website: <https://www.epcrugby.com> accessed 11/05/2023. A study, made after the rugby club of Munster in Ireland had won this competition in 2008, showed for instance that children living in the province of Munster had significantly higher level of awareness of the sponsor of that cup (Heineken) if compared to those outside the province, see Frank Houghton and others, 'Children's Awareness of Alcohol Sponsorship of Sport in Ireland: Munster Rugby and the 2008 European Rugby Cup' (2014) 59 International Journal of Public Health 829.

[1908] Katherine Brown, 'Association Between Alcohol Sports Sponsorship and Consumption: A Systematic Review' (2016) 51 Alcohol and Alcoholism 747.

[1909] Fiona Davies, 'An Investigation into the Effects of Sporting Involvement and Alcohol Sponsorship on Underage Drinking' (2009) 11 International Journal of Sports Marketing and Sponsorship 20; Kerry S O'Brien and others, 'Alcohol Industry Sponsorship and Hazardous Drinking in UK University Students Who Play Sport' (2014) 109 Addiction 1647; Kerry O'Brien and Brian Vandenberg, 'Report on the Extent, Nature, and Consequences of Children and Young People's Exposure to Alcohol Advertising and Sponsorship' (2021) Monash University.

[1910] Helen Dixon, Angelyna Lee and Maree Scully, 'Sports Sponsorship as a Cause of Obesity' (2019) 8 Current Obesity Reports 480. See also Timothy Chambers and Franco Sassi, 'Unhealthy Sponsorship of Sport' (2019) 367 British Medical Journal 16718; Robin Ireland and others, 'Commercial Determinants of Health: Advertising of Alcohol and Unhealthy Foods during Sporting Events' (2019) 97 Bulletin of the World Health Organization 290.

[1911] See Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns' (n 34); Bartlett and Garde, 'The EU's Failure to Support Member States in Their Implementation of the WHO Recommendations: How to Ignore the Elephant in the Room?' (n 1899); Garde, 'Harmful Commercial Marketing and Children's Rights: For a Better Use of EU Powers' (n 1853).

[1912] WHO, 'Set of recommendations on the marketing of foods and non-alcoholic beverages to children' (2010) <https://www.who.int/dietphysicalactivity/marketing-food-to-children/en/> accessed 11/05/2023. See Amandine Garde and Godfrey Xuereb, 'The WHO Recommendations on the Marketing of Food and Non-Alcoholic Beverages to Children' (2017) 8 European Journal of Risk Regulation 211.

[1913] Amandine Garde and others, 'For a Children's Rights Approach to Obesity Prevention: The Key Role of an Effective Implementation of the WHO Recommendations' (2017) 8 European Journal of Risk Regulation 327; Garde, 'Harmful Commercial Marketing and Children's Rights: For a Better Use of EU Powers' (n 1853).

[1914] Emma Boyland and others, 'Systematic Review of the Effect of Policies to Restrict the Marketing of Foods and Non-Alcoholic Beverages to Which Children Are Exposed' [2022] Obesity Reviews e13447.

[1915] European Commission, 'Ex-post REFIT evaluation of the Audiovisual Media Services Directive 2010/13/EU' (n 1893) 53-54.

of all advertising seen by minors were for alcoholic beverages, as compared to 2.2% for advertising seen by adults.[1916]

In 2005, the Green Paper on healthy diets and physical activity mentioned that 'other options [than self-regulation] would need to be considered should self-regulation fail to deliver satisfactory results'.[1917] The moment has probably come to draw such conclusion. Yet, the EU stands firm on its preference for non-binding and non-effective schemes, as illustrated by the recent adoption of an EU Code of Conduct on Responsible Food Business and Marketing Practices in the framework of the Farm to Fork Strategy.[1918] Under the Beating Cancer Plan, the Commission only commits to 'develop and implement guidance for codes of practice on reducing unhealthy food marketing to children, including online marketing through the provisions of AVMSD'[1919] and to further monitor the implementation of the AVMSD.[1920] No significant changes are therefore to be expected, and the discrepancy between the treatment of commercial communications across lifestyle risks factors is likely to remain in the near future.

2.3. A residual action on gambling

No rules on commercial communications regulate gambling activities specifically. As previously mentioned, the recommendation on responsible gambling advertising announced by the Commission in 2012 was ultimately never adopted. The AVMS Directive does not apply to gambling services themselves[1921] – a betting or a poker website, for instance, do not constitute audio visual media services – but applies to broadcasts or programmes devoted to gambling or to audiovisual commercial communications made in favour of gambling operators. Hence, Article 9(1)(c)(iii), which provides that audiovisual commercial communications shall not 'encourage behaviour prejudicial to health or safety', is applicable. Recital 30 of Directive 2018/1808 amending the AVMS Directive mentions the importance of effectively protecting minors from exposure to audiovisual commercial communications relating to gambling and refers to the role played by self- or co-regulatory systems in this regard.[1922] The European Gaming and Betting Association published in 2020 the first pan-European code on responsible

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[1916] European Commission, 'Study on the exposure of minors to alcohol advertising on linear and non-linear audio-visual media services and other online services, including a content analysis' (2015) 177-178, <https://op.europa.eu/en/publication-detail/-/publication/2cb53181-8fbf-4fec-b04a-ec927f511e6a/language-en> accessed 11/05/2023.

[1917] European Commission, Green Paper 'Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases' (n 1464) 8.

[1918] See <https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy/sustainable-food-processing/code-conduct_fr> accessed 11/05/2023.

[1919] European Commission, 'Europe's Beating Cancer Plan' (n 23) annexes.

[1920] ibid 10-11.

[1921] Recital 22 of the AVMS Directive reads as follows: 'games of chance involving a stake representing a sum of money, including lotteries, betting and other forms of gambling services, as well as on-line games and search engines, *but not broadcasts devoted to gambling or games of chance*, should also be excluded from the scope of this Directive', emphasis added. See Sibony and Michail (n 1249) 42.

[1922] Directive 2018/1808, recital 30.

gambling advertising,[1923] which contains provisions on advertising, sponsorship and the protection of minors.

Recent developments show however that the gambling sector is far from having complied uniformly with more responsible practices. In recent years, football has for instance seen a surge in advertising and sponsorship for sports betting,[1924] sometimes aggressively and in direction of vulnerable groups. In France, this has for instance been the case during the last European Football Championship of 2021, where numerous adds targeting young people have been released, aiming in particular at those from disadvantaged backgrounds for whom gambling's appeal is particularly luring.[1925] This prompted a strong reaction from the national gambling regulator.[1926] More needs to be done to protect children from gambling advertisements and to promote more responsible practices towards the general population.[1927]

3. Informing choice: towards more behavioural reality?

Most EU rules on lifestyles relate to information, whether to impose the disclosure of information to business operators or to regulate information that operators voluntarily give. These rules are contained, as regards food and alcoholic beverages, in two main instruments: Regulation 1169/2011 on the provision of food information to consumers and Regulation 1924/2006 on nutrition and health claims made on food. As regards tobacco products, the relevant piece of legislation is the Tobacco Products Directive. Information is here understood in a broad sense, as covering textual messages but also other graphical elements used on the labelling and packaging of products.

The overall objective of EU information requirements is to provide consumers with an accurate knowledge and perception of the risk so that, as a result, consumers adopt healthier behaviours. This is done in two manners. First, a number of provisions mandate operators to disclose information considered relevant for consumer choice. This mostly applies to food. Second, EU law regulates the information voluntarily given by operators, to ensure that it does not mislead consumers. In the second case, the law can either way set requirements as to the content of the information given or its form, to ensure its truthfulness and non-misleading character, or simply bar operators from providing that information altogether. This section presents these two types

[1923] European Gaming and Betting Association, Code of Conduct on Responsible Advertising for Online Gambling (2020) <https://www.egba.eu/uploads/2020/04/200428-Code-of-Conduct-on-Responsible-Advertising-for-Online-Gambling.pdf > accessed 11/05/2023.
[1924] Steve Sharman, 'Gambling in Football: How Much Is Too Much?' (2022) 27 Managing Sport and Leisure 85.
[1925] Stéphanie Marteau, 'Euro et paris sportifs en ligne : l'overdose du « marketing de la misère »' (2021) Le Monde, <https://www.lemonde.fr/m-le-mag/article/2021/06/23/euro-2021-et-paris-sportifs-en-ligne-l-overdose-du-marketing-de-la-misere_6085376_4500055.html> accessed 11/05/2023.
[1926] Autorité Nationale des Jeux, 'Euro de football et paris sportifs : l'ANJ réunit les opérateurs et annonce un plan d'action énergique et structurant' (2021), <https://anj.fr/euro-de-football-et-paris-sportifs-lanj-reunit-les-operateurs-et-annonce-un-plan-daction-energique> accessed 11/05/2023.
[1927] Murat Akçayır and others, 'Whose Responsibility Is It to Prevent or Reduce Gambling Harm? A Mapping Review of Current Empirical Research' (2021) 20 International Journal of Mental Health and Addiction 1516, 7–8.

of information requirements in turn, followed by specific developments regarding the rules applicable to certain categories of foods, addressed in bulk for the sake of clarity.

A key objective of this section is to critically assess the various EU lifestyle information requirements in light of the behavioural insights discussed throughout this thesis, to determine the extent to which EU rules on information have moved away from the classic 'information paradigm' and its vision of the rational and diligent consumer. For that purpose, we examine three upcoming reforms of packaging and labelling rules at the EU level: plain tobacco packaging, front-of-pack nutrition labelling and enhanced alcohol labelling.

3.1. Mandatory disclosure of information

A variety of rules apply to the mandatory disclosure of information for tobacco products, food and alcoholic beverages. Among these, two main policy tools emerge: the provision of a nutrition declaration for foods and the inclusion of health warnings on the packaging of tobacco products. Although these are both examples of mandatory information requirements, they are based on entirely different logics. As well summarised by Advocate General Saugmandsgaard Øe in *Planta Tabak*:

> In certain fields, including that of *food*, *consumers must indeed be given information about the ingredients in the products they consume*, so that they can identify and make appropriate use of a food and make choices that suit their individual needs.
>
> However, *tobacco products are not ordinary commodities*. The aim is not to enable consumers to choose more easily between different products. Here, *giving consumers appropriate information amounts essentially to highlighting the particularly harmful effects of tobacco on their health*.[1928]

As we shall see, the difference is not only in the nature of the information that is given to consumers, but also its form. While health warnings have integrated behavioural insights so as to maximise their potential for behaviour change, nutrition information, and food information in general, continues to be given in a format that is largely ineffective.

3.1.1. Foods, alcoholic beverages and the nutrition declaration

Transparency as regards the composition and the nutritional content of foods is a cornerstone of EU food law. It aims at providing consumers with the necessary elements to make informed choices.[1929] But food information is not only a matter of consumer protection, of consumers' right to be informed, it is also seen, as far as nutrition is concerned, as a public health tool. It is believed that 'if consumers are aware of what each foodstuff contains, they should be trusted

[1928] Case C-220/17 *Planta Tabak* [2018] EU:C:2018:530, Opinion of Advocate General Saugmansgaard Øe, paras 76-77, emphasis added.

[1929] Under Article 8(1) of the General Food Law Regulation: 'Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume.'

to apply their nutrition knowledge and make appropriate choices',[1930] thus following the traditional assumptions of consumer rationality and diligence.

The general requirements on food information, in particular nutrition information, are contained in the Food Information Regulation.[1931] Its adoption in 2011 brought clarity to a fragmented field and considerably upscaled the obligations applicable to food business operators.[1932] It repealed the two main instruments in place at the time: Directive 2000/13 on the labelling, presentation and advertising of foodstuffs[1933] and Directive 90/496 on nutrition labelling for foodstuffs.[1934] Under the Regulation, food information is defined as 'information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication'.[1935]

Articles 9 and 10 of the Regulation lay down a list of information items that must be provided to consumers, applicable respectively to all foods or to specific types or categories of foods,[1936]

[1930] Friant-Perrot and Garde (n 95) 137. See in that regard Article 3(1) of the Food Information Regulation :'[t]he provision of food information shall pursue a *high level of protection of consumers' health and interests* by providing a basis for final consumers to *make informed choices and to make safe use of food, with particular regard to health*, economic, environmental, social and ethical considerations', emphasis added. See also European Commission, Communication to the Council and the European Parliament, 'The completion of the internal market: Community legislation on foodstuffs' (1985) COM (85) 603 final, 10: '[d]etails of the nature and quantity of the ingredients used are not sufficient to allow the average consumer to judge the nutritional quality of a food since products with apparently similar lists of ingredients can have very different nutritional properties'.

[1931] The Food Information Regulation applies to all foods intended for the final consumer, including mass catering, without prejudice to labelling requirements provided for in other Union instruments applicable to particular foods: arts 1(3) and (4). The final consumer is 'the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity': General Food Law Regulation, art 3(18). Food that is not intended for the final consumer but is used as part of a food business operation or activity falls outside the scope of the Food Information Regulation.

[1932] Under Article 3(3) of the General Food Law Regulation: 'food business operator' means 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control'.

[1933] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [2000] OJ L109/29.

[1934] Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs [1990] OJ L276/40. Under Article 2 of Directive 90/496, the provision of nutrition information remained optional, save for cases where a nutrition claim was made on the food (see below Section 3.2.1). Prior to Directive 90/496, there were no EU rules applicable to nutrition labelling: see Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [1979] OJ L33/1.

[1935] Food Information Regulation, art 2(2)(a). Food information is mostly made available through labelling, defined as 'any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food': ibid, art 2(2)(j).

[1936] For specific mandatory particulars, see ibid, annex III. The Food Information Regulation also contains a set of detailed provisions governing the display of these mandatory particulars, including their presentation, the language used, and possible derogations: see arts 13, 15 and 16. Regarding language, the general principle is that 'mandatory food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed': art 15(1). Member States may impose on their territory the use of one or more of the

including a nutrition declaration.[1937] These items are referred to as 'mandatory particulars'. In the case of prepacked food, mandatory particulars shall appear directly on the package or on a label attached thereto.[1938] Apart from the nutrition declaration, analysed in detailed below, others of these particulars have a link with health and nutrition, such as the list and quantity of ingredients or the name and net quantity of the food.[1939] It is also the case for some of the food-specific mandatory particulars. The labelling of food containing added sugars and sweeteners must for instance include a statement reading 'with sugar(s) and sweetener(s)'.[1940] For beverages with high caffeine content, a statement reading 'High caffeine content. Not recommended for children or pregnant or breast-feeding women' must be included.[1941]

Inclusion of the quantity of an ingredient or category of ingredients is required in certain circumstances: (i) where the ingredient or category of ingredient 'appears in the name of the food or is usually associated with that name by the consumer', (ii) where it 'is emphasised on the labelling in words, pictures or graphics' or (iii) where the ingredient or category of ingredients 'is essential to characterise a food and to distinguish it from products with which it might be confused because of its name or appearance'.[1942] These requirements prevent consumers from being misled in situations where, for instance, an 'orange juice' would mostly contain water, colorants and sweeteners and it would not be possible to know how much of actual orange juice is present in the beverage.

The mandatory nutrition declaration is governed by Articles 29 to 35 of the Food Information Regulation. This declaration contains a number of mandatory elements – the energy value and the amounts of fat, saturates, carbohydrates, sugars, protein and salt – to which other optional elements, such as fatty acids or fibre, may be added.[1943] Some foods are exempted from the declaration, such as unprocessed products that comprise a single ingredient or category of ingredients, processed products which have only been processed through maturing and that comprise a single ingredient or category of ingredients, and products such as water, salt, coffee or tea.[1944]

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official languages of the European Union, not precluding food business operators from making use of supplementary languages: arts 15(2) and (3).

[1937] ibid, art 9(1)(l).

[1938] ibid, art 12(2).

[1939] ibid, art 9(1)(a) to (e). See art 20 for situations where constituents of food can be omitted from the list of ingredients.

[1940] ibid, annex III.

[1941] ibid.

[1942] ibid, arts 9(1)(d) and 22.

[1943] Food Information Regulation, art 30. The energy value and the amounts of nutrients referred to in Article 30(1) to (5) shall be those of the food as sold: art 31(3). 'Where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption': ibid. Article 31(3) must be interpreted as applying only to foods for which preparation is necessary and the method of preparation is predetermined, see Case C-388/20 *Dr. August Oetker Nahrungsmittel* [2021] EU:C:2021:913.

[1944] ibid, art 16(3), see the complete list in annex V.

The energy value and the content of nutrients must be given per 100 grams or 100 millilitres and may also additionally be expressed per portion or consumption unit,[1945] 'provided that the portion or the unit used is quantified on the label and that the number of portions or units contained in the package is stated'.[1946] For cereals, a portion would for instance represent what is typically consumed in a regular size bowl. For beverages, it is usually equivalent to the amount of liquid contained in a single glass. Although expressing the nutrition declaration per portion or per unit can be useful to consumers, who may struggle to grasp what 100 grams or millilitres of a product represent, it can also be misleading, as food business operators can set portion sizes freely. Operators may select sizes that are smaller than what is typically consumed in one serving, so as to make consumers believe that a serving contains less fat, salt or sugar than it actually does.[1947] This practice, which appears to be widespread,[1948] threatens the truthfulness of the information given and may lead to increased consumption of the products whose portion sizes have been manipulated.

The Food Information Regulation seems to have anticipated this problem, to a certain extent. 'In order to ensure the uniform implementation of the expression of the nutrition declaration [...] and to provide for a uniform basis of comparison for the consumer', Article 33(5) requires the Commission to adopt rules on the expression per portion or per consumption unit for specific categories of foods, based on the actual consumption behaviour of consumers as well as dietary recommendations. No such rules have been adopted to date, a missed opportunity when considering that portion sizes do not vary markedly across Member States.[1949] That being said, if it is important that potential future harmonised portion or unit sizes are based on the actual consumption behaviour of consumers, the reliance on dietary recommendations could lead to a suboptimal result if sizes where to be set according to how people should eat rather than how they actually eat.[1950] The use of visual portion sizes could also be explored, so that consumers better understand how operators divide their products.

As it stands, the mandatory nutrition declaration suffers from several defects (see Figure 1). The information given is first of all difficult to understand. It is expressed with words or

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[1945] ibid, arts 32 and 33. Under Article 32(4) the energy value and the amounts of nutrients may also be expressed as a percentage of the reference intakes set out in Annex XIII.
[1946] ibid, art 33(1).
[1947] Gina S Mohr, Donald R Lichtenstein and Chris Janiszewski, 'The Effect of Marketer-Suggested Serving Size on Consumer Responses: The Unintended Consequences of Consumer Attention to Calorie Information' (2012) 76 Journal of Marketing 59; Ossama Elshiewy, Steffen Jahn and Yasemin Boztug, 'Seduced by the Label: How the Recommended Serving Size on Nutrition Labels Affects Food Sales' (2016) 1 Journal of the Association for Consumer Research 104; Nathalie Kliemann and others, 'Serving Size and Nutrition Labelling: Implications for Nutrition Information and Nutrition Claims on Packaged Foods' (2018) 10 Nutrients 891.
[1948] ibid.
[1949] L Kirwan and others, 'Comparison of the Portion Size and Frequency of Consumption of 156 Foods across Seven European Countries: Insights from the Food4ME Study' (2016) 70 European Journal of Clinical Nutrition 642.
[1950] Caoimhín MacMaoláin, 'Regulating consumer information: use of food labelling and mandatory disclosures to encourage healthier lifestyles' in Alemanno and Garde, *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (n 31) 57; MacMaoláin, *Food Law: European, Domestic and International Frameworks* (n 32) 239.

numbers,[1951] so consumers need to have sufficient nutrition knowledge and computational skills to be able to determine whether a product contains too much of a given nutrient, taking into account their overall diet and the daily reference intake for that nutrient.[1952] This information is also difficult to notice. It must be given in tabular format, if space permits, otherwise in linear format,[1953] in characters using a font size with a minimum x-height of 1,2 mm.[1954] All mandatory nutrition information must be presented in the same 'field of vision', defined as 'all the surfaces of a package that can be read from a single viewing point'.[1955] Although this is not required under the Food Information Regulation,[1956] food business operators usually choose to include the mandatory nutrition declaration on the back rather than on the front of the packaging of foods, which means that it is not immediately accessible to consumers when looking at products in a retail environment.

Figure 1: EU mandatory nutrition declaration[1957]

energy	**kJ/kcal**
fat	g
of which	
— saturates,	g
— mono-unsaturates,	g
— polyunsaturates,	g
carbohydrate	g
of which	
— sugars,	g
— polyols,	g
— starch,	g
fibre	g
protein	g
salt	g
vitamins and minerals	the units specified in point 1 of Part A of Annex XIII

As could be expected, there is ample evidence showing that nutrition information of the kind provided for in the Food Information Regulation does not have any significant impact on people's dietary choices and is unlikely to lead to any meaningful improvement from a public

[1951] Food Information Regulation, art 9(2).
[1952] See ibid, annex XIII.
[1953] ibid, art 34. See also annex XV.
[1954] Food information Regulation, art 13(2). In case of packaging or containers the largest surface of which has an area of less than 80 cm2, the minimum x-height is reduced to 0,9 mm: ibid, art 13(3). The 'x-height' is defined at Annex IV.
[1955] Food Information Regulation, art 2(2)(k).
[1956] According to Article 34(1) of the Food Information Regulation, the particulars referred to in Article 30(1) and (2) shall be included in the 'same field of vision', without any reference to its location.
[1957] Taken from ibid, annex XV.

health perspective.[1958] This is in line with the more general conclusion that mandated disclosure of information as a policy tool suffers from serious shortcomings: it is often ignored, misunderstood and not acted upon. In the area of nutrition, most consumers consider that more information is better, despite the fact that the majority of them is 'not equipped to interpret all this information due to factors such as low levels of nutrition knowledge, time pressure and competing priorities'.[1959] Hence, as it is currently expressed and presented, the nutrition declaration fails to 'appeal to the average consumer and to serve the informative purpose for which it is introduced' and, 'given the current level of knowledge on the subject of nutrition', cannot be considered as 'simple and easily understood', in contradiction with the objectives of the Food Information Regulation.[1960]

To address this problem, Article 35 of the Food Information Regulation allows food business operators to give the mandatory nutrition declaration using additional forms of expression and presentation, including graphical forms or symbols.[1961] The implication of that article and the relevance of these additional forms of expression and presentation for EU nutrition information are further discussed in Section 3.4.2.

The Food Information Regulation applies to all foods intended for the final consumer, including alcoholic beverages. As regards alcohol, however, there are two important caveats to the rules that have just been exposed. Beverages containing more than 1,2 % by volume of alcohol are exempted from the mandatory nutrition declaration as well as the obligation to provide the list of ingredients.[1962] Food business operators are encouraged to provide the energy value on a voluntary basis[1963] and Member States are authorised to adopt binding measures requiring the provision of the list of ingredients for these beverages.[1964] The only supplementary rule that alcoholic beverages must comply with is the indication of the actual alcoholic strength by volume ('% vol').[1965]

These exemptions for alcoholic beverages are a long-standing feature of EU food labelling legislation. Directive 79/112 already provided that 'in the case of beverages containing more than 1,2 % vol, the Council, acting on a proposal from the Commission, shall, […] determine

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[1958] Gill Cowburn and Lynn Stockley, 'Consumer Understanding and Use of Nutrition Labelling: A Systematic Review' (2005) 8 Public Health Nutrition 21; MacMaoláin, 'Regulating consumer information: use of food labelling and mandatory disclosures to encourage healthier lifestyles' (n 1950) 47; Bauer and Reisch (n 321) 29; Shmuel I Becher and others, 'Hungry for Change: The Law and Policy of Food Health Labeling' (2019) 54 Wake Forest Law Review 1305, 1314, 1318.

[1959] Zenobia Talati and others, 'Consumers' Perceptions of Five Front-of-Package Nutrition Labels: An Experimental Study Across 12 Countries' (2019) 11 Nutrients 1934, 1945.

[1960] Food Information Regulation, recital 41.

[1961] ibid, art 35 and recital 43.

[1962] ibid, art 16(4).

[1963] ibid, art 30(4) and recital 42.

[1964] ibid, art 41.

[1965] ibid, art 9(1)(k). Pursuant to Article 28(1) of the Food Information Regulation, rules governing the indication of the alcoholic strength are contained in Annex XII. In particular, the alcoholic strength must be determined at 20 °C and must be indicated by a figure followed by the symbol '% vol.'.

the rules for labelling ingredients'.[1966] Throughout the years, none of the proposals presented by the Commission managed to gather the support of the Council and this exemption was kept in the Food Information Regulation, [1967] along with the one concerning the mandatory nutrition declaration. The Food Information Regulation offers little by way of justifying this difference in treatment, simply referring to the 'specific nature' of the alcohol sector.[1968] The original legislative proposal only excluded beer, wine and spirits from the mandatory nutrition declaration,[1969] on grounds of the existence of specific legislation for wine labelling and so as to keep consistency with beer and spirits.[1970] The European Parliament subsequently extended this exemption to all alcoholic beverages.[1971]

Specific labelling rules apply to wine, aromatised wines and spirits, supplementing those contained in the Food Information Regulation.[1972] Rules on wine labelling and presentation are contained in Articles 117 to 123 of Regulation 1308/2013 establishing a common organisation of the markets in agricultural products, which provide for the inclusion of a number of mandatory particulars.[1973] The only health-related particulars currently mandatory are the indication of the actual alcoholic strength by volume[1974] and, in the case of sparkling wine, the indication of the sugar content.[1975] From 8 December 2023, the labelling and presentation of wine will be aligned with that of other foods regulated under the Food Information Regulation, and will have to include the nutrition declaration and the list of ingredients provided for in that Regulation.[1976]

3.1.2. Tobacco health warnings

If compared to foods and alcoholic beverages, tobacco and related products have to comply with far fewer information disclosure requirements. The regulatory goal is not to enable consumers to choose more easily between different products but to discourage them to consume tobacco altogether. Here, as already underlined, 'giving consumers appropriate information

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[1966] Directive 79/112, art 6(3).
[1967] For further elements, see European Commission, 'Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages' COM (2017) 58 final, 4.
[1968] Food Information Regulation, recital 40.
[1969] European Commission, Food Information Regulation Proposal (n 2176), art 20(e).
[1970] ibid, recital 28.
[1971] European Commission, 'Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages' (n 1967) 4.
[1972] CMO Regulation, art 118; Regulation 251/2014, art 1; Regulation 2019/787, art 9.
[1973] CMO Regulation, art 119.
[1974] ibid, art 119(1)(c).
[1975] ibid, art 119(1)(g).
[1976] Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December 2021 amending Regulations (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union [2021] OJ L435/262, art 1, point (32)(a)(ii). Regarding the entry into force of that provision, see art 6.

amounts essentially to highlighting the particularly harmful effects of tobacco on their health',[1977] which is done by means of various textual and pictorial health warnings.

Tobacco health warnings were first introduced in 1989 at the European level. Under Directive 89/622, these text-only warnings were required to cover between 4 and 8% of the large surfaces of unit packets.[1978] The 2001 TPD strengthened the requirement on health warnings and widely increased their size, which ranged from 30 to 35% of the front of the packets for general warnings and 40 to 50% of the back of the packets for additional warnings.[1979] The TPD reinforces these rules once again, further increasing the size of the warnings and introducing for the first time pictorial warnings.

The general provisions on health warnings are contained in Article 8 TPD, which contains requirements on language(s) and presentation, as well as on the visibility and integrity of the warnings.[1980] In particular, Article 8(8) requires that 'images of unit packets and any outside packaging targeting consumers in the Union' comply with the TPD provisions applicable to packaging and labelling, including that applicable to health warnings. This provision seeks to prevent a situation where tobacco business operators would use images of tobacco products free of the TPD requirements, with a commercial intent, thus undermining the level of protection reached under the Directive.

In *Pro Rauchfrei*,[1981] the Court of Justice was called to interpret the concept of 'images of unit packets' contained in Article 8(8). The dispute in the main proceedings involved two German supermarkets selling cigarette packets through vending machines. The selection buttons on the machines allowed to identify different cigarette brands with graphical representations that did not display the health warnings prescribed in the TPD. The Court, while leaving it to the national court to decide whether the graphical representations at stake constituted images within the meaning of Article 8(8), strongly inclined in that direction, ruling that the concept of 'images of unit packets' must be interpreted as including not only faithful depictions of unit packets but also 'images that a consumer associates with such unit packets on account of their design in terms of outline, proportions, colour and brand logo'.[1982] According to the Court, 'an image which the consumer associates with a unit packet of tobacco products may, in the same way as a faithful depiction, trigger a desire to purchase, a desire which, however, the health

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[1977] *Planta Tabak*, Opinion of Advocate General Saugmansgaard Øe (n 1928), para 77, emphasis added.
[1978] Directive 89/622/EEC, art 4.
[1979] Directive 2001/37/EC, art 5.
[1980] Article 14 lays down a number of requirements regarding the appearance and content of unit packets of cigarettes and roll-your-own tobacco. In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, the article prescribes rules on the shape and opening mechanism of unit packets. See Tobacco Products Directive, recital 28. See also *Philip Morris* (n 28), para 197, where the Court added that 'innovative, novel or unusual shapes may help to maintain or enhance the attraction of the product and encourage its use'.
[1981] Case C-370/20 *Pro Rauchfrei* [2021] EU:C:2021:988.
[1982] ibid, para 32. The Court further clarified that, were the graphical representations used on the vending machines to be considered as 'images of unit packets', the fact that consumers have an opportunity to see the health warnings on unit packets before purchase is not enough to ensure compliance with Article 8(8) TPD: ibid, para 36.

warnings prescribed by law serve to discourage', which follows that the concept of 'images of unit packets' must be given a broad interpretation'.[1983]

Article 8(3) TPD requires that the health warnings are irremovably printed when tobacco products are placed on the market, and not partially or totally hidden. In *Pro Rauchfrei II*, the Court clarified that Article 8(3) does not prevent tobacco to be sold in vending machines, where the unit packet it is not at all visible from the outside, provided that the unit packet complies with the obligation contained in that provision.[1984]

The specific provisions on health warnings are contained in Articles 9 to 12 TPD. Rules are most stringent for tobacco products for smoking, the most harmful form of tobacco products. Each unit packet and any outside packaging must carry one of two general warnings, 'Smoking kills – quit now' or 'Smoking kills', as well as an information message, 'Tobacco smoke contains over 70 substances known to cause cancer'.[1985] Both the general warning and the information message shall cover 50 % of the surfaces on which they are printed and need complying with a number of other presentation requirements.[1986] Importantly, from the perspective of consumer attention, Article 9 requires that the font size used 'occupies the greatest possible proportion of the surface reserved for these health warnings'.[1987] This should be contrasted with the provisions applicable to the mandatory nutrition declaration, setting a minimum size at only 1.2 mm. Moreover, the provisions of Article 9(3) on the minimum dimensions of lateral health warnings actually translate into a ban on slim cigarette packs that are less than 20 mm deep,[1988] which have been shown to lead to a lowered perception of the harmfulness of tobacco.[1989]

Unit packets and outside packaging of tobacco products for smoking must also carry combined health warnings consisting of a text warning and a colour photograph, which shall cover 65% of both the external front and back surface of the packaging (see Figure 2).[1990] Article 10 contains specific requirements as to the layout, design and shape of these combined health warnings, that differ in function of the type of packet.[1991] The required text warnings and

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[1983] ibid, para 30.
[1984] Case C-356/22 *Pro Rauchfrei e v V JS eK* [2023] EU:C:2023:174.
[1985] Tobacco Products Directive, arts 9(1) and (2).
[1986] Tobacco Products Directive, arts 9(3) and (4). See also the Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches [2015] OJ L252/49.
[1987] Tobacco Products Directive, art 9(4)(a).
[1988] See the Report on the application of Directive 2014/40/EU (n 1429) 7. It seems that this was ambiguous and hence not consistently applied by Member States, see European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 71.
[1989] Jennifer L Brown and others, 'Misleading Tobacco Packaging: Moving Beyond Bans on "Light" and "Mild"' (2020) 6 Tobacco Regulatory Science 369.
[1990] Tobacco Products Directive, art 10(1).
[1991] ibid. See also the Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking [2015] OJ L267/5.

photographs are contained, respectively, in Annex I and Annex II of the Directive.[1992] Text warnings include for instance 'Smoking damages your lungs' or 'Your smoke harms your children, family and friends'.[1993] The combined health warnings are grouped into three sets which must be used in a given year and rotated on an annual basis.[1994] Each set contains fourteen combined health warnings which must be displayed to the extent possible in equal numbers on each brand of tobacco products.[1995]

Figure 2: EU combined health warnings

The Guidelines for implementation of Article 11 of the FCTC provide the rationale for the introduction of combined warnings, explaining that 'in comparison with small, text only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption', and are also 'more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people'.[1996] A 2020 study from the EUREST-PLUS

[1992] Regarding Annex II, see the Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products [2014] OJ L360/22.

[1993] Annex I contains fourteen text warnings in total, a number that is similar to that of the 2001 Directive on tobacco products. The messages contained in the TPD are however different from those used in the 2001 Directive. Th is lower than the twenty-four warnings that the study commissioned by the European Commission in view of the revision of the 2001 Directive had suggested, see Sambrook Research International, 'A review of the science base to support the development of health warnings for tobacco packages' (2009) 81.

[1994] Tobacco Products Directive, art 10(2).

[1995] ibid and Annex II. The colour photographs change for each rotation, meaning that Annex II contains 42 of them.

[1996] WHO, 'Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)', para 7, <https://www.fctc.org/wp-content/uploads/2007/06/fca-2007-cop-article11-cop2-recommendations-en.pdf> accessed 11/05/2023. See also *Philip Morris* (n 28), para 204. For evidence on the effectiveness of combined warnings on smoking reduction and deterrence, see Seth M Noar and others, 'The Impact of Strengthening Cigarette Pack Warnings: Systematic Review of Longitudinal Observational Studies' (2016) 164 Social Science & Medicine 118; Israel T Agaku, Filippos T Filippidis and Constantine I Vardavas, 'Effectiveness of Text versus Pictorial Health Warning Labels and Predictors of Support for Plain Packaging of Tobacco Products within the European Union' (2015) 21 European Addiction Research 47; Bo Pang and others, 'The Effectiveness of Graphic Health Warnings on Tobacco Products: A Systematic Review on Perceived Harm and Quit Intentions' (2021) 21 BMC Public Health 884.

Consortium offered mixed results regarding the effectiveness of the new TPD warnings, showing that the salience of the warnings had been increased without, however, clear improvements in consumer's cognitive reactions – thinking about the health risks of smoking or thinking of quitting smoking – and behavioural reactions – refraining from having a cigarette when about to smoke.[1997]

The introduction of tobacco combined health warnings illustrates the 'behavioural turn' in EU tobacco control and EU lifestyle risks policy more generally.[1998] The disgusting and troubling character of the images used is meant to induce fear and to negatively affect consumers' emotions and evaluation of the risk, counteracting for instance the tendency to overoptimism.[1999] Health warnings may also have a 'goal priming' effect, providing a cue that activates the latent long term health goals present in individuals, such as quitting smoking, although there seems to be a disagreement as to whether this works best with negative cues, like warnings, or positive ones.[2000] The rotation of the warnings is meant to ensure that consumers are not too often confronted to the same texts and images, thus avoiding a 'washing out' or 'wear out' effect from materialising, whereby exposure to similar messages leads to habituation and decreased attention.[2001] The study supporting the TPD changes on health warnings also advised for a complete renewal of the images used after a maximum of five years,[2002] something which has not yet been done and does not seem to planned in the near future.

The use of pictorial health warnings has ethical implications, because these warnings are nudges that overtly seek to manipulate consumers' risk perception, what is more by relying on fear inducing mechanisms. There are 'third-degree nudges', following Baldwin's classification, interventions whereby '[t]he target is influenced but reflection is obstructed or reflection materially fails to unpack the nature and extent of the decision or preference

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[1997] Sarah Kahnert and others, 'Effectiveness of Tobacco Warning Labels before and after Implementation of the European Tobacco Products Directive—Findings from the Longitudinal EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health 84.

[1998] Alberto Alemanno, 'Nudging smokers: The behavioural turn of tobacco risk regulation' (2012) 3 European Journal of Risk Regulation 32.

[1999] Blumenthal-Barby and Burroughs (n 456) 5-6; Sophie Lacoste-Badie and others, 'How Do Smokers Respond to Pictorial and Threatening Tobacco Warnings? The Role of Threat Level, Repeated Exposure, Type of Packs and Warning Size' (2019) 36 Journal of Consumer Marketing 461, 461–471.

[2000] Gareth J Hollands and Theresa M Marteau, 'Pairing Images of Unhealthy and Healthy Foods with Images of Negative and Positive Health Consequences: Impact on Attitudes and Food Choice.' (2016) 35 Health Psychology 847, 847–861; Esther K Papies, 'Health Goal Priming as a Situated Intervention Tool: How to Benefit from Nonconscious Motivational Routes to Health Behaviour' (2016) 10 Health Psychology Review 408.

[2001] Papies (n 2000) 419; Eva Woelbert and Béatrice d'Hombres, 'Pictorial Health Warnings and Wear-out Effects: Evidence from a Web Experiment in 10 European Countries' (2019) 28 Tobacco Control e71, 71–76. See also Sambrook Research International (n 1993).

[2002] Sambrook Research International (n 1993) 109.

shaping',[2003] which raises specific questions as regards consumer autonomy.[2004] Not all the of images used are equal in that regard. Those that faithfully depict the consequences of smoking, such as the image of damaged lungs, appear less objectionable than those that display exaggerated or even quasi-fictional situations, such as the picture of a smoking child (see Figure 2 above).[2005]

Tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco may be exempted by Member States from the obligations to carry the information message 'Tobacco smoke contains over 70 substances known to cause cancer' and the combined health warnings, in which case these products must comply with additional health warnings and specific requirements.[2006] Similarly to the exemption from the ban on characterising flavours, the reason for this is that these products 'are mainly consumed by older consumers and small groups of the population'.[2007]

As regards tobacco products other than for smoking, the applicable rules are far more lenient, reflecting their lower harmfulness. Smokeless tobacco products must carry the message 'This tobacco product damages your health and is addictive'.[2008] For e-cigarettes and refill containers, choice is left between the following health warnings: 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non- smokers' or 'This product contains nicotine which is a highly addictive substance'.[2009] For unit packets and outside packaging of herbal products for smoking, finally, the applicable warning is 'Smoking this product damages your health'.[2010] None of these categories of tobacco and related products is required to carry a pictorial health warning.

E-cigarettes and refill containers are the only category of products regulated under the TPD that need complying with 'classic' information disclosure requirements. Unit packets and outside packaging shall include a list of ingredients contained in the product, an indication of the nicotine content and delivery per dose, the batch number and a recommendation to keep the product out of reach of children.[2011] Unit packets must include a leaflet containing a number of information relating to health and safety: (i) instructions for use and storage, including a

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[2003] Robert Baldwin, 'From Regulation to Behaviour Change: Giving Nudge the Third Degree' (2014) 77 The Modern Law Review 831, 837.
[2004] Ensuring the publicity of the nudge and transparency as regards its mechanism of action, a solution which is often put forward to alleviate concerns of manipulation, may for instance not be an option with such types of third-degree nudges, as their effectiveness is directly linked to their capacity to induce subconscious behavioural reactions. A further concern about such interventions relates to their longer-term and extensive use, as these 'do not seek to improve rational, informed decision-making but serve to reduce the citizen's voice in his or her destiny': ibid 849.
[2005] Blumenthal-Barby and Burroughs (n 456) 6. See further Tobacco Products Directive, annex II.
[2006] Tobacco Products Directive, art 11. From 23 October 2023, Member States may not apply this exemption to heated tobacco products any longer: see Commission Delegated Directive 2022/2100, art. 1.
[2007] ibid, recital 26.
[2008] ibid, art 12.
[2009] ibid, art 20(4)(b)(iii).
[2010] ibid, art 21(1)-(3).
[2011] ibid, art 20(4)(b)(i).

reference that the product is not recommended for use by young people and non-smokers, (ii) contra-indications and warnings for specific groups, and (iii) information on possible adverse effects, addictiveness and toxicity.[2012] Nothing is said in the Directive as regards the format of the leaflet, its size or the font used. Available evidence shows only a limited engagement of consumers with the leaflet,[2013] which is not surprising considering that many manufacturers still fail to comply with this requirement[2014] and that, where they do, information is given in a format that is unlikely to attract consumer attention, much less to create any willingness to read it (see Figure 3).

Recourse to lengthy disclosure requirements for e-cigarettes may be justified by the complexity of the product and the necessity to ensure that consumers understand how to properly use them, two elements which are absent as regards tobacco products for smoking. As always, good intentions will fail if consumers, as seems to be the case, vastly ignore the information provided. The 2021 Eurobarometer on tobacco products shows that only two-thirds of respondents (65%) think e-cigarettes are harmful to health, an increase by ten percentage points compared to 2017, which still leaves a sizeable minority of the population ignorant of the health risks incurred.[2015] At the same time, smokers continue to overestimate the relative harmfulness of e-cigarettes if compared to that of combustible cigarettes,[2016] a problematic situation from a harm reduction perspective. As the regulatory environment influences the perceived harmfulness of e-cigarettes,[2017] some have called for changes in the TPD so that the risks of e-cigarettes are communicated in a more appropriate manner and so that smokers are better aware of the risk reduction potential of e-cigarettes.[2018]

Figure 3: Example of an EU e-cigarette leaflet[2019]

[2012] Tobacco Products Directive, art 20(4)(a).

[2013] Van Mourik and others found that only a third of e-cigarette users reported noticing the leaflets present in unit packets : Dirk-Jan A van Mourik and others, 'Did E-Cigarette Users Notice the New European Union's E-Cigarette Legislation? Findings from the 2015–2017 International Tobacco Control (ITC) Netherlands Survey' (2019) 16 International Journal of Environmental Research and Public Health 2917. Nikitara and others found that, among those having noticed the leaflets, only 22% actually read it: Katerina Nikitara and others, 'Changes in Electronic Cigarette Use and Label Awareness among Smokers before and after the European Tobacco Products Directive Implementation in Six European Countries: Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health iii62.

[2014] Charis Girvalaki and others, 'Compliance of E-Cigarette Refill Liquids with Regulations on Labelling, Packaging and Technical Design Characteristics in Nine European Member States' (2020) 29 Tobacco Control 531.

[2015] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 166.

[2016] Shannon Gravely and others, 'European Adult Smokers' Perceptions of the Harmfulness of e-Cigarettes Relative to Combustible Cigarettes: Cohort Findings from the 2016 and 2018 EUREST-PLUS ITC Europe Surveys' (n 448).

[2017] Hua-Hie Yong and others, 'Prevalence and Correlates of the Belief That Electronic Cigarettes Are a Lot Less Harmful Than Conventional Cigarettes Under the Different Regulatory Environments of Australia and the United Kingdom' (2017) 19 Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco 258.

[2018] McNeill and others (n 162).

[2019] Taken from Van Mourik and others (n 2013).


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DANGER
CONTAINS NICOTINE 0%, 0,15%, 0,3%, 0,6%, 1,2%, 1,8%
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PROPYLENE GLYCOL F.U., VEGETABLE GLYCERINE F.U., DEIONISED WATER, NICOTINE (U.S.P. – B. PH). 0%, 0,3%, 0,6%, 1,2%, 1,8%

COMPOSITION FOR LIQUIDS WITH AROMA'S
INGREDIENTS FOR 100 GRAM PRODUCT:
PROPYLENE GLYCOL F.U., VEGETABLE GLYCERINE F.U., DEIONISED WATER, AROMA'S NICOTINE (U.S.P. – B. PH). 0%, 0,3%, 0,6%, 1,2%, 1,8%

SAFETY ADVICE
P101 – IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND. P102 – KEEP OUT OF REACH OF CHILDREN. P103 – READ LABEL BEFORE USE. P321 – SPECIFIC TREATMENT: IF SWALLOWED, DO NOT INDUCE VOMITING. P302+P352 – IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER. P501 – DISPOSE OF CONTAINER AT RECYCLINGPOINT, DO NOT DISPOSE IN THE ENVIRONMENT. H311 – TOXIC IN CONTACT WITH SKIN.

STORAGE ADVICE
KEEP OUT OF REACH OF CHILDREN – STOREDRY, COOL AND CLOSED – USE UNTIL: SEE DATE ON PACKAGING OR CONTAINER LABEL – PERISHABLE AFTER OPENING.

USAGE ADVICE
SHAKE WELL BEFORE USE. LIQUID ONLY TO BE USED WITH AN E-CIGARETTE. FOLLOW E-CIGARETTE INSTRUCTIONS ON FILLING, USAGE AND CORRECT SETTINGS. TREAT PRODUCT WITH CARE AND READ THE INSERT CLOSELY. USAGE BY MINORS UNDER 18 AND NON-SMOKERS IS NOT ADVISED. E-CIGARETTE TANKS WHICH PRODUCE MORE VAPE, WARMTH AND TASTE MORE LIQUID PER PUFF, THIS CAN INCREASE THE NICOTINE STRENGTH EXPERIENCED COMPARE TO REGULAR TANKS.

WARNING
NOT SUITABLE FOR PREGNANT AND LACTATING WOMEN, PERSONS WITH LUNG DISEASE, CANCER OR HEART AND VESSIL DISEASE. NICOTINE IS A HIGHLY ADDICTIVE SUBSTANCE. AT CONTACT WITH THE EYES, RINSE WITH OPEN EYES FOR 10 MINUTES WITH PLENTY OF WATER, SEEK MEDICAL HELP, DO NOT USE EYEWASH. AT CONTACT WITH THE SKIN, WASH IMMEDIATELY WITH PLENTY OF WATER AND SOAP. REMOVE EXPOSED CLOTHING IMMEDIATELY. DO NOT DUMP LIQUID IN SINK OR THE ENVIRONMENT. DO NOT LEAVE IN THE SUN OR NEXT TO HEAT SOURCES. DO NOT SWALLOW; CONTACT A DOCTOR WHEN FEELING UNWELL.

3.2. Voluntary disclosure of information

Information voluntarily given by business operators can be useful to consumers, in which case its provision may be encouraged. Considering that any disclosure of information entails costs, it is however reasonable to consider that operators will rarely give information that cannot benefit them in one way or another. Voluntary information often has a promotional intent, in which case it has the potential to mislead consumers, especially as regards hazardous products. Rules are therefore enacted to ensure that this information is accurate and that it does not distort risk perception and encourage the consumption of unhealthy products. As regards foods, this is the role played by the Claims Regulation in particular. In certain circumstances, information is deemed to be misleading per se, regardless of its accurate character, in which case its provision is prohibited.

3.2.1. Foods and alcoholic beverages

Generally, food law, 'shall aim at the prevention of fraudulent or deceptive practices [and] other practices which may mislead the consumer'.[2020] Relevant provisions as regards health and nutrition are contained in the Claims Regulation and, to a much lesser extent, in the Food Information Regulation.

3.2.1.1. Misleading information under the Food Information Regulation

[2020] General Food Law Regulation, art 8.

Pursuant to Article 7 of the Food Information Regulation, food information shall not be misleading and shall be accurate, clear, and easy to understand for the consumer.[2021] In particular, Article 7(1)(a) prohibits the provision of misleading information relating to the characteristics of the food, including its ingredients.

In *Teekanne*, the Court of Justice provided an important interpretation of that provision.[2022] The case dealt with a fruit tea whose packaging included depictions of raspberries and vanilla flowers, and a claim that the tea was made from natural ingredients. The product was in fact not made from natural ingredients, as was clear from the list of ingredients. In such a situation, would a consumer be misled into thinking that the tea contained natural ingredients, or would the presence of the ingredient list suffice to alleviate this concern? One could have expected the Court to rule in favour of the second approach, considering its long-standing position that the average consumer is deemed 'reasonably well informed, and reasonably observant and circumspect'[2023] and that consumers 'whose purchasing decisions depend on the composition of the products in question will first read the list of ingredients'.[2024] Yet, the Court adopted a more protective approach, ruling that the mere presence of the ingredients list was not sufficient to exclude the possibility for the consumer to be misled. This list, said the Court, 'even though correct and comprehensive, may in some situations not be capable of correcting sufficiently the consumer's erroneous or misleading impression' induced by the other parts of the packaging.[2025] This can occur, the Court continued, when the labelling gives the impression that a certain ingredient is present in a product when in fact it is not.[2026] This judgement represents an important milestone in the path towards a more realistic vision of the average consumer (see Chapter 4, Section 3.1.2).[2027] The interpretation chosen protects consumers' legitimate expectations and prevent them from being misled when making dietary choices.

Under the Food Information Regulation, food business operators are allowed to provide information on a voluntary basis. If this information refers to mandatory particulars mentioned in Articles 9 or 10 of the Regulation, it shall comply with the requirements applicable to these

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[2021] Pursuant to article 7(1), 'food information shall not be misleading, particularly: (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production; (b) by attributing to the food effects or properties which it does not possess; (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients; (d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.'

[2022] *Teekanne* (n 1167).

[2023] ibid, para 36.

[2024] ibid, para 37.

[2025] ibid, paras 39-40.

[2026] ibid, para 41.

[2027] See in this regard, Hanna Schebesta and Kai Purnhagen, 'The Behaviour of the Average Consumer: A Little Less Normativity and a Little More Reality in the Court's Case-law? Reflections on Teekanne' (2016) 41 European Law Review 590.

particulars, as provided for in the Regulation, and with the general prohibition on misleading information contained in Article 7.[2028] It shall also not be ambiguous or confusing, shall be based, where relevant, on scientific data,[2029] and shall not be displayed to the detriment of the space available for mandatory food information.[2030]

3.2.1.2. Conditions applicable to the use of food claims

The Claims Regulation is one of the main pieces of EU food law. It regulates the use of health-related claims on products. Health-related claims are messages used by food operators to claim particular health benefits for their products, such as 'good for your heart', 'rich in fibre' or 'increases your well-being'. These claims are very useful for food operators as promotional tools. Evidence shows that claims are generally perceived very positively by consumers and that foods carrying claims are more purchased and consumed than foods that do not.[2031] When truthful and correctly understood, claims are beneficial to consumers, enabling them to make dietary choices aligned with their needs or interests.

A number of behavioural phenomena suggest however that consumers can easily be misled by claims. The 'halo effect', for instance, is a widely known psychological phenomenon whereby the positive or negative impression one has of an aspect of a person or object is extended to other unrelated aspects.[2032] In the context of claims, 'marketing actions that emphasize one aspect of the food as being healthy lead to the creation of a "health halo," which makes the food appear healthier than it is, and in turn leads to overconsumption'.[2033] Consumers could for instance wrongly infer from a low cholesterol claim on butter that this product also has less calories. Another of these phenomena is the 'positivity bias', which can lead consumers to think that products carrying a claim are healthier than those without, which is not necessarily the case.[2034] A product with a 'rich in fibre' claim that contains a lot of salt and fat is not necessarily healthier than a product with no claim but with less salt and fat. The existence of

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[2028] Food Information Regulation, art 36(1) and (2)(a).
[2029] ibid, art 36(2)(b) and (c).
[2030] ibid, art 37.
[2031] Asha Kaur, Peter Scarborough and Mike Rayner, 'A Systematic Review, and Meta-Analyses, of the Impact of Health-Related Claims on Dietary Choices' (2017) 14 International Journal of Behavioral Nutrition and Physical Activity 93.
[2032] Kai Purnhagen, Erica van Herpen and Ellen van Kleef, 'The Potential Use of Visual Packaging Elements as Nudges' in Mathis and Tor, *Nudging - Possibilities, Limitations and Applications in European Law and Economics* (n 453) 204. See also Richard E Nisbett and Timothy D Wilson, 'The halo effect: Evidence for unconscious alteration of judgments' (1977) 35 Journal of Personality and Social Psychology 250.
[2033] Pierre Chandon, 'How Package Design and Packaged-Based Marketing Claims Lead to Overeating' (2013) 35 Applied Economic Perspectives and Policy 7, 9; Zenobia Talati and others, 'Consumers' Responses to Health Claims in the Context of Other on-Pack Nutrition Information: A Systematic Review' (2017) 75 Nutrition Reviews 260, 261. For the impact of the halo effect on food labelling more generally, see Aparna Sundar and others, 'Is Unnatural Unhealthy? Think about It: Overcoming Negative Halo Effects from Food Labels' (2021) 38 Psychology & Marketing 1280.
[2034] Asha Kaur and others, 'The Nutritional Quality of Foods Carrying Health-Related Claims in Germany, The Netherlands, Spain, Slovenia and the United Kingdom' (2016) 70 European Journal of Clinical Nutrition 1388, 94; Talati and others, 'Consumers' Responses to Health Claims in the Context of Other on-Pack Nutrition Information: A Systematic Review' (n 2033).

these phenomena is acknowledged in the Claims Regulation, which states that '[f]oods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added'.[2035]

No specific set of rules applied to claims prior to the adoption of the Claims Regulation. Under the general legal framework applicable to food information, claims had to respect the basic principle of not misleading consumers[2036] and foods carrying claims were required to provide nutrition information.[2037] In view of the proliferation of unregulated claims, which put the integrity of internal market and consumer protection in jeopardy, a specific regulation was proposed in 2003,[2038] and adopted in 2006 after more than 3 years of intense debate.[2039] When considering the behavioural effects involved, the inherent scientific complexity of assessing the effects of food on health and hence the truthfulness of claims, and the economic interests at stake, it is not surprising that the regulation of claims has encountered numerous difficulties and given rise to a number of controversies. As was rightly said, the Claims Regulation is 'perhaps the most controversial, certainly the most complicated piece of food legislation that the European Union has ever adopted'.[2040]

The Claims Regulation pursues two main functions: ensuring that the claims used by food business operators are accurate, based on appropriate scientific evidence and are not misleading to consumers, and restricting the use of claims for products that are deemed too harmful to human health. The latter function is dealt with in the next section.

Under the Regulation, a claim is 'any message or representation, which is not mandatory under [EU] or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics'.[2041] What matters is not the form of a claim but the impact that it has on consumer perception.[2042] A simple picture of a heart on the packaging of food or a trademark could for instance fall within the definition of a claim, although it does not explicitly refer to any benefit.[2043] Non-beneficial claims do not fall within the scope of the Regulation.[2044] Indeed, food business operators have

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[2035] Claims Regulation, recital 10.
[2036] Directive 2000/13, art 2(1)(a).
[2037] Council Directive 90/496, art 3.
[2038] European Commission, Claims Regulation Proposal (n 1462).
[2039] Wieke Huizing Edinger, 'Promoting Educated Consumer Choices. Has EU Food Information Legislation Finally Matured?' (2016) 39 Journal of Consumer Policy 9, 17.
[2040] Patrick Coppens, 'Regulation (EU) No. 432/2012 Establishing a List of Permitted Health Claims' (2012) 2012 European Food and Feed Law Review 162, 162.
[2041] Claims Regulation, art 2(2)(1).
[2042] Ellen Van Nieuwenhuyze, 'Regulating nutrition and health claims: EU food law's poisoned chalice?' (2015) Thèse présentée en vue de l'obtention du grade de docteur en sciences juridiques, 44, <https://dial.uclouvain.be/pr/boreal/object/boreal:167583> accessed 11/05/2023.
[2043] ibid.
[2044] This follows, for nutrition claims, directly from Recital 6 of the Regulation: 'non-beneficial nutrition claims are not covered by the scope of this Regulation' and, for health claims, from the very definition of what constitutes a health claim.

little interest in making non-beneficial statements on their products, which therefore need not be regulated.

The Regulation covers two kind of claims: nutrition claims and health claims.[2045] A nutrition claim is defined as 'any claim which states, suggests or implies that a food has particular beneficial nutritional properties', due to its content of energy, nutrients or other substances, or to its lack thereof.[2046] Typical examples include 'low sugars' or 'sugars-free', for a nutrient whose intake must be limited, or 'source of fibre' or 'high fibre', for a nutrient whose intake is recommended.[2047] Health claims form a broader category, and are defined as 'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health'.[2048]

The Court clarified in *Deutsches Weintor* that the concept of 'health claim' does not only cover messages implying an improvement in health but also those implying 'the absence or reduction of effects that are adverse or harmful to health and which would otherwise accompany or follow such consumption, and, therefore, the mere preservation of a good state of health despite that potentially harmful consumption'.[2049] The Court further added that it was not necessary for a message to imply a sustained improvement in physical condition to be considered a health claim. An alleged temporary effect, limited in particular to the time taken by the intake and digestion of the food, is enough.[2050] At stake in this case was the use of the message 'easily digestible' for a wine, accompanied by a reference to the low level of acidity of the beverage, which the company marketing the wine did not consider a health claim, a line ultimately rejected by the Court.

The Regulation applies to nutrition and health claims made in commercial communications on foods 'to be delivered as such to the final consumer', whether in the labelling, presentation or

[2045] For a critical discussion of the difference made between those two categories of claims in the Claims Regulation, see Ellen Van Nieuwenhuyze, 'Regulating nutrition and health claims : EU food law's poisoned chalice ?' (2015 UCLouvain) 269-271.
[2046] Claims Regulation, art 2(2)(4).
[2047] See ibid, annex.
[2048] ibid, art 2(2)(5). Distinguishing between a health and a nutrition claim is not always easy, as both refer, directly or indirectly, to health benefits. According to Gokani, 'when determining which type of claim a message is classified as, the decisive factor is that a nutrition claim must only refer to levels of substances/nutrients; whereas a health claim refers to health with or without levels of nutrient/substances': Nikhil Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (2022) 47 European Law Review 153, 163.
[2049] Case C-544/10 *Deutsches Weintor* [2012] EU:C:2012:526, para 35.
[2050] ibid, para 36.

advertising.[2051] Labelling is defined in a similar way as in the Food Information Regulation.[2052] The Court clarified in *Verband Sozialer Wettbewerb* that the Claims Regulation not only applied to commercial communications addressed to consumers but also to those addressed exclusively to health professionals.[2053] While recognising that health professionals may have scientific knowledge superior to that of an average consumer, the Court still considered that these professionals could not 'be regarded as being in a position to permanently have all specialised and up-to-date scientific knowledge necessary to evaluate each food and the nutrition or health claims used'.[2054] As professionals may be misled by claims, it is important that this incorrect information is not passed on to patients, considering especially that the latter would be inclined to believe that information.[2055]

The Claims Regulation sets a number of general principles applicable to all claims and lays down specific requirements applicable to nutrition and health claims. Claims must not (i) be false, ambiguous or misleading, (ii) 'give rise to doubt about the safety and/or the nutritional adequacy of other foods', (iii) 'encourage or condone excess consumption of a food', (iv) 'state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general' and, finally, (v) 'refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations'.[2056]

Nutrition and health claims shall in general be based on and substantiated by generally accepted scientific evidence, which must be adduced by the food business operators using them.[2057] They must fulfil a number of general conditions as to their truthfulness.[2058] The presence, absence or reduced content of the substance or nutrient on which the claim is based must have been shown 'to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence'.[2059] The alleged effect should arise from a quantity of the food that can reasonably be expected to be consumed[2060] and must be expressed so as to be understood by the average consumer.[2061] When a health or nutrition claim is based on a nutrient or substance

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[2051] Food Information Regulation, art 1(2). See also recital 4: 'This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.'
[2052] ibid, art 2(1)(d).
[2053] Case C-19/15 *Verband Sozialer Wettbewerb* [2016] EU:C:2016:563.
[2054] ibid, para 43.
[2055] ibid, paras 44-45.
[2056] Claims Regulation, art 3.
[2057] ibid, art 6(1).
[2058] ibid, art 5.
[2059] ibid, art 5(1)(a).
[2060] ibid, art 5(1)(d).
[2061] ibid, art 5(2). Generally, the Claims Regulation 'takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and

whose inclusion on the mandatory nutrition declaration provided for in the Food Information Regulation is optional, or simply not foreseen, the amount of that nutrient or substance must be declared in accordance with that Regulation.[2062] Hence, a product labelled as 'high in fibre' must also indicate its fibre content, although the mention of that nutrient is not mandatory under the Food Information Regulation.[2063]

Authorised nutrition claims are contained in a list annexed to the Regulation, which may be amended by way of an implementing act.[2064] This list lays down the conditions governing the use of each claim. The message 'energy-reduced' may for instance only be used 'where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value'.[2065] The use of claims based on percentages is not authorised, on grounds of their misleading effect on consumers.[2066] Referring to a product as '90% fat-free' may for instance give the impression that this product contains little fat, even though a 10% fat content can be very high for certain categories of products. In its legislative proposal, the Commission relied on a study showing that half of the consumers surveyed judged a '90% fat-free' product as containing the least fat if compared to products bearing a 'low fat' or 'reduced fat' claim, where it was in fact the opposite.[2067] At play here is a behavioural phenomenon known as 'framing', which the prohibition of percentage-based claims seeks to neutralise.[2068] Framing refers to a situation where people are influenced by the way information is presented and judge differently equivalent statements depending on the point of reference chosen.[2069] In our example, people would believe that a product '90% fat-free' is healthier than one containing '10% fat', where these two statements are obviously equivalent.

To be lawfully used, health claims must comply with a number of specific requirements.[2070] In particular, health claims must clearly specify the benefits brought by the nutrient or food. References attributing general and non-specific health benefits to a product are prohibited, unless accompanied by a specific health claim as authorised by the Regulation.[2071] This

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linguistic factors': recital 15. Nonetheless, '[w]here a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group': ibid.

[2062] ibid, art 7.

[2063] Food Information Regulation, art 30(2)(e).

[2064] Claims Regulation, art 8 and annex. An exception applies for trademarks brand names or fancy names, see art 1(3). For additional requirements applicable to comparative claims, see art 9.

[2065] ibid, annex.

[2066] European Commission, Claims Regulation Proposal (n 1462), Explanatory Memorandum, para 18.

[2067] ibid.

[2068] See Baggio and others (n 453) 4.

[2069] Zamir and Teichman, *Behavioral Law and Economics* (n 110) 46-48.

[2070] Claims Regulation, art 10. In particular, '[h]ealth claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising: (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle; (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; (c) where appropriate, a statement addressed to persons who should avoid using the food; and (d) an appropriate warning for products that are likely to present a health risk if consumed to excess': ibid, art 10(2).

[2071] ibid, art 10(3).

prohibition aims at preventing consumers from being misled by a potential halo effect.[2072] The meaning of 'accompanied' was discussed by the Court in the *Willmar Schwabe* case. The Court held that this requirement implied, in principle, the 'spatial proximity or immediate vicinity' between the general reference and the specific claim.[2073] It added that 'accompanying' could however be exceptionally satisfied, in a situation where the reference and the specific claims do not appear on the same side of the packaging, 'by means of an explicit reference, such as an asterisk, where that ensures, in a manner that is clear and perfectly comprehensible to the consumer, that, in spatial terms, the content of the health claims and the reference match'.[2074]

The use of claims making reference to the rate or amount of weight loss is not allowed.[2075] This prohibition was originally contained in Commission Directive 96/8 on foods intended for use in energy-restricted diets for weight reduction,[2076] which the Claims Regulation extended to all foods.[2077] This extension was rendered necessary by the growing use of that kind of claims for foods not especially designed for weight control.[2078] The rationale for this prohibition should probably be found in the impossibility to reliably promise a certain weight loss with the use of a product, considering that many other factors are involved.

The Regulation differentiates between two kinds of health claims, governed by specific sets of conditions. The first category contains claims referring to a reduction of disease risk[2079] or to children's development. The second category contains so-called 'function claims', which refer to (i) 'the role of a nutrient or other substance in growth, development and the functions of the body', (ii) 'psychological and behavioural functions' or (iii) 'slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet'.[2080] Examples of these function claims are, for each respective sub-category: 'calcium contributes to normal muscle function', 'magnesium contributes to normal psychological function' and 'substituting two of the main daily meals of an energy restricted diet with meal replacements contributes to weight loss'.[2081]

[2072] See point 3 of the Annex to Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council [2013] OJ L22/25.
[2073] Case C-524/18 *Willmar Schwabe* [2020] EU:C:2020:60, para 47.
[2074] ibid, para 48.
[2075] Claims Regulation, art 12(b)
[2076] Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction [1996] OJ L55/22, art 5(3). See also Commission Delegated Regulation 2017/1798, art 4(3).
[2077] Claims Regulation, recital 25.
[2078] European Commission, Claims Regulation Proposal (n 1462) explanatory memorandum, para 21.
[2079] Article 2 (1)(b) of Directive 2000/13 prohibited labelling attributing 'to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties', which was interpreted by the Court in Case C-221/00 *Commission v Austria* [2003] EU:C:2003:44 as banning all health claims relating to human diseases. The Claims Regulation takes a softer approach. Prevention, treatment or curing may not be claimed but only a more general 'reduction of disease risk' may be.
[2080] Claims Regulation, art 13(1).
[2081] See the Annex of Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health [2012] OJ L136/1.

Claims referring to a reduction of disease risk or to children's development must undergo an authorisation procedure.[2082] They are first reviewed by EFSA, to ensure proper scientific substantiation and compliance with the Regulation, before being authorised by the Commission.[2083] Function claims escape this authorisation procedure if they are based on generally accepted scientific evidence, are well understood by the average consumer and feature on a pre-approved list adopted by the Commission on the basis of submissions made by Member States before 31 January 2008.[2084] The reason is that these claims are less controversial and were based, at the time of the adoption of the Regulation, on long-standing evidence.[2085] The list was finally adopted in 2012, after some difficulties,[2086] and contains, to this date, 235 health claims.[2087] This information may be retrieved from a register which keeps a record of all authorised nutrition and health claims and the conditions applying to them, and of all rejected health claims and the reasons for their rejection.[2088]

3.2.1.3. Restrictions on the use of food claims

Apart from these general conditions dealing with the truthfulness and the clarity of claims, the Claims Regulation also sets requirements as to the composition of products carrying claims, contained in Article 4. The idea is that unhealthy products should not benefit from claims, however accurate, so as to limit their attractiveness.[2089] This applies to two categories of products: alcoholic beverages and products that contain certain nutrients in excess.

The situation is simple as regards alcoholic beverages. Article 4(3) prohibits the use of health or nutrition claim for beverages containing more than 1,2 % vol of alcohol, to the exception of nutrition claims that refer to low alcohol levels, to the reduction of the alcohol content or the reduction of the energy content.[2090] As the Court said in *Deutsches Weintor*, claims made on alcoholic beverages are 'likely to encourage [the consumption of these products] and, ultimately, to increase the risks for consumers' health inherent in the immoderate consumption of any alcoholic beverage'.[2091]

[2082] Claims Regulation, art 14.
[2083] ibid, arts 15-17.
[2084] ibid, art 13. Supplementary claims may be added to this list in light of newly developed scientific evidence after complying with a specific authorisation procedure: ibid, see also art 18.
[2085] Coppens (n 2040) 163.
[2086] Commission Regulation (EU) No 432/2012. See Coppens (n 2040) 162-163.
[2087] The list available of these claims is available at <https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search> accessed 11/05/2023.
[2088] Claims Regulation, art 20. For the register, see ibid. Few authorisations have been granted for health claims until now. According to Todt and Lujan, this is due to the strictness of the evaluation process conducted by EFSA, which focuses primarily on ensuring that EU consumers are protected from false claims. See Oliver Todt and José Luis Luján, 'Constructing Consumers: Regulatory and Methodological Consequences of Defining Consumer Preferences in European Health Claim Regulation' (2021) 24 Journal of Risk Research 1532.
[2089] For a detailed description of the behavioural phenomena that can lead to these wrong inferences, see Ellen Van Nieuwenhuyze (n 2045) 285-289.
[2090] In the absence of Union legislation, relevant national rules apply to these three kinds of permitted alcohol claims, see Claims Regulation, art 4(4).
[2091] *Deutsches Weintor* (n 2049) para 52.

This situation is more complex as regards foodstuffs containing certain nutrient in excess. To prevent a situation 'where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet',[2092] Article 4(1) of the Regulation provides for the establishment of nutrient profiles for foods or categories of foods, with which products need to comply in order to use claims.[2093] In addition to preventing consumers from being misled about the nutritional quality of foods, it was also hoped that the establishment of nutrient profiles would provide an incentive for food business operators to reformulate their products so as to keep using claims.[2094] Nutrient profiles would hence not only result in better food choices but also in a healthier food supply.

Nutrient profiling can be defined as 'the classification of foods for specific purposes based on their nutrient composition'.[2095] In the context of the Claims Regulation, nutrient profiles are thresholds of nutrients above which nutrition and health claims are prohibited. To take a concrete example, a nutrient profile set at 5 grams of fat per 100 grammes for a certain category of foods would mean that all products in this category that contain fat above that threshold would be prevented from using any claim. Nutrient profiles have multiple purposes. They are used in relation to food claims as well as in the context of front-of-pack nutrition labelling (see Section 3.4.2). They may also be used in order to restrict the advertising of unhealthy foodstuffs. The nutrient profiles adopted under the Claims Regulation must take into account: (i) 'the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium', (ii) 'the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children' and (iii) 'the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health'.[2096]

There are two exceptions to the general rule that products not complying with nutrient profiles should not be allowed to use claims. First, claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium may be used without reference to a profile for the specific nutrient for which the claim is made.[2097] Second, foods that contain a single nutrient in excess of the nutrient profiles chosen are allowed to use nutrition claims, in which

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[2092] Claims Regulation, recital 11. See also Pierre Chandon, 'How Package Design and Packaged-Based Marketing Claims Lead to Overeating' (2013) 35 Applied Economic Perspectives and Policy 7; Asha Kaur and others (n 2034); Talati and others, 'Consumers' Responses to Health Claims in the Context of Other on-Pack Nutrition Information: A Systematic Review' (n 2033).
[2093] Claims Regulation, art 4(1).
[2094] European Commission, 'Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods' (Staff Working Document) SWD (2020) 95 final, 6.
[2095] Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies, 'The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to article 4 of the Regulation (EC) no 1924/2006' (2008) 644 EFSA Journal 1,1.
[2096] Claims Regulation, art 4(1). See also recital 11.
[2097] ibid, art 4(2)(a).

case a statement reading 'high (name of the nutrient in excess) content' must appear in close proximity and with the same prominence as the claim.[2098] This second exception, absent from the original proposal from the Commission, was introduced by the European Parliament during the legislative procedure.[2099]

The 19 January 2009 was set as a deadline for the adoption of the nutrient profiles by the Commission.[2100] More than ten years later, no profiles have been adopted. In January 2008, the European Food Safety Authority (EFSA)[2101] adopted its opinion on the matter, stressing that 'when classifying food products as eligible to bear claims, the potential of the food to adversely affect the overall dietary balance is the main scientific consideration', in particular for nutrients involving health risks for which there is evidence of a dietary imbalance in the European population.[2102] It acknowledged that setting nutrient profiles at the EU level was a difficult endeavour, due to the lack of uniform data for food composition and consumption across the EU and the differences in nutrient intake recommendations and food based dietary guidelines existing between Member States.[2103]

In 2009, the Commission presented a proposal defining thresholds of nutrients for certain categories of foods above which the use of nutrition and health claims would be prohibited.[2104] These profiles would never be adopted, due to the simultaneous opposition of certain Member States and food business operators, which sought to establish exemptions or apply more lenient conditions to certain categories of foods.[2105] They worried in particular that applying the nutrient profiles proposed by the Commission would lead to a segregation of the market between 'traditional products, for which reformulation would be challenging, if not impossible, due to their legal composition specifications […] and [which] therefore would be perceived as nonhealthy foods' and 'processed foods which could be more easily reformulated and […] would be perceived as healthy foods'.[2106]

In view of this stalemate, the European Parliament called on the Commission in 2016 to reflect on the possibility to eliminate nutrient profiles from the Claims Regulation, under the argument

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[2098] ibid, art 4(2)(b).
[2099] MacMaoláin, *EU Food Law: Protecting Consumers and Health in a Common Market* (n 32) 229.
[2100] Claims Regulation, art 4(1).
[2101] The European Food Safety Authority was established by the General Food Law Regulation, see art 22(1). Its task is to 'provide scientific advice and scientific and technical support for the [EU]'s legislation and policies in all fields which have a direct or indirect impact on food and feed safety': GFL Regulation, art 22(2). Alongside its core food safety activity, EFSA also has responsibilities in the field of nutrition, see art 22(5)(a).
[2102] Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies, 'The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to article 4 of the Regulation (EC) no 1924/2006' (n 2394) 1-2.
[2103] ibid, 4. See also Friant-Perrot and Garde (n 95) 142.
[2104] European Commission, 'Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods' (n 2094) 17. For the proposed thresholds, see ibid, appendix 2.
[2105] ibid 17.
[2106] ibid. See also Pierre Médevielle, 'Allégations nutritionnelles et de santé : pour une application effective de la réglementation' (2021) Rapport d'information fait au nom de la commission des affaires européennes 346, 35, <https://www.senat.fr/notice-rapport/2020/r20-346-notice.html> accessed 11/05/2023.

that the labelling obligations contained in the Food Information Regulation, adopted afterwards, would be sufficient for consumers to assess the nutritional quality of products and to not be misled by claims made on unhealthy foods.[2107] However, in its 2020 evaluation report on the Claims Regulation, the Commission concluded that the adoption of nutrient profiles was still necessary to fulfil the objectives of the Regulation and ensure coherence with the broader EU policy objectives on nutrition.[2108] As part of its Farm to Fork Strategy, the Commission also announced that it would 'seek opportunities to facilitate the shift to healthier diets and stimulate product reformulation, including by setting up nutrient profiles to restrict the promotion (via nutrition or health claims) of foods high in fat, sugars and salt'.[2109] A proposal in this regard is expected for the end of 2022.[2110]

Renouncing to the adoption of nutrient profiles restricting the use of claims for unhealthy foodstuffs would be a step back for consumer protection and public health. In a 2017 study of five European countries' food markets, the Commission found that well over 30% of the foods and drinks surveyed that bore claims did not comply with the nutrient profiles it had proposed in 2009, with significant disparities across categories.[2111]A 2016 study conducted in five EU Member States, concluded that, although foods bearing claims tended to be marginally healthier than those that did not, 30% of the foods surveyed bearing health claims and 39% of those bearing nutrition claims did not comply with the nutrient profiling system chosen in the study.[2112] The problem is not small in scale since around a quarter of foods in these five Member States were reported to bear claims.[2113]

Nutrient profiles are a scientifically complex and politically sensitive issue,[2114] without doubt the most controversial aspect of the Regulation. The use of nutrient profiles is often opposed on the ground that its dichotomous effect, sorting foods into two 'healthy' and 'unhealthy'

[2107] European Parliament, Resolution of 12 April 2016 on Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook [2018] OJ C58/39, 47.

[2108] European Commission, 'Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods' (n 2094) 83-85. It is only one of the challenges faced by the Claims Regulation identified in the report. For further developments on this see Alie de Boer, 'Fifteen Years of Regulating Nutrition and Health Claims in Europe: The Past, the Present and the Future' (2021) 13 Nutrients 1725.

[2109] European Commission, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' (n 1477)12

[2110] ibid, annex. See also European Commission, 'Europe's Beating Cancer Plan' (n 23) 10.

[2111] European Commission, 'Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods' (n 2094) 36-38.

[2112] Kaur and others, (n 2034). A specific assessment of the Slovenian market showed that a considerable proportion of foods labelled with any type of health-related claims were found to have poor nutritional quality, see Urška Pivk Kupirovič and others, 'Nutrient Profiling Is Needed to Improve the Nutritional Quality of the Foods Labelled with Health-Related Claims' (2019) 11 Nutrients 287.

[2113] Asha Kaur and others, 'The Nutritional Quality of Foods Carrying Health-Related Claims in Germany, The Netherlands, Spain, Slovenia and the United Kingdom' (n 2034); Sophie Hieke and others, 'Prevalence of Nutrition and Health-Related Claims on Pre-Packaged Foods: A Five-Country Study in Europe' (2016) 8 Nutrients 137.

[2114] See Friant-Perrot and Garde (n 95) 141–143, 150-153.

categories, is a simplification that does not reflect the contribution that all foods can make to a balanced diet. For a long time, nutrition science and policy focused on the overall equilibrium of the diet, through the use of dietary guidelines referring to broad categories of products,[2115] rather than recommending the consumption or avoidance of specific foods. These guidelines are however not always easy to use for consumers and are of limited interest when it comes to choosing between products from a similar category.[2116] Dietary guidelines and nutrient profiles should therefore be construed as complementary rather than alternative tools. The adoption of the nutrient profiles provided for in the Claims Regulation, with at least fifteen years of delay, would signal that health and nutrition are taken seriously in the European Union and prevail over economic or national interests (for further discussion, see Chapter 7, Section 3.1).[2117]

3.2.2. Prohibition of misleading tobacco information

Following a logic similar to the prohibition of claims, the Tobacco Products Directive prohibits the use of a number of elements on the packaging and labelling of tobacco products, which, while factually true, may mislead consumers or reinforce the attractiveness of these products.[2118] Under Article 13 TPD:

> 1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:
>
> (a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;
>
> (b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;
>
> (c) refers to taste, smell, any flavourings or other additives or the absence thereof;
>
> (d) resembles a food or a cosmetic product;
>
> (e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.
>
> 2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.[2119]

[2115] T Lobstein and S Davies, 'Defining and Labelling "Healthy" and "Unhealthy" Food' (2009) 12 Public Health Nutrition 331; Chantal Julia and others, 'Are Foods "Healthy" or "Healthier"? Front-of-Pack Labelling and the Concept of Healthiness Applied to Foods' (2022) 127 The British Journal of Nutrition 948.

[2116] ibid.

[2117] Although some consider that the exceptions provided for in the Regulation already go too far in favour of food business operators and threaten its very rationale, see MacMaoláin, 'Regulating consumer information: use of food labelling and mandatory disclosures to encourage healthier lifestyles' (n 1950) 63.

[2118] See Tobacco Products Directive, recitals 24, 25, 27; *Philip Morris* (n 28), paras 138-145. See also David Hammond and Carla Parkinson, 'The Impact of Cigarette Package Design on Perceptions of Risk' (2009) 31 Journal of Public Health 345.

[2119] Article 13 is partially applicable to e-cigarettes and herbal products for smoking: TPD, arts 20(4)(b)(ii) and 21(4).

Concretely, tobacco products are prevented under Article 13 from using words such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim'.[2120] The prohibition of any reference to the TNCO content of products was introduced by the TPD after it was found that this information was used by manufacturers to present some of their products as light and less dangerous.[2121] Article 13 TPD can be seen as complementary to the TPD provisions on health warnings, ensuring that information on tobacco products only highlights the harmful effects of tobacco on health, to the exclusion of any promotional feature.

3.3. Rules on specific foods

Three food-specific legislative instruments, already mentioned in Chapter 5 Section 3.3.2, contain provisions that combine elements related to mandatory and voluntary information, as well as advertising: Directive 2002/46 on food supplements, Regulation 1925/2006 on fortified foods and Regulation 609/2013 on food for specific groups.

Regarding food for specific groups, their labelling, presentation and advertising must provide information for their appropriate use and must not be misleading or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties.[2122] Formulae and follow-on formulae, in particular, are highly regulated.[2123] The objective is to encourage breastfeeding and limit the use of these substitute products.[2124] The labelling, presentation and advertising of these products shall not 'include pictures of infants, or other pictures or text which may idealise the use of such formulae'.[2125] It must also, as regards formula, include a statement 'concerning the superiority of breast feeding and a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care'.[2126] The labelling of follow-on formula must include a statement 'that the product is suitable only for infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six

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[2120] TPD, Recital 27. As regards Article 13 in general, the Court declared the following in *Philip Morris* (n 28), para 160: 'It cannot be accepted that those elements and features may be included for the purpose of giving consumers clear and precise information, inasmuch as they are intended more to exploit the vulnerability of consumers of tobacco products who, because of their nicotine dependence, are particularly receptive to any element suggesting there may be some kind of benefit linked to tobacco consumption, in order to vindicate or reduce the risks associated with their habits.'

[2121] Nigel Gray and Peter Boyle, 'Publishing Tobacco Tar Measurements on Packets' (2004) 329 BMJ: British Medical Journal 813. The press release published upon expiration of the deadline for transposition of the Tobacco Products Directive stressed that 'research has shown that TNCO labelling is misleading to consumers as it makes them believe that some products are less risky to their health. The new information message will more accurately reflect the true health consequences of smoking': European Commission, '10 key changes for tobacco products sold in the EU' (n 1431). See also Tobacco Products Directive, recital 25.

[2122] Regulation 609/2013, art 9(5).

[2123] Commission Delegated Regulation (EU) 2016/127. For further restrictions on the promotion and advertising of infant formula, see art 10 specifically.

[2124] See Regulation 609/201, art 10(1); Delegated Regulation 2016/127, art 6(6).

[2125] Regulation 609/2013, art 10(2). This only concerns the labelling of follow-on formula.

[2126] Delegated Regulation 2016/127, art 6(2)(c).

months of life' and must inform that it should only be used on the advice of duly qualified professionals.[2127] Further, formulae are subjected to a specific nutrition declaration[2128] and the use of claims on infant formula is prohibited.[2129]

Member States must also take measures 'ensuring that objective and consistent information is provided on infant and young child feeding'.[2130] 'Informational and educational materials […] dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children' must cover, inter alia, 'the benefits and superiority of breast feeding', 'the possible negative effect on breast feeding of introducing partial bottle feeding' and 'the difficulty of reversing the decision not to breast feed'.[2131]

This strong support in favour of breastfeeding, which also appears from EU rules on health and safety at work,[2132] can be explained by its benefits for the development of infants.[2133] These benefits include 'healthy growth and expected cognitive development as well as possibly reduced risk of becoming overweight or obese and developing non-communicable diseases later in life'.[2134] Global and regional guidelines recommend that infants should exclusively be breastfed for the first 6 months of life and that breastfeeding continues until at least the age of 2.[2135] Breastfeeding is also beneficial to women, as it associated with a protective effect on various cancers and a more rapid return to pre-pregnancy weight.[2136] Breastfeeding in Europe remains however below the WHO recommendations.[2137]

Regulation 609/2013 also contains specific information requirements for total diet replacements for weight control. These must include a specific nutrition declaration and are prohibited to use claims.[2138] As for all foods, '[t]he labelling, presentation and advertising of total diet replacement for weight control products shall not make any reference to the rate or amount of weight reduction which may result from its use'.[2139]

[2127] ibid, art 6(3)(a).
[2128] ibid, art 7.
[2129] ibid, art 8.
[2130] ibid, art 11(1).
[2131] ibid.
[2132] See Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding [1992] OJ L348/1.
[2133] European Commission, Green Paper 'Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases' (n 1464) 18, see also Delegated Regulation 2016/127, recital 22.
[2134] Willett and others (n 140) 459.
[2135] ibid.
[2136] Joachim Schüz and others, 'European Code against Cancer 4th Edition: 12 Ways to Reduce Your Cancer Risk' (n 1397) 5.
[2137] Ayse Tulay Bagci Bosi and others, 'Breastfeeding Practices and Policies in WHO European Region Member States' (2016) 19 Public Health Nutrition 753.
[2138] Commission Delegated Regulation 2017/1798, arts 5 and 7. This does not apply to the claim 'added fibre'.
[2139] ibid, art 4(3).

Regarding fortified foods and food supplements, finally, a number of provisions ensure that consumers are not misled as to the quality of these foods and the necessity to keep a balanced diet. The labelling of food supplements must include a statement indicating that these products 'should not be used as a substitute for a varied diet',[2140] and their labelling, presentation and advertising 'shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general'.[2141] Further, the labelling, presentation and advertising of fortified foods shall not 'include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients' and 'shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients'.[2142]

3.4. The future of EU information regulation

To remedy some of the gaps and weaknesses identified in the EU's information regulatory apparatus, the Commission will put forward, as part of the Beating Cancer Plan, a number of proposals to enhance and improve packaging and labelling obligations for tobacco products, foods and alcoholic beverages. These concern the introduction of plain tobacco packaging, front-of-pack nutrition labelling and alcohol health warnings, as well as an extension of the general rules on nutrition and ingredients labelling to alcohol beverages.[2143]

These reforms are largely behaviourally informed and seek to communicate information on health risks in a better, more understandable and effective way rather than adding an extra layer of information. If adopted, these would fundamentally alter the difference in the approach taken as regards tobacco and foods. For tobacco products, it is more than ever about stressing the health risks incurred and depriving the packaging of any element that could be favourably interpreted by consumers. For food, it is mostly about simplifying the information given. As regards alcohol, finally, the upcoming changes will at the same time, and for good reasons, integrate alcoholic beverages further into the food legal framework, while bringing elements borrowed to the tobacco legal framework with the use of health warnings.

3.4.1. Plain tobacco packaging

Recommended by the Guidelines on Article 11 of the FCTC,[2144] plain packaging, or standardised packaging, is the most stringent form of regulation affecting the labelling and packaging of tobacco products. It consists in removing from unit packets all visual elements,

[2140] Directive 2002/46, art 6(3)(d).
[2141] ibid, art 7.
[2142] Regulation 1925/2006, art 7.
[2143] European Commission, 'Europe's Beating Cancer Plan' (n 23) 9-10.
[2144] WHO, 'Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (n 1996)', para 46.

such as branding, colours, or logos, which contribute to the attractiveness of tobacco products and are used to influence consumers' brand choices, perceptions of harm and experience of the taste and strength of tobacco.[2145] The packaging area that is not covered by health warnings and other mandated elements must be in plain, standardised colour, usually brown or grey. The brand name is displayed in a discrete font and size (see Figure 4). A number of countries, in Europe mostly,[2146] have now experimented with plain packaging, evidence showing that it is effective to increase intentions to quit and increase negative attitudes towards smoking, as well as reducing brand awareness and the appeal of tobacco products.[2147]

Figure 4: Plain tobacco packaging[2148]

Plain packaging is currently not mandated under EU law but Article 24(2) TPD, which allows Member State 'to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the *standardisation of the packaging* of tobacco products',[2149] was inserted in the Directive so as permit the adoption of plain packaging at the national level.[2150] The introduction of an EU plain packaging requirement was contemplated upon revision of the 2001 TPD, but was finally not included in the proposal for the current TPD,[2151] due, in part, to

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[2145] Hammond and Parkinson (n 2118); Lauren K Lempert and Stanton Glantz, 'Packaging Colour Research by Tobacco Companies: The Pack as a Product Characteristic' (2017) 26 Tobacco control 307.
[2146] Australia was the first country to adopt plain tobacco packaging in 2012.
[2147] Constantine Vardavas and others, 'Plain Packaging of Tobacco Products in the European Union: An EU Success Story?' (2017) 50 European Respiratory Journal 1; Nick Lilic, Matthew Stretton and Minesh Prakash, 'How Effective Is the Plain Packaging of Tobacco Policy on Rates of Intention to Quit Smoking and Changing Attitudes to Smoking?' (2018) 88 ANZ Journal of Surgery 825.
[2148] UK standardised packaging of tobacco products, see <https://smokefreeaction.org.uk/smokefree/standardpacksindex-html/> accessed 11/05/2023.
[2149] Emphasis added.
[2150] European Commission, TPD Proposal (n 1430) 6. For some early legal reflections on the legality under EU law of EU and national measures on plain packaging, see Alemanno, 'Out of Sight, Out of Mind. Towards a New EU Tobacco Products Directive' (n 33).
[2151] European Commission, 'Possible revision of the Tobacco Products Directive 2001/37/EC' (2010) Public consultation document, 7, <https://ec.europa.eu/health/document/download/617e72aa-7318-48be-adc0-dc5db27bca2b_en?filename=consultation_report_en.pdf> accessed 11/05/2023.

the reduced possibilities for brand differentiation and the negative impact on the tobacco industry that would have resulted from its adoption.[2152] Moreover, as plain packaging was still a new measure when the TPD was passed in 2014, with limited evidence available regarding its effectiveness, granting Member States the possibility to adopt this measure allowed to build an evidence base that would inform a potential future adoption by the EU.[2153] The TPD impact assessment observed in this regard that it was 'appropriate to wait for real life experience'.[2154]

To date, seven EU countries have introduced plain packaging.[2155] Evidence from France, Ireland and the United Kingdom, which have had plain packaging in place for a number of years, show that it has brought a range of benefits: a reduction in the perceived attractiveness of tobacco, an increase in the perception of the harmfulness of smoking and a decrease in smoking prevalence.[2156]

3.4.2. Front-of-pack nutrition labelling

To remedy the insufficiencies of traditional, textual and numerical, back-of-pack (BoP) nutrition information, governments and food business operators have developed alternative front-of-pack (FoP) labels. With the help of various graphical forms or symbols, these convey information in a more salient and simplified way.

The legal framework applicable to FoP labelling in the EU suffers from major defects. Although it is supposed to allow food business operators to voluntarily employ FoP labels, it restricts their use in practice. The adoption of a common and mandatory FoP nutrition label by the EU would be a welcome development, bringing order to a fragmented legal field and providing for a higher level of consumer and health protection.

3.4.2.1. What is front-of-pack nutrition labelling?

[2152] European Commission, 'Impact assessment accompanying the document: Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member states concerning the manufacture, presentation and sale of tobacco and Related products' (n 1642), part 1, 95.
[2153] See European Commission, TPD impact assessment (n 1642), part 1, 118. See also, regarding reporting: TPD, art 28(2)(a).
[2154] European Commission, TPD impact assessment (n 1642), part 1, 118.
[2155] In the order of applicability of the measure: France, Ireland, Belgium Slovenia, the Netherlands, Denmark and Hungary. The UK has also adopted it. See European Commission, 'Support study to the report on the application of Directive 2014/40/EU' (n 192) 157-158.
[2156] ibid 159. Regarding France, see Fabienne El-Khoury, Camille Bolze and Maria Melchior, 'Perceptions of Plain Tobacco Packaging: DePICT, a French National Survey' (2017) 27 European Journal of Public Health 420; Fabienne El-Khoury Lesueur and others, 'Plain Tobacco Packaging, Increased Graphic Health Warnings and Adolescents' Perceptions and Initiation of Smoking: DePICT, a French Nationwide Study' (2019) 28 Tobacco Control 31; A Pasquereau and others, 'Smokers' Perception of Cigarette Packaging in France before and after the Plain Packaging' (2020) 30 European Journal of Public Health.

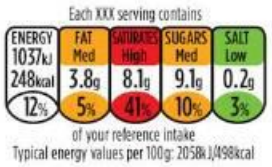
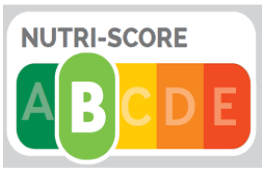
Front-of-pack nutrition labelling can be defined as the provision of nutrition information situated in the principal field of vision on food packaging.[2157] Under the Food Information Regulation, the 'principal field of vision' is 'the field of vision […] which is most likely to be seen at first glance by the consumer at the time of purchase and that enables the consumer to immediately identify a product in terms of its character or nature and, if applicable, its brand name'.[2158] Beyond this basic common feature, FoP labels vary widely in their design (shape, colour, use of symbols, etc.) and purpose.[2159] Various categories have been proposed in the literature.[2160] Table 3 below provides a summary of these categories and gives examples of some of the FoP labels currently in use in Europe and other regions.[2161]

FoP labels differ along three main dimensions. Some are nutrient-specific and provide detailed information on the amount of energy and nutrients present in a product, usually expressed per serving or 100 g/ml (Reference Intakes Label, MTL), while others provide a summary of the overall nutrition quality of products (Keyhole, Nutri-Score). Labels can also be reductive, conveying nutrition information in a simpler but 'neutral' way, or evaluative, in which case they assess the nutritional quality of products. Summary labels tend to be evaluative. The Multiple Traffic Lights and the Nutri-Score are both evaluative and based on a 'traffic light' colour code, but the MTL evaluates different aspects of the food composition separately, whereas the Nutri-Score gives a general grade to products. Finally, evaluative labels can be positive or negative. The Keyhole is a positive label, as it endorses the healthiest choices within a food category. Warning labels, on the other hand, signal to consumers when a product contains excessive quantities of certain nutrients (e.g. salt, sugar, saturated fat) or a high energy content.

All evaluative FoP labels use nutrient profiling in order to determine the healthiness of products. Different criteria can be used for this purpose,[2162] nutrient thresholds, such as those discussed in the context of the Claims Regulation, or algorithms that result in a summary score.[2163]

[2157] Stefan Storcksdieck Gennant Bonsmann and others 'Front-of-pack nutrition labelling schemes: a comprehensive review' (2020) Joint Research Centre, 18. See also Food Information Regulation, recital 41.
[2158] Food Information Regulation, art 2(2)(l).
[2159] Storcksdieck and others (n 2157) 20-28.
[2160] See ibid 29; European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration', COM (2020) 207 final 5.
[2161] For Chile, see Marcela Reyes and others, 'Development of the Chilean Front-of-Package Food Warning Label' (2019) 19 BMC Public Health 906; for Australia and New Zealand, see Becher and others (n 1958).
[2162] For an overview, see Storcksdieck and others (n 2157) 31-34.
[2163] ibid 31.

Table 3: Front-of-pack nutrition labels in use in Europe and other regions[2164]

Categories of FoP labels				Examples of FoP labels	Countries of use
Nutrient-specific labels	Reductive (non-interpretative)	Numerical	Reference Intakes Label		Across Europe
			NutrInform Battery		Italy
	Evaluative (interpretative)	Colour-coded	Multiple Traffic Lights (MTL)		UK
		Textual	Chilean Warning Labels		Chile
Summary labels	Evaluative (interpretative)	Endorsement logos	Keyhole		Sweden, Denmark, Lithuania
		Graded indicators	Health Star Ratings		Australia, New Zealand
			Nutri-Score		France, Belgium, Netherlands, Luxembourg, Germany, Spain, Switzerland

[2164] Adapted from European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' (n 2160) 5, with additional graphical elements taken from Becher and others (n 1958). The countries referred to are those where the use of the label has been recommended by health authorities or made mandatory.

Based on the existing evidence, there are reasons to believe that, in contrast to traditional BoP information of the kind provided for in the Food Information Regulation, simplified front-of-pack information could yield better results in terms of consumer understanding of the nutritional value of food and, ultimately, healthier consumer choices.[2165] Using the principal field of vision increases salience and several studies have concluded that FoP labels are noticed earlier and receive more attention than BoP nutrition information.[2166] In particular, since most consumers have difficulties interpreting complex information, recourse to visual forms such as symbols should be encouraged.[2167] In addition to providing nutrition information in an accessible manner, FoP labels can also function as nudges, guiding consumer choice towards the healthier option in a non-conscious way by relying on a number of cues. Vivid elements, such as colours, help retain consumers' attention but may also have an impact on feelings and emotions, which has been shown to have an influence on behaviour.[2168] As for tobacco health warnings, the provision of health-related information at the point of purchase may also have a 'goal priming' function.[2169]

Against this background, it is thus unsurprising that evaluative and colour-coded labels, the Nutri-Score especially, appear most effective when compared to other FoP labelling schemes.[2170] These labels facilitate the assessment of the nutritional quality of foods and comparison between products. They also seem to work best across different segments of the population, in terms of consumer understanding and product healthfulness assessment, and their strongest impact is observed amongst individuals with no nutritional knowledge.[2171] FoP

[2165] Sarah Campos, Juliana Doxey and David Hammond, 'Nutrition Labels on Pre-Packaged Foods: A Systematic Review' (2011) 14 Public Health Nutrition 1496; Storcksdieck and others (n 2157). See also Vincent Delhomme, 'Front-of-Pack Nutrition Labelling in the European Union: A Behavioural, Legal and Political Analysis' (2021) 12 European Journal of Risk Regulation 825. However, most studies being done online, evidence remains limited regarding the effect of FoP labels in 'real life' retail environments, where food choices are actually being made.

[2166] Storcksdieck and others (n 2157) 49.

[2167] ibid 67; Bauer and Reisch (n 321) 29.

[2168] Purnhagen, Van Herpen and Van Kleef (n 2032) 208; Amy L Wilson and others, 'Nudging Healthier Food and Beverage Choices through Salience and Priming. Evidence from a Systematic Review' (2016) 51 Food Quality and Preference 47, 59. The use of green in labels has for instance been proven to increase the perceived healthiness of products: see Jonathon P Schuldt, 'Does Green Mean Healthy? Nutrition Label Color Affects Perceptions of Healthfulness' (2013) 28 Health Communication 814. A study on the MTL found that consumers were more concerned with avoiding red lights than choosing green lights, see Peter Scarborough and others, 'Reds are more important than greens: how UK supermarket shoppers use the different information on a traffic light nutrition label in a choice experiment' (2015) 12 International Journal of Behavioral Nutrition and Physical Activity 151.

[2169] Esther K Papies, 'Health Goal Priming as a Situated Intervention Tool: How to Benefit from Nonconscious Motivational Routes to Health Behaviour' (2016) 10 Health Psychology Review 408; Bauer and Reisch (n 321) 19.

[2170] For an overview of the evidence base underpinning evaluative labels and the Nutri-Score in particular, see 'Front-of-Pack Nutrition Labelling in the European Union: A Behavioural, Legal and Political Analysis' (n 2165) 7-12. In a vast scientific literature, see the brief of the International Agency for Research on Cancer (IARC): IARC, 'The Nutri-Score: A Science-Based Front-of-Pack Nutrition Label. Helping consumers make healthier food choices' (2021) 2 IARC Evidence Summary Brief. See also Hannah U Nohlen, 'Front-of-pack nutrition labelling schemes: an update of the evidence' (2022) Joint Research Centre.

[2171] Delhomme, 'Front-of-Pack Nutrition Labelling in the European Union: A Behavioural, Legal and Political Analysis' (n 2165) 834.

labels may therefore contribute to the reduction in health inequalities and be a part of the broader effort for towards a 'just transition'.

That being said, FoP labels also present certain limitations and may lead to unforeseen and undesirable effects.[2172] Evaluative labels that 'grade' the nutrition quality of products positively could for instance, through a halo effect, provoke inaccurate inferences about other aspects of these products or competing products.[2173] Indeed, 'designating a given food as "healthy" or "unhealthy" might overlook important attributes apart from its nutritional composition. In fact, a number of food characteristics have recently been linked to health outcomes: degree of processing, organic production, presence of additives, or neo-formed contaminants.'[2174]

3.4.2.2. Front-of-pack labelling under EU law: a regulatory failure?

The superiority of FoP nutrition information over BoP nutrition information is not an entirely new finding. Before the Food Information Regulation was adopted in 2011, a consultative document from the European Commission was already exploring the possibility of introducing alternative forms of presentation for nutrition information, pointing at the evidence suggesting that 'simplified front of pack labelling ('signposting') may offer significant advantages in terms of increasing consumer use'.[2175] The legislative proposal for the Food Information Regulation actually provided for the mandatory display of the energy value and the amount of key nutrients on the front of food packaging.[2176] This was later dropped during the legislative process, due in part to the heavy opposition of the agri-food industry, supported by the European Parliament.[2177] Interestingly enough, the decision not to include TFAs on the mandatory nutrition declaration also proceeded from doubts as to the effectiveness of that information. [T]he co-legislator was not convinced that the introduction of trans fats amounts on food labels would consistently enable consumers to identify the healthier choice'.[2178] This, eventually, would lead the EU to directly regulate the TFAs content of foods (see Chapter 5, Section 3.3.2).

[2172] See Storcksdieck and others (n 2157) 148–51.

[2173] Iina Ikonen and others, 'Consumer Effects of Front-of-Package Nutrition Labeling: An Interdisciplinary Meta-Analysis' (2020) 48 Journal of the Academy of Marketing Science 360, 373. By analogy in the context of nutrition claims, see Purnhagen, Van Herpen and Van Kleef (n 2032); Erica van Herpen and Hans CM van Trijp, 'EU health claims: a consumer perspective' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU: A Legal-Economic Perspective* (Springer International Publishing 2018) 98–99.

[2174] Chantal Julia and others, 'Are Foods "Healthy" or "Healthier"? Front of Pack Labelling and the Concept of Healthiness Applied to Foods' (n 2115). See also Lobstein and Davies (n 2115).

[2175] European Commission, 'Labelling: competitiveness, consumer information and better regulation for the EU' (2006) 8, <https://ec.europa.eu/food/system/files/2016-10/labelling-nutrition_better-reg_competitiveness-consumer-info_en.pdf > accessed 11/05/2023.

[2176] European Commission, European Commission, Food Information Regulation Proposal (n 2176), art 34.

[2177] Kurzer and Cooper (n 1453) 64-65; MacMaoláin 'Regulating consumer information: use of food labelling and mandatory disclosures to encourage healthier lifestyles' (n 1950) 62; Iris Goldner Lang, 'Public Health in European Union Food Law' in Hervey, Alasdair Young and Bishop (n 37) 410.

[2178] European Commission, 'Impact assessment accompanying the document: Proposal for Commission Regulation (EU) amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in animal fat, in foods intended for the final consumer' (Trans Fat impact assessment) (Staff Working Document) SWD (2019) 162 final, part 1, 10.

The decision not to introduce mandatory FoP information in the Food Information Regulation also resulted from the uncertainty existing at that time regarding its use and its effectiveness. There was 'insufficient evidence across all the Union on how the average consumer understands and uses the alternative forms of expression or presentation of the information'.[2179] The impact assessment observed in this regard that:

> At the moment there are different schemes for the presentation of information on the front of pack which are either endorsed by Governments, industry associations or are company specific schemes. However, *there is a need for mor research* on use and preference of consumers across the EU as the use of schemes is not universal across all the Member States. The provision of a framework for the inclusion of information on the front of pack would ensure that where such information is given then certain nutritional elements are included. It would be necessary to *provide some flexibility to allow for the evidence on the most useful presentation or interpretive elements to develop* and for voluntary mechanism to optimise a common approach.[2180]

Unlike for plain tobacco packaging however, it was decided not to allow Member States to adopt binding requirements on FoP labels, which would have resulted in food business having to comply with different sets of rules, thus undermining the harmonising effect of the Regulation and the free movement of foodstuffs. In order to allow for experimentation to take place at the national level, an interesting system was put in place, whereby FoP labels may be used voluntarily by food business operators under the official recommendation of Member States' public health authorities.

'[I]n order to help consumers to easily see the essential nutrition information when purchasing foods',[2181] the Food Information Regulation allows the repetition in the principal field of vision of the most important elements of the mandatory declaration: the energy value alone or the energy value together with the amounts of fat, saturates, sugars, and salt.[2182] This supplementary and voluntary FoP nutrition information may be expressed using graphical forms or symbols, provided a number of requirements are met.[2183] Under Article 35(2) of the Food Information Regulation Member States may recommend the use of FoP labels to food business operators, in which case a notification must be made to the Commission.[2184] The Commission is invited to 'facilitate and organise the exchange of information between Member

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[2179] Food Information Regulation, recital 43.
[2180] European Commission, Food Information Regulation impact assessment (n 466) 63, emphasis added. See also European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' (n 2160).
[2181] ibid, recital 41.
[2182] ibid, arts 30(3) and 34(3) and recital 41.
[2183] ibid, art 35(1). The requirements are the following: (i) FoP labels ' are based on sound and scientifically valid consumer research and do not mislead the consumer as referred to in Article 7' of the Food Information Regulation; (ii) 'their development is the result of consultation with a wide range of stakeholder groups'; (iii) 'they aim to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet'; (iv) 'they are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer'; (v) 'in the case of other forms of expression, they are based either on the harmonised reference intakes set out in Annex XIII, or in their absence, on generally accepted scientific advice on intakes for energy or nutrients'; (vi) 'they are objective and non-discriminatory'; and (vii) 'their application does not create obstacles to the free movement of goods'.
[2184] ibid, art 35(2).

States, itself and stakeholders'[2185] as regards the use of FoP labels and to submit by December 2017 a report on the use of additional forms of expression and presentation and the advisability of further harmonisation of those forms.[2186] The delayed report was submitted in May 2020,[2187] paving the way for the adoption of a common and mandatory front-of-pack nutrition label at the EU level.[2188]

As illustrated in Table 3, food business operators and Member States have largely taken advantage of the possibility granted to them to voluntarily use or recommend the use of FoP labels. From the point of view of evidence gathering, the solution adopted in the Food Information Regulation has been a success. The use of various labels in different cultural contexts has allowed the Commission to publish a voluminous study on FoP labels and a report,[2189] both of which will largely inform the upcoming revision of EU nutrition labelling rules.

Despite this success, however, the 'hybrid' regulatory solution found in the Food Information Regulation is not without flaws, both from the point of view of free movement and that of health and consumer protection. As regards free movement, first of all, even voluntary schemes may give rise to obstacles. Having to adapt to different labels entails costs and uncertainty for operators, even if these remain optional. Indeed,

> The fact that a FoP scheme is recommended by a Member State could create expectations for consumers that food products marketed in that country, including those coming from other countries, should be labelled with the official scheme […] and could create a pressure on EU food business operators to label all products present on the national market with the official scheme promoted by the Member State.[2190]

This lack of uniformity is also problematic as regards health and consumer protection. The proliferation of different labels is a source of confusion and misunderstanding,[2191] while having a single one of them helps consumers better understanding information and making relevant comparisons between products.[2192] The mandatory character of a label is crucial so that

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[2185] ibid, art 35(4).
[2186] ibid, art 35(5).
[2187] European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' (n 2160).
[2188] See European Commission, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' (n 1477); European Commission, 'Europe's Beating Cancer Plan' (n 23). For further discussions of the legal and political implications of the development of an EU front-of-pack label, see Delhomme, 'Front-of-Pack Nutrition Labelling in the European Union: A Behavioural, Legal and Political Analysis' (n 2165).
[2189] Storcksdieck and others (n 2157); European Commission, Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration (n 2160).
[2190] European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' (n 2160) 16. See also Nikhil Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (2022) 47 European Law Review 153, 160.
[2191] Storcksdieck and others (n 2157) 150–51. See also Gokani (n 2190) 160.
[2192] Désirée Hagmann and Michael Siegrist, 'Nutri-Score, Multiple Traffic Light and Incomplete Nutrition Labelling on Food Packages: Effects on Consumers' Accuracy in Identifying Healthier Snack Options' (2020) 83 Food Quality and Preference 103894, 8; Becher and others (n 1958) 1348.

consumers can have access to relevant and effective nutrition information at all times. Furthermore, voluntary schemes may bias consumers favourably towards products bearing a label that are actually less nutritious than products without a label.[2193]

Worse, from a legal perspective, Member States and food business operators' current use of FoP labels contravene the applicable law, which effectively prohibits the use of certain FoP labels. As it happens, Article 35 of the Food Information Regulation, which was introduced to allow Member States to make official recommendations as regards the use of FoP labels, does not actually cover summary indicators such as the Nutri-Score, but only nutrient-specific FoP labels such as the Reference Intakes Label and, arguably, the MTL (see Table 3).[2194] It is ironical that the provision of the Regulation meant to regulate FoP labels actually fails to apply to the type of label that is now most used in the EU, the Nutri-Score. It is true that the Nutri-Score was first conceptualised in 2014 and introduced in 2016, after the Food Information Regulation had been adopted. Its development could therefore not necessarily have been foreseen by the EU legislator. Nonetheless, the Commission and the Member States have acted as if the Nutri-Score was regulated by Article 35 of the Regulation,[2195] even though it is actually covered by its Article 36 (see above Section 3.2.1.1), which says nothing about any recommendation by Member States authorities or any notification to the Commission.

In addition, labels such as the Nutri-Score actually fall within the scope of the Claims Regulation, which had not been drafted with the intention of allowing labels to proliferate, quite the contrary. Evaluative FoP labels that give information on the overall quality of food, with the use of the colour green and letter A for the Nutri-Score or the presence of an endorsement logo for the Keyhole (see Table 3), constitute 'nutrition claims' within the meaning of the Claims Regulation, 'any claim which states, suggests or implies that a food has particular beneficial nutritional properties'.[2196] The problem is that the Claims Regulation, as we have seen, only allows for the use of a limited list of textual nutrition claims on products, thereby preventing the use of FoP labels that positively evaluate products. Some also consider that these FoP labels constitute 'health claims', 'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health'.[2197]

[2193] Storcksdieck and others (n 2157) 148–49.

[2194] Indeed, Article 35 refers to 'the energy value and the amount of nutrients referred to in Article 30(1) to (5)' of the Food Information Regulation. Gokani considers that the coloured/interpretative aspect of the MTL is not regulated by Article 35: Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (n 2190) 166.

[2195] See ibid 166-167.

[2196] Claims Regulation, art 2(2) (4). This would not be the case for nutrient-specific evaluative claims, such as the MTL. See Recital 46 of the Food Information Regulation: 'The declaration in the same field of vision of the amounts of nutritional elements and comparative indicators in an easily recognisable form to enable an assessment of the nutritional properties of a food should be considered in its entirety as part of the nutrition declaration and should not be treated as a group of individual claims.' See also in that regard Van Nieuwenhuyze (n 2045) 71. See contra Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (n 2190) 166.

[2197] Claims Regulation, art 2(2) (5). See Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (n 2190) 162.

Here again, none of the evaluative FoP labels currently in use respect the substantive conditions set in the Claims Regulation as regards health claims.[2198]

Hence, not only is the current legal framework not fully satisfactory for consumer protection, health promotion and the internal market, but it actually prohibits Member States and food business operators to use most of the available FoP labels, such as the Nutri-Score. The fact the Commission has decided not to act upon that breach of EU law does not alter the reality of that breach.[2199] It is perhaps not too strong to say that the EU's dealings with front-of-pack nutrition information over the last fifteen years have been a regulatory failure.

3.4.2.3. Towards a common and mandatory EU front-of-pack label

A good way to remedy that failure would be to adopt a common and mandatory FoP label at the EU level. The Commission is set to present a proposal for that purpose before the end of 2022,[2200] which would require amendments to bot the Food Information Regulation and the Claims Regulation to be made.

The introduction of a common EU FoP nutrition label would bring about several benefits. It would ensure that all foodstuffs marketed in the EU convey appropriate nutrition information that is noticed and understood by consumers, hopefully leading to healthier food choices. The common and mandatory character of the EU FoP label is crucial so that consumers can have access to relevant and effective nutrition information at all times and make relevant comparisons between products. An interesting additional potentiality of FoP nutrition labels lies in their interaction with other nutrition and health claims. FoP labels could limit the halo effect arising from claims by ensuring that consumers can correctly identify healthier and less healthy products.[2201] An EU FoP nutrition label would therefore contribute to the general objective of the Claims Regulation to limit the misleading character of claims.

Adopting an EU FoP label could create a strong incentive for the reformulation of foods marketed in the EU,[2202] as food manufacturers would want to avoid seeing their nutritionally poorer products shunned by consumers. Evidence actually suggests that, where they have been adopted, evaluative FoP labels led to an improvement in the nutritional quality of food

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[2198] See in particular Claims Regulation, arts 5 and 10.

[2199] The European Commission recognises for instance that the Nutri-Score, when positively evaluating a product, constitutes a nutrition claim, without drawing the proper conclusion as to the illegality of such a claim: see European Commission, 'Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' (n 2160).

[2200] European Commission, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' (n 1477), annex.

[2201] Zenobia Talati and others, 'Consumers' Responses to Health Claims in the Context of Other on-Pack Nutrition Information: A Systematic Review' (n 2033) 271; Zenobia Talati and others, 'Can Front-of-Pack Nutrition Labels Overcome Any Biasing Effects of Nutrient and Health Claims?' (2019) 13 Obesity Research & Clinical Practice 247.

[2202] For the Nutri-Score, see Chantal Julia and Serge Hercberg, 'Development of a New Front-of-Pack Nutrition Label in France: The Fivecolour Nutri-Score' (2017) 3 Public Health Panorama 712, 712–713; Fabien Szabo de Edelenyi and others, 'Ability of the Nutri-Score Front-of-Pack Nutrition Label to Discriminate the Nutritional Quality of Foods in the German Food Market and Consistency with Nutritional Recommendations' (2019) 77 Archives of Public Health 28, 29.

products.[2203] A common scheme would, to a certain extent, also be good for food business operators. It would limit the fragmentation of the internal market that is already occurring at the EU and Member State levels, as countries and companies are experimenting with a growing number of different schemes.

The Commission has not expressed a preference for a specific scheme yet, but in light of the evidence gathered and the backing of a growing number of Member States, the Nutri-Score clearly appears as a front-runner. In its 2020 FoP report, the Commission concluded itself that evaluative schemes that use colour-coding with a graded indicator appear most promising to improve the nutritional quality of food choices.[2204] The European Food Safety Authority (EFSA) was tasked by the Commission to provide advice in this regard.[2205] Ideally, the adopted label should provide sufficient flexibility to allow scientific experts to redefine it when needed, in order to keep pace with new findings and correct possible mistakes or insufficiencies.[2206]

If a summary and graded indicator such as the Nutri-Score were to be adopted, thresholds could be introduced alongside the underlying algorithm, in order to avoid the possibility that products containing problematic levels of certain nutrients be attributed a 'good score', cereals labelled 'A' despite a high sugar content, for instance. Above the set levels, products that would otherwise be positively labelled because of their overall composition would be prevented from featuring in the best categories.[2207] The nutrient profiles referred to in the Claims Regulation serve a similar purpose. The work done in that context could hence usefully be transposed to inform the design of the EU FoP label.[2208] Ideally, the nutrient profiling system adopted under the Claims Regulation and the one adopted for the purpose of developing the FoP label should not contradict each other.

It is of paramount importance that the roll-out of the label is accompanied by a vast communication and education campaign reaching consumers in all Member States. Consumers must become familiar with the new scheme and the way it functions in order to be able to build trust, especially if the scheme is a summary label that does not convey as much information as

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[2203] Storcksdieck and others (n 2157) 143. For nutrition labelling more generally, see Mathilde Gressier, Franco Sassi and Gary Frost, 'Healthy Foods and Healthy Diets. How Government Policies Can Steer Food Reformulation' (2020) 12 Nutrients 1992, 1994–1995.

[2204] European Commission, Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration (n 2160) 19.

[2205] See EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) and others, 'Scientific Advice Related to Nutrient Profiling for the Development of Harmonised Mandatory Front-of-Pack Nutrition Labelling and the Setting of Nutrient Profiles for Restricting Nutrition and Health Claims on Foods' (2022) 20 EFSA Journal 7259.

[2206] Becher and others (n 1958) 1347. See, as regards the Nutri-Score: Scientific Committee of the Nutri-Score, 'Update of the Nutri-Score Algorithm: Yearly report from the Scientific Committee of the Nutri-Score' (2021), <https://t.co/7WNJ5jhQfL> accessed 11/05/2023.

[2207] See Becher and others (n 1958) 1346-1347.

[2208] The Commission has clearly expressed its intention to work simultaneously and in a coherent manner on the development of harmonised FoP nutrition labelling and on the setting of nutrient profiles; see the inception impact assessment, <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12748-Facilitating-healthier-food-choices-establishing-nutrient-profiles_en> accessed 11/05/2023.

the classic nutrition declaration.[2209] Any labelling scheme has its blind spots and can be misinterpreted by consumers, it is therefore important that consumers understand that nutrition labels do not aim at summarising all food information that is relevant to health.

As already briefly touched upon in the introduction, and further explored in Chapter 7 (see Section 3.1), FoP labels are contested tools. The adoption of an EU FoP label may therefore prove to be difficult, not only because of the resistance of food business operators but also because of that of certain Member States. If it proved to be impossible to adopt a common label, the EU should at the very minimum revise the existing legal framework to permit Member States to make FoP labels mandatory on their territory.[2210]

3.4.3. Enhanced information requirements for alcoholic beverages

The last of the three reforms of the lifestyle information legal framework currently under consideration concerns the labelling of alcoholic beverages. Current labelling obligations appear particularly weak for this category of products, if compared especially to those applicable to tobacco products, with which alcoholic beverages are largely comparable in terms of risk. Apart from the indication of the alcoholic strength, no other health-related element supports consumer choice. Strengthened labelling obligations, whether through greater transparency as to the content of alcoholic beverages or an adequate communication of the health risks associated with it, would be no panacea for tackling the EU's alcohol problem, but would constitute a first step and, at the very least, would ensure a more consistent treatment with other unhealthy commodities.[2211] An important aspect to keep in mind is that, unlike for food labelling, consumer research in this domain lacks breadth and is characterised by a higher degree of uncertainty.[2212]

3.4.3.1. Ingredients and nutrition information

The indication of the list of ingredients and the nutrition declaration on alcoholic beverages is the Commission's main priority regarding alcohol labelling. As discussed in Section 3.1.1, this

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[2209] See Zenobia Talati and others, 'Consumers' Perceptions of Five Front-of-Package Nutrition Labels: An Experimental Study Across 12 Countries' (n 1959) 1945.

[2210] Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle between EU Food Law and National Measures' (n 2190) 173.

[2211] Labelling is part of the policy actions recommended by the WHO to reduce the negative consequences of drinking and alcohol intoxication: WHO Regional Office for Europe, 'European action plan to reduce the harmful use of alcohol 2012–2020' (2012) 26-27, <https://www.euro.who.int/__data/assets/pdf_file/0008/178163/E96726.pdf> accessed 11/05/2023. See also Jose M Martin-Moreno and others, 'Enhanced Labelling on Alcoholic Drinks: Reviewing the Evidence to Guide Alcohol Policy' (2013) 23 The European Journal of Public Health 1082; WHO Regional Office for Europe, 'Alcohol labelling A discussion document on policy options' (2017), <https://apps.who.int/iris/handle/10665/350744> accessed 11/05/2023; Eva Jané-Llopis and others, 'What is the current alcohol labelling practice in the WHO European Region and what are barriers and facilitators to development and implementation of alcohol labelling policy?' (2020) WHO Health Evidence Network Synthesis Report 68.

[2212] Jose M Martin-Moreno and others (n 2211); Louise M Hassan and Edward Shiu, 'A Systematic Review of the Efficacy of Alcohol Warning Labels: Insights from Qualitative and Quantitative Research in the New Millennium' (2018) 8 Journal of Social Marketing 333; Hanna Schebesta and Kai Purnhagen, 'Limits to Behavioural Consumer Law and Policy: The Case of EU Alcohol Labelling' in Mathis and Tor (n 453).

will already be the case for wine as of 8 December 2023. This reform is surely the most obvious one to carry forward, as nothing justifies the current lack of transparency as to the content of drinks and the difference in treatment between alcoholic beverages and non-alcoholic food products. A mention of the energy content appears particularly important if one considers that alcohol contains 7 calories per gram, meaning that it is more calorie dense than carbohydrates or proteins (both 4 calories per gram), and a little less calorie dense than fat (9 calories per gram).[2213] It is estimated that the average Canadian drinker receives for instance 11.2% of its recommended daily calorie intake in the form of alcohol,[2214] an amount that is probably higher for Europeans, the world's heaviest drinkers. The current exemption appears particular absurd if considering that 'alcopops', beverages containing a mix of alcohol and sugary drink that are particularly attractive to young people,[2215] are not under the obligation to feature a nutrition declaration while non-alcoholic soft drinks are.

As requested by Article 16(4) of the Food Information Regulation, the Commission presented a report in 2017 exploring the possibility to make the list of ingredients and the nutrition declaration mandatory for alcoholic beverages.[2216] The report clearly establishes that consumers have a knowledge deficit as regards the composition and nutritional value of alcoholic beverages that they would like to remedy and that such information would help a significant number of them adjusting their drinking habits.[2217] The Commission logically concluded that it '*ha[d] not identified objective grounds that would justify the absence of information on ingredients and nutrition information on alcoholic beverages*' but decided nonetheless not to take legislative action, relying instead on voluntary commitments made by

[2213] Adam Sherk and others, 'Calorie Intake from Alcohol in Canada: Why New Labelling Requirements Are Necessary' (2019) 80 Canadian Journal of Dietetic Practice and Research 111, 111.
[2214] ibid 113.
[2215] See Food Information Regulation, recital 40.
[2216] European Commission, 'Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages' (n 1967).
[2217] ibid 7. See also TNS European Behaviour Studies Consortium (n 309) 144, 146. For more evidence on this, see Azzurra Annunziata and others, 'Do Consumers Want More Nutritional and Health Information on Wine Labels? Insights from the EU and USA' (2016) 8 Nutrients 416; Azzura Annunziata and others, 'Nutritional Information and Health Warnings on Wine Labels: Exploring Consumer Interest and Preferences' (2016) 106 Appetite 58; Klaus G Grunert, Sophie Hieke and Hans Jørn Juhl, 'Consumer Wants and Use of Ingredient and Nutrition Information for Alcoholic Drinks: A Cross-Cultural Study in Six EU Countries' (2018) 63 Food Quality and Preference 107. A survey conducted by GfK for The Brewers of Europe in nine European countries shows that a sizeable majority of consumers (86%) think that the mandatory inclusion of ingredients and nutrition information should be the same for alcoholic beverages as any other food, see GfK Consumer Insights Study, Report for the Brewers of Europe by GfK Belgium (2016) 4 <http://www.beerwisdom.eu/downloads/GfK-Consumer-Insights-Study.pdf> accessed 11/05/2023. Studies show however that the provision of this new information could be surprising for consumers and change the perception of certain beverages which are seen as 'natural' and hence not made of any supplementary ingredients, such as wine. See Evelyn Pabst, Gergely Szolnoki and Simone Mueller Loose, 'The Effects of Mandatory Ingredient and Nutrition Labelling for Wine Consumers – A Qualitative Study' (2019) 8 Wine Economics and Policy 5. For the wine industry position on ingredients and nutrition labelling, see Evelyn Pabst, Gergely Szolnoki and Simone Mueller Loose, 'How Will Mandatory Nutrition and Ingredient Labelling Affect the Wine Industry? A Quantitative Study of Producers' Perspectives' (2019) 8 Wine Economics and Policy 103.

the industry.[2218] A self-regulatory proposal was presented by the industry in 2018, under which the signatories committed to provide nutrition and ingredient information. This information would however mostly be given off-label, accessible only through a web-link, a QR code or a bar code.[2219] Considering the limited time and attention that consumers have when shopping, it is doubtful that such means represent an effective way to convey information.

Based on the existing evidence, it is difficult to anticipate the effect that nutrition labelling on alcoholic beverages would have on consumer choice. If consumers' lack of knowledge regarding the calorie content of their drinks is an undisputed fact, whether this leads to an underestimation or an overestimation of that content remains unclear.[2220] This is an important parameter. Consumers faced with a calorie content higher than they had expected could decide to lower their consumption, whereas consumers faced with a calorie content lower than expected could decide, on the contrary, to increase their consumption,[2221] which would run contrary to the public health objective of the measure. A similar effect could be observed with the labelling of fat or carbohydrate information on drinks that do not contain any. Benefitting from a halo effect, these beverages could appear as healthier than they would have had this information not been included.[2222]

This warrants for a certain degree of caution in the changes that will be proposed and calls for further research to be undertaken, so as to ensure that enhanced labelling obligations do not backfire, making some alcoholic beverages appear more appealing than before. Different options are currently under review by the Commission.[2223] Ideally, as discussed in the section devoted to front-of-pack nutrition labelling, this information should be given in an accessible and understandable manner rather than being displayed in small letters at the back of

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[2218] European Commission, 'Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages' (n 1967) 12, emphasis added.

[2219] Self-regulatory proposal from the European alcoholic beverages sectors on the provision of nutrition information and ingredients listing (2018) 6-7 <https://ec.europa.eu/food/document/download/e900347f-bbc9-45df-83d7-22736de901a4_en> accessed 11/05/2023. See the more detailed commitments made in 2019 by the specific alcohol industries: <https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/alcohol_en.> accessed 11/05/2023. For an analysis of these commitments, see Cesare Varallo and Chiara Cravetto, 'Alcoholic Beverages Labelling: Analysis of the Joint-Self Regulatory Proposal of the Industry on Nutrition Labelling and Ingredients' Declaration' (2018) 9 European Journal of Risk Regulation 329.

[2220] For studies concluding in an underestimation, see Azzurra Annunziata and others, 'Do Consumers Want More Nutritional and Health Information on Wine Labels? Insights from the EU and USA' (n 2217); Azzura Annunziata and others, 'Nutritional Information and Health Warnings on Wine Labels: Exploring Consumer Interest and Preferences' (n 2217). For studies concluding in an overestimation, see My Bui and others, 'What Am I Drinking? The Effects of Serving Facts Information on Alcohol Beverage Containers' (2008) 42 The Journal of Consumer Affairs 81; Olivia M Maynard and others, 'No Impact of Calorie or Unit Information on Ad Libitum Alcohol Consumption' (2018) 53 Alcohol and Alcoholism 12; Pabst, Szolnoki and Loose (n 2217).

[2221] My Bui and others (n 2220); Maynard and others (n 2220); Pabst, Szolnoki and Loose (n 2217). See also Martin-Moreno and others (n 2211).

[2222] My Bui and others (n 2220).

[2223] See European Commission, Proposal for a revision of Regulation (EU) No 1169/2011 on the provision of food information to consumers, for what concerns labelling rules on alcoholic beverages, Inception Impact Assessment (2021) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13028-Food-labelling-revision-of-rules-on-information-provided-to-consumers-for-alcoholic-beverages_fr> accessed 11/05/2023.

containers. It remains unclear whether any of the current FoP labels would be relevant for alcoholic beverages, or whether it is best to conceive specific nutrition labelling tools for this category of products.

3.4.3.1. Information on alcohol units

Information on the alcoholic strength of beverages in the form of '% vol' gives consumers an idea of the amount of alcohol contained in their drinks. That information, however, has limited relevance in practice, since the total ingestion of alcohol depends on the quantity of the drink consumed. This forces consumers to make a calculation to be able to compare drinks with each other and to have an idea of their total alcohol consumption.

To help consumers compare beverages and better monitor their overall consumption of alcohol, health professionals and governments promote the use of another measurement method, the 'unit of alcohol' or 'standard drink', 'an unvarying unit of measurement that takes into account the strength and volume of a beverage and allows for meaningful comparisons across different alcohol products.'[2224] A unit of alcohol contains a fixed amount of alcohol, set in most countries at 10 grams of alcohol, but in some others at 8, 12 grams or more.[2225] For instance, if taking the 8 grams unit used in the United Kingdom, there is twice as much alcohol in a pint of regular strength beer (50 cl, 5,2% vol, 3 units) than there is in a small glass of wine (12,5 cl, 12% vol, 1,5 units).[2226] These alcohol units are also used to provide guidance for low-risk alcohol consumption, usually expressed as a maximum of unit consumed per week.[2227]

Providing unit information on beverages could help consumers better identify the amount of alcohol contained and keep their consumption to a lower-risk level, provided that they understand what an alcohol unit stands for and are aware of official consumption guidelines.[2228] Little evidence exist to date, however, on the contribution of unit information to reduced alcohol consumption.[2229] Facilitating comparison across drinks also runs the risk of unit information being used by certain segment of the population to increase the 'cost-effectiveness' of drinking, maximising the number of units ingested for the lowest price. This risk has been particularly highlighted for young people, who are usually the ones having less purchasing power and engaging in heavy episodes of drinking.[2230]

There seems to be no intention on the Commission's part to propose a system of alcohol unit labelling at the EU level. Any such move would require, first, to gain greater certainty as to the

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[2224] Ashley Wettlaufer, 'Can a Label Help Me Drink in Moderation? A Review of the Evidence on Standard Drink Labelling' (2018) 53 Substance Use & Misuse 585, 585.
[2225] Kalinowski and Humphreys (n 199).
[2226] See <https://www.nhs.uk/live-well/alcohol-support/calculating-alcohol-units/> accessed 11/05/2023.
[2227] See ibid: in the UK 'men and women are advised not to drink more than 14 units a week on a regular basis' and to 'spread [their] drinking over 3 or more days if [they] regularly drink as much as 14 units a week'.
[2228] See Martin-Moreno and others, 'Enhanced Labelling on Alcoholic Drinks: Reviewing the Evidence to Guide Alcohol Policy' (n 2211); Sandra Tricas-Sauras, Aleksandra Kaczmarek, Leticia San Martin, 'Consumer survey on communication of alcohol associated risks', European Alcohol Policy Alliance (2015).
[2229] Sandra C Jones and Parri Gregory, 'The Impact of More Visible Standard Drink Labelling on Youth Alcohol Consumption: Helping Young People Drink (Ir)Responsibly?: Young People's Use of Standard Drink Labelling' (2009) 28 Drug and Alcohol Review 230; Maynard and others (n 2220); Wettlaufer (n 2224).
[2230] Jones and Gregory (n 2229), Maynard and others (n 2220).

way that information is used by consumers, the youngest of them in particular, and, second, to investigate the effect of adopting a common definition of an alcohol unit in Member States that have used a different measurement until now.

3.4.3.2. Health warnings

The inclusion of health warnings would constitute a small revolution in the treatment of alcoholic beverages at the EU level. It would help better communicate the specific health risks associated with alcohol consumption to the public and would more clearly distinguish between alcoholic beverages and non-alcoholic foods, bringing the regulatory regime for alcohol closer to the one applicable to tobacco products.

Consumers seem to welcome the inclusion of health warnings on the packaging of alcoholic beverages,[2231] although it is hard to generalise given the many different forms that these labels can take, as it is to generalise on their effectiveness to reduce alcohol consumption.[2232] Like nutrition labelling, this depends on a number of factors such as the content of the warning, its size and its location. Combined textual and pictorial warnings similar to those used in the Tobacco Products Directive could yield similar results, helping to decrease the positive image of alcohol.[2233] It seems highly unlikely, however, that the Commission would propose such warnings, even in a version less stringent than the ones provided for in the TPD. The industry and Member States would surely oppose it with vigour, perhaps even the public, considering that many alcoholic beverages are perceived as quality, superior products.

What the Commission has in mind are probably smaller and more targeted health warnings, addressing for instance the risks of alcohol consumption during pregnancy or when driving. Evidence from France has shown that the pregnancy warning used in that country lacked visibility and was largely ineffective due to its small size, its location on the back side of bottles and containers, and the lack of strength of the message.[2234] The pregnancy warnings introduced in Australia and New Zealand in 2020, which combine textual and pictorial elements, may yield better results in this regard (see Figure 5 below).

[2231] Annunziata and others, 'Nutritional Information and Health Warnings on Wine Labels: Exploring Consumer Interest and Preferences' (n 2217); Annunziata and others, 'Do Consumers Want More Nutritional and Health Information on Wine Labels? Insights from the EU and USA' (n 2217); Louise M Hassan and Edward Shiu, 'A Systematic Review of the Efficacy of Alcohol Warning Labels: Insights from Qualitative and Quantitative Research in the New Millennium' (2018) 8 Journal of Social Marketing 333.

[2232] Gloria Dossou, Karine Gallopel-Morvan and Jacques-François Diouf, 'The Effectiveness of Current French Health Warnings Displayed on Alcohol Advertisements and Alcoholic Beverages' (2017) 27 The European Journal of Public Health 699, 700; Hassan and Shiu (n 2186).

[2233] Mohammed Al-Hamdani, 'The Case for Stringent Alcohol Warning Labels: Lessons from the Tobacco Control Experience' (2014) 35 Journal of Public Health Policy 65; Mohammed Al-Hamdani and Steven Smith, 'Alcohol Warning Label Perceptions: Emerging Evidence for Alcohol Policy' (2015) 106 Canadian Journal of Public Health 395.

[2234] Gloria Dossou, Karine Gallopel-Morvan and Jacques-François Diouf (n 2232). See also Agnès Dumas and others, 'Warning about Drinking during Pregnancy: Lessons from the French Experience' (2018) 15 Reproductive Health 20, showing that the warning is well-known but that it is not properly understood since a large proportion of women believe that beer or wine are less dangerous than spirits, in spite of the fact that the warning appears on all alcohol containers.

Figure 5: Alcohol pregnancy warnings[2235]

France

Australia and New Zealand

Ireland is also set to introduce new health warning labels on alcoholic beverages after the European Commission raised no objection to its draft regulation, notified in June 2022.[2236] These labels would contain the following messages, 'drinking alcohol causes liver disease' and 'there is a direct link between alcohol and fatal cancers', and a symbol representing the dangers of drinking alcohol while pregnant.[2237] Amidst opposition from a number of other Member States, this represents a further incentive for the European Commission to act.[2238]

3.5. Interim conclusion

Plain tobacco packaging, front-of-pack nutrition labelling and alcohol labelling: the most concrete elements of the 2021 Beating Cancer Plan are all information-related, revealing the enduring place occupied by this type of intervention in the EU regulator's toolbox. These upcoming reforms illustrate the evolution in EU information regulation, towards more behavioural reality. The use of behavioural findings in this area of the law is not an entirely new endeavour – the Claims Regulation bears witness to this fact, as do most of the rules applicable to tobacco information – but such findings appear to be used more systematically now. The direct regulation of the TFAs content in food (see Chapter 5, Section 3.3.2) also shows that, where information fails, the EU may (sometimes) be ready to take stronger regulatory action.

It is tempting to see in these developments a change in the nature of the 'average' consumer, less diligent and circumspect than previously assumed. This is to a certain extent true. If the aforementioned reforms become law, consumers will overall have access to less information

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[2235] For France, see the 'Arrêté du 2 octobre 2006 relatif aux modalités d'inscription du message à caractère sanitaire préconisant l'absence de consommation d'alcool par les femmes enceintes sur les unités de conditionnement des boissons alcoolisées'. For Australia and New Zealand, see <https://www.foodstandards.gov.au/industry/labelling/Pages/pregnancy-warning-labels-downloadable-files.aspx> accessed 11/05/2023.

[2236] The text of the notification can be retrieved at <https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2022&num=441>. The notification was made pursuant to Directive (EU) 2015/1535 and the Food Information Regulation.

[2237] The Lancet Gastroenterology & Hepatology, 'Distilling the Message: Irish Plans for Alcohol Warning Labels' (2023) 8 The Lancet Gastroenterology & Hepatology 199.

[2238] Euractiv, 'Ireland 'surprised' to receive EU green light on alcohol health label' (2023), accessed 11/05/2023 <https://www.euractiv.com/section/alcohol/news/ireland-surprised-to-receive-eu-green-light-on-alcohol-health-label/>.

than they used to in the past, whether because the provision of this information is prohibited, as it is the case for tobacco, or because the information immediately available is highly simplified, as would be the case with a European Nutri-Score. Yet, what the analysis reveals is the picture of a 'split consumer', split between risk factors – tobacco, food and alcohol information are regulated very differently – but also within them. In function of the product at stake and the risk entailed, consumers are more or less protected against potentially misleading information and more or less trusted in their capacity to make judgements.

This is particularly true for food. The main rationale underpinning the Food Information Regulation, on the one hand, is that, provided with adequate and reliable information, consumers are able to make choices that are best aligned with their preferences. The Claims Regulation, on the other hand, is based on the premise that consumers may be abused by messages claiming benefits for food, even if factually accurate, especially when these apply to unhealthy food and drinks.[2239] This goes 'against the idea that the provision of information constitutes an important consumer protection tool and enables well-considered choice'.[2240]

A closer look yet reveals an even more contrasted picture. While Article 7 of the Food Information Regulation provides more protection to the consumer, especially as interpreted in *Teekanne*,[2241] certain provisions of the Claims Regulation seem to make far-reaching demands on consumers. The distinctions made in the Claims Regulation between nutrition and health claims on the one hand, and between 'function' health claims and disease risk reduction claims on the other, providing for a different level of protection for each category, implies that consumers can understand the difference between those.[2242] It is, however, 'unknown whether consumers can make that same distinction between different types of claims, let alone whether these claims differently influence purchasing and consumption behaviour'.[2243]

4. Recommendations and other non-binding measures

At the lowest end of the regulatory spectrum, one finds various initiatives which share the common feature of not being binding in nature. These schemes aim at steering Member States and companies towards the adoption of certain measures or the revision of certain practices. In particular, the Council and the Commission have adopted various recommendations addressed to Member States regarding their national policies on tobacco, alcohol and, most remarkably, gambling. As regards foods and alcohol, the Commission has also tried, unsuccessfully, to foster the adoption of voluntary commitments by the industry. Although their nature and content vary, most of these initiatives lay an emphasis on the protection of children and minors. It is also important to stress that, while all being non-binding in nature, the interventions

[2239] For a discussion of the different rationales underlying the two instruments, see Ellen Van Nieuwenhuyze (n 2045) 185-188; Edinger, 'Promoting Educated Consumer Choices. Has EU Food Information Legislation Finally Matured?' (n 2039).
[2240] Ellen Van Nieuwenhuyze (n 2045) 290-298.
[2241] Regarding Article 7 of the Food Information Regulation, see Andreas Meisterernst, 'A New Benchmark for Misleading Advertising' (2013) 8 European Food and Feed Law Review 91, 96. See more generally Edinger, 'Promoting Educated Consumer Choices. Has EU Food Information Legislation Finally Matured?' (n 2039).
[2242] Ellen Van Nieuwenhuyze (n 2045) 273-274.
[2243] De Boer (n 2108) 1736.

presented here fundamentally differ as regards the role devoted to industry actors. Through its official recommendations, the EU promotes the adoption of useful and scientifically validated policy measures, which, if adopted, may considerably constrain economic operators. This is not the case with the self-regulation schemes put in place at the EU level, which closely involve industry actors in the design of the recommended measures, and remain unsurprisingly timid on substance.

4.1. The Gambling Recommendation

The Commission Recommendation of 14 July 2014 on principles for the protection of consumers and players of online gambling services and for the prevention of minors from gambling online ('Gambling Recommendation') is the only legal instrument relating to the public health dimension of gambling currently in force in the EU. [2244] It aims 'to achieve a high level of protection for consumers, players and minors through the adoption of principles for online gambling services and for responsible commercial communications of those services, in order to safeguard health and to also minimise the eventual economic harm that may result from compulsive or excessive gambling'.[2245]

The Recommendation covers various interventions across the regulatory spectrum, a number of which aim at preventing the development of gambling disorder and protect minors.[2246] It recommends for instance that certain information be displayed prominently on the landing page of operators' websites and retrievable from all their pages, including a 'no underage gambling' sign, a 'responsible gambling message'[2247] and a link to at least one organisation providing information and assistance in respect of gambling disorders.[2248] Regarding commercial communications and sponsorship, the Recommendation contains a number of provisions designed to ensure that promotion is made in a transparent way and that operators that benefit from it are clearly identifiable.[2249] Commercial communications should not carry misleading or exploitative messages, such as suggesting that skill can influence the outcome of a game or

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[2244] See Case C-16/16 P *Belgium v Commission* [2018] EU:C:2018:79, in which the Court confirmed that the recommendation was devoid of any binding character and could not be subjected to an action for annulment under Article 263 TFEU. Advocate General Bobek concluded otherwise, arguing that the recommendation had legal effect and was amenable to judicial review, see Case C-16/16 P *Belgium v Commission* [2017] EU:C:2017:959, Opinion of Advocate General Bobek.

[2245] Gambling Recommendation, para 1. An online gambling services is defined as 'any service which involves wagering a stake with monetary value in games of chance, including those with an element of skill, such as lotteries, casino games, poker games and betting transactions that are provided by any means at a distance, by electronic means or any other technology for facilitating communication, and at the individual request of a recipient of services': ibid, para 3(a).

[2246] Regarding minors, see ibid paras 8-14.

[2247] This 'responsible gambling' message shall provide '(i) information that gambling can be harmful if not controlled; (ii) information about the player support measures on the website; (iii) self-assessment tests for the players to check their gambling behaviour': ibid, para 4.

[2248] ibid, para 4.

[2249] ibid, paras 39, 44 and 46.

that gambling can be an alternative to employment,[2250] and should also not target vulnerable players.[2251]

The Recommendation advises that only persons holding a player account be permitted to participate in online gambling activities.[2252] To avoid deterring players from registering with a legal operator and flocking to an illegal and unregulated offer, Member States are invited not to make the registration process unnecessarily burdensome.[2253] The player account serves to bar access to minors and to set up a number of support tools for players. Players should for instance be able to set default monetary deposit limits at the registration stage. These limits may be lowered immediately at any point during the game but can only be increased at the player's request after a twenty-four hours cooling period.[2254] Players should also be able to set temporal limits, to take time out and to self-exclude.[2255] Time out should be at least twenty-four hours long and self-exclusion be of a duration of at least six months.[2256] Players should also receive regular alerts about their gains and losses while playing, as well as be informed of the time spent playing. Upon receiving the alerts, they should be required to confirm that they wish to continue playing or be able to suspend the game.[2257]

A behavioural study commissioned by the European Commission and finalised shortly before the Recommendation was adopted seems to have informed the design and inclusion of most of these mechanisms.[2258] The study concluded that pre-gambling treatments (e.g. warnings, overconfidence task, terms and conditions) were not effective to reduce gambling, measured as the time spent playing and the amount of money bet, but could nonetheless be considered a useful source of information for consumers.[2259] On the contrary, the study found that in-gambling treatments, such as those contained in the Recommendation, money limits and alerts, were most effective to slow down the rhythm of gambling and reduce the amounts bet.[2260]

The Recommendation invites Member States to notify to the Commission the measures adopted and to collect relevant data on players and commercial communication, information on the basis of which the Commission should evaluate its implementation.[2261] Although the Recommendation sets a deadline for 19 January 2017, no evaluation has so far taken place, which makes it difficult to know whether the Recommendation was taken up by Member States and had any effect in practice.

[2250] ibid para 41
[2251] ibid para 43. The Recommendation does not define 'vulnerable'.
[2252] ibid, paras 15-20.
[2253] ibid, para 21(a) and recital 18.
[2254] ibid, paras 24 and 29(a)-(b).
[2255] ibid, paras 24 and 29(c). See also paras 34 to 38.
[2256] ibid, para 33.
[2257] ibid, para 26.
[2258] Consortium LSE & Partner, 'Study on online gambling and adequate measures for the protection of consumers of gambling services' (2014) Final report for the European Commission.
[2259] ibid 105-112.
[2260] ibid.
[2261] ibid paras 52-54.

4.2. The recommendations on smoking prevention and on smoke-free environments

Two recommendations have been adopted by the Council in the field of tobacco, covering areas where no binding rules are currently in force. Council Recommendation of December 2002 on the prevention of smoking and on initiatives to improve tobacco control[2262] and Council Recommendation of 30 November 2009 on smoke-free environments.[2263]

The Recommendation on the prevention of smoking contains a number of provisions applicable to the sale of tobacco products, aimed in particular at preventing access to these products to minors, and to tobacco advertising and promotion. As regards sales to minors, Member States are for instance invited to require vendors to conduct age checks, to remove tobacco products from self-service displays in retail outlets, to ensure that underage persons do not have access to tobacco vending machines and to prohibit 'the sale of sweets and toys intended for children and manufactured with the clear intention that the product and/or packaging would resemble in appearance a type of tobacco product'.[2264] It is also recommended that Member States prohibit all forms of advertising and promotion for tobacco products. These include 'the use of promotional items (ashtrays, lighters) and tobacco samples', 'the use of static advertising techniques such as billboards, posters, tobacco vending machines' and the use of advertising in cinemas,[2265] precisely the forms of promotional techniques for which, as ruled in *Tobacco Advertising*, the EU cannot adopt binding legislation. It is also recommended that Member States monitor the expenditure of tobacco companies on advertising, marketing and sponsorship.[2266]

As regards smoke-free environments, already in 1989 did the Council invite Member States to ban smoking in enclosed premises open to the public, including public transport,[2267] a call reiterated in the Council Recommendation of 2002.[2268] In its 2005 Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level', the European Commission explored the possibility of adopting binding legislation.[2269] It was finally decided in 2009 to adopt a specific Council recommendation.

The Recommendation on smoke-free environments is highly influenced by the FCTC. Indeed, its main provision recommends that Member States 'provide effective protection from exposure to tobacco […] as stipulated by Article 8 of the WHO Framework Convention on Tobacco Control (FCTC) and based on the annexed guidelines on protection from exposure to tobacco smoke adopted by the Second Conference of the Parties to FCTC'.[2270] Member States

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[2262] Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control [2002] OJ L22/31.
[2263] Council Recommendation of 30 November 2009 on smoke-free environments [2009] OJ C296/4.
[2264] Recommendation on the prevention of smoking, para 1.
[2265] ibid, para 2.
[2266] ibid, para 3.
[2267] European Council, Resolution of the Council and the Ministers for Health of the Member States, meeting within the Council of 18 July 1989 on banning smoking in places open to the public [1989] OJ C189/1.
[2268] Recommendation on the prevention of smoking, para 4.
[2269] European Commission, 'Towards a Europe free from tobacco smoke: Policy options at EU level' (n 350).
[2270] Recommendation on smoke-free environments, para 1.

are invited to 'provide effective protection from exposure to tobacco smoke in indoor workplaces, indoor public places, public transport and, as appropriate, other public places […] within five years of the FCTC's entry into force for that Member State, or at the latest within three years following the adoption of this Recommendation',[2271] by taking steps in particular to reduce exposure to second-hand tobacco smoke of children and adolescents.[2272]

Measures adopted by the Member States should be in line with Article 8 of the FCTC on smoke-free environments and the Guidelines on protection from exposure to tobacco smoke adopted by the Second Conference of the Parties to the FCTC, annexed to the Recommendation. According to the Guidelines, these measures should 'require the total elimination of smoking and tobacco smoke in a particular space or environment in order to create a 100 % smoke-free environment'. As there is no safe level of exposure to tobacco smoke, 'approaches other than 100% smoke-free environments, including ventilation, air filtration and the use of designated smoking areas (whether with separate ventilation systems or not)' should not be pursued.[2273]

The measures that Member States are invited to adopt should cover a very wide scope, providing 'universal protection by ensuring that all indoor public places, all indoor workplaces, all public transport and possibly other (outdoor or quasi-outdoor) public places are free from exposure to second-hand tobacco smoke',[2274] public places being defined 'as broadly as possible [to] cover all places accessible to the general public or places for collective use, regardless of ownership or right to access'.[2275] If taken literally, that would mean that smoking only remains possible in some private places, including private homes. The Guidelines reckon that regulating smoking in private homes would not be feasible or appropriate. Certain targeted bans have however been enacted. Since 2015, the United Kingdom has for instance decided to ban smoking in private vehicles with children present, although compliance with this measure appears to have been weak.[2276]

The Guidelines, and hence the Recommendation, apply to tobacco smoke, 'the smoke emitted from the burning end of a cigarette or from other tobacco products usually in combination with the smoke exhaled by the smoker',[2277] meaning that e-cigarettes vapour and emanation from heated tobacco products are not covered by this instrument.[2278] Even though these emissions are far less harmful to health than tobacco smoke, allowing the use of e-cigarettes, HTPs and other related products in public spaces could have the effect of renormalising smoking,[2279]

[2271] ibid, para 1.
[2272] ibid, para 2.
[2273] ibid, annex para 6.
[2274] ibid, annex para 24.
[2275] ibid, annex para 8.
[2276] Timor Faber and others, 'Investigating the Effect of England's Smoke-Free Private Vehicle Regulation on Changes in Tobacco Smoke Exposure and Respiratory Disease in Children: A Quasi-Experimental Study' (2019) 4 The Lancet Public Health 607.
[2277] Recommendation on smoke-free environments, para 15.
[2278] See European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (n 1855) 118
[2279] Fairchild, Bayer and Colgrove (n 1448); Voigt (n 198).

which is why many health experts call for an extension of smoke-free legislation to all tobacco and related products. The European Commission is considering, as part of the Beating Cancer Plan, to propose to formally include e-cigarettes and HTPs within the scope of the Recommendation, along with the adoption of more stringent requirements on outdoor spaces.[2280] A recent study from the EUREST-PLUS Consortium found that the use of e-cigarettes in public was positively associated with the intention to quit smoking, allaying concerns that the use of e-cigarettes is renormalising smoking in the eyes of current smokers.[2281]

Overall, Member States have reached a moderate level of implementation of the Recommendation.[2282] Concerning the actual exposure of citizens to tobacco smoke, the 2021 Eurobarometer shows a high level of protection for indoor public places throughout the EU, although with wide disparities. For instance, only 16% of respondents who visited a drinking establishment in the last six months indicate that people were smoking inside the last time they did so, a proportion in continuous decline since 2014. However, this EU average hides significant intra-EU differences. The proportion of those having witnessed smoking the last time they visited a drinking establishment is 3% in Sweden but 73% in Croatia.[2283] For outdoor and quasi-outdoor places, only a minority of people (30%) indicate that people were not smoking on terraces the last time they visited a drinking or eating establishment.[2284]

Enacting binding EU legislation on smoke-free environments would be more effective than a simple recommendation but the EU does not currently have the power to do so, as will be further investigated in the next chapter (Section 2.2.2). However, the EU could adopt specific binding legislation on workplaces, under its competence in social policy. This was one of the options identified by the 2005 Green Paper.[2285] Yet, as of today, no workplace smoking ban may be found in Directive 89/654/EEC on minimum health and safety requirements at work[2286] or Directive 2004/37/EC on the protection from carcinogens and mutagens at work.[2287] Directive 89/654/EEC only requires for appropriate measures to be introduced 'for the protection of non-smokers against discomfort caused by tobacco smoke' in restrooms and rest areas.[2288]

4.3. The Alcohol Recommendation

[2280] European Commission, 'Europe's Beating Cancer plan' (n 23) 9.
[2281] McDermott and others (n 198).
[2282] See European Commission, 'Study on smoke-free environments and advertising of tobacco and related products' (n 1855) 122.
[2283] European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 137.
[2284] ibid 146.
[2285] European Commission, Green Paper, 'Towards a Europe free from tobacco smoke: policy options at EU level', (n 350) 19.
[2286] Council Directive 89/654.
[2287] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work [2004] OJ L158/50.
[2288] Directive 89/654/EEC, annexes I and II.

Council Recommendation of 5 June 2001 on the drinking of alcohol by young people in particular children and adolescents contains a number of provisions aiming at preventing access to and consumption of alcoholic beverages for young people.[2289] It recommends that Member States take priority action against the illegal sale of alcohol to underage consumers and adopt various awareness and educational measures.[2290] Member States are also invited to ensure that alcoholic beverages are not designed or promoted to appeal to children and adolescents, paying attention for instance to 'advertising during, or sponsorship of, sporting, musical or other special events which a significant number of children and adolescents attend as actors or spectators, to 'advertising in media targeted at children and adolescents or reaching a significant number of children and adolescents' or to the 'free distribution of alcoholic drinks to children and adolescents, as well as sale or free distribution of products which are used to promote alcoholic drinks and which may appeal in particular to children and adolescents'.[2291]

4.4. The EU Platform and EU Forum

The reliance of the European Commission on self-regulation, clearly visible from the legal framework applicable to commercial communications, extends to the regulation of foods and alcoholic beverages more generally. To steer the industry towards the adoption of voluntary commitments in these two areas, the Commission has created two dedicated bodies, the EU Platform for Action on Diet, Physical Activity and Health[2292] and the European Alcohol and Health Forum,[2293] established in 2005 and 2007 respectively.

After fifteen years of existence, the two entities have had a limited output. If more than 300 commitments have been made in the context of the EU Platform, these remain limited in scope and substance. The same can be said of the EU Forum, which, far from being the 'cornerstone' of the EU Alcohol Strategy,[2294] seems to have rather been a vehicle for the industry's influence, only leading to the adoption of weak commitments related to consumer information and education.[2295] These commitments may not only be ineffective but are, in certain cases, even harmful.[2296] In 2015, to protest against this lack of results and the decision of the Commission

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[2289] Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents [2001] OJ L161/38.
[2290] ibid, art I.
[2291] ibid, art II(1)(b).
[2292] See <https://health.ec.europa.eu/other-pages/basic-page/eu-platform-diet-physical-activity-and-health-database_en#the-platform-visualised> accessed 11/05/2023.
[2293] See European Commission, 'Charter establishing the European Alcohol and Health Forum' (2007), <https://ec.europa.eu/health/ph_determinants/life_style/alcohol/documents/Alcohol_charter2007.pdf> accessed 11/05/2023.
[2294] ibid 2.
[2295] Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns ' (n 34); Oliver Bartlett and Amandine Garde, 'The EU Platform and the EU Forum: new modes of governance or a smokescreen for the promotion of conflicts of interests?', in Alberto Alemanno and Amandine Garde (eds), *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (Cambridge University Press, 2015) ; Bartlett and Garde, 'EU Public Health Law and Policy – on the Rocks? A Few Sobering Thoughts on the Growing EU Alcohol Problem' (n 1906) 383–386.
[2296] In a highly revealing study, Petticrew and others show that the alcohol industry, when communicating about risks and responsible drinking, uses a range of behavioural techniques aimed at promoting drinking and misinforming the public: Mark Petticrew and others, 'Dark Nudges and Sludge in Big Alcohol: Behavioral

not to prepare any new EU alcohol strategy, a number of public health NGOs decided to resign from the European Alcohol and Health Forum,[2297] which has been inactive since then. In 2019, seven civil society organisations, including the European Public Health Alliance and the European consumer organisation BEUC, decided to leave the EU Platform, considering that it was 'not fit for purpose' as currently built.[2298]

As some would argue, this approach, which involves a constant interference of businesses with the design of policies aimed at restraining their operations constitute a 'smokescreen' for the promotion of conflict of interests rather than sound public policy.[2299] To be effective, self-regulation must be accompanied by the credible threat that, without meaningful steps taken by private operators, binding regulation will follow.[2300] This threat, however, is clearly absent at the EU level right now, nearly twenty years after the creation of various forums that have not resulted in any concrete progress. The same conclusion holds for the approach of the EU towards harmful commercial communications.

4.5. The EU School scheme

To support the consumption of these products among children, the EU created a scheme for the distribution of fruit, vegetables and milk in schools. The provisions applicable to this scheme are contained in the CMO Regulation, one of the core instruments of the Common Agricultural Policy.[2301] The scheme aims at 'durably increasing the share of [fruit, vegetables and milk] in the diets of children at the stage when their eating habits are being formed',[2302] so as to help fighting childhood obesity and improve consumption habits currently geared towards highly processed foods and foods high in fat, salt and sugar.[2303] Union aid can be granted for the direct

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Economics, Cognitive Biases, and Alcohol Industry Corporate Social Responsibility' (2020) 98 The Milbank Quarterly 1290. An example given is that of an industry-controlled website where information on alcohol harm is deliberately made difficult to access. In the section on alcohol and health, information on pregnancy harms, 'one of the most important and well-established harms of alcohol consumption' is for instance placed well below sections such as 'How does alcohol affect my beer belly?' and 'Why does alcohol make you pee more?'.

[2297] Letter to Commissioner for Health and Food Safety Andriukaitis (2015), <https://epha.org/wp-content/uploads/2015/06/Commissioner-Andriukaitis-resignation-EAHF.pdf> accessed 11/05/2023.

[2298] European Public Health Alliance, 'NGOs leave EU Platform on Diet, Physical Activity & Health' (2019) <https://epha.org/ngos-leave-eu-platform-on-diet-physical-activity-health/> accessed 11/05/2023.

[2299] Bartlett and Garde, 'The EU Platform and the EU Forum: new modes of governance or a smokescreen for the promotion of conflicts of interests?' (n 2295).

[2300] Fabrice Etilé, 'Les Chartes d'Engagements Nutritionnels: Une Analyse Economique de l'Echec d'un Pari Théorique' (2020) 38 Sciences Sociales et Santé 103, 106–107.

[2301] Regulation 1308/2013, arts 22 to 25. See Commission Implementing Regulation (EU) 2017/39 of 3 November 2016 on rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments [2017] JO L5/1; Commission Delegated Regulation (EU) 2017/40 of 3 November 2016 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments and amending Commission Delegated Regulation (EU) No 907/2014 [2017] JO L5/11.

[2302] Regulation 1308/2013, recital 26.

[2303] Regulation (EU) 2016/791 of the European Parliament and of the Council of 11 May 2016 amending Regulations (EU) No 1308/2013 and (EU) No 1306/2013 as regards the aid scheme for the supply of fruit and vegetables, bananas and milk in educational establishments [2016] OJ L135/1, recital 2.

supply and distribution of products and for educational measures.[2304] The overall budget for the scheme cannot exceed 250 million euros per school year, of which 150 million can be used for fruits and vegetables.[2305] For the school year 2022/2023, more than 125 million euros are allocated to fruits and vegetables and 95 million euros to milk.[2306]

5. Conclusion

The analysis of the least restrictive of EU lifestyle interventions, taking consumer choice as the yardstick, reveals enduring divergences between risk factors. Taken together, rules on tobacco information and commercial communications form a tight regulatory net whose goal is to communicate clearly and vividly the hazardous nature of the products concerned to the consumer, and which deprives manufacturers of most of the promotional techniques at their disposal. Once again, the picture appears more fragmented for food and alcoholic beverages. While certain practices are tightly controlled, such as the use of food claims, others are left mostly unregulated, such as advertising, sponsorship and other forms of commercial communications.

This chapter also illustrates the dynamics in EU lifestyle risks policy that had been identified in Chapter 5. Rules on information, which had been originally adopted for internal market purposes, facilitating the free movement of products through the EU and ensuring a minimum level of consumer protection, have taken over the years a more affirmed public health coloration. The objective of an EU front-of-pack nutrition label, especially in the form of a colour-coded summary scheme, is less to ensure transparency as regards the composition of foods than to steer consumers towards the consumption of healthier foods. This also means that the vision of the consumer evolves, less rational and diligent than previously thought, although conflicting provisions persist in this regard.

Another notable feature of EU lifestyle risks policy is the reliance on industry self-regulation and the shortcomings of this approach. The various codes of conducts and pledges for food and alcohol that exist have not resulted in the adoption of significant measures on commercial communications and product composition. This is especially problematic as regarding minors, a vulnerable group whose protection is presented as a priority by the EU, but who are not currently protected from unhealthy advertising and promotion.

What has been the effect of EU interventions? Which contribution has the EU made to the promotion of healthier lifestyles? As previously mentioned, measuring the effect of a given policy in a sector characterised by a multi-level and multi-sectoral regulatory mix is a difficult endeavour. What is sure is that, in parallel to the development of EU tobacco policy, the EU has witnessed a drop in the prevalence of tobacco use. The overall objective of the TPD,

[2304] Regulation 1308/2013, art 23.
[2305] ibid, art 23a.
[2306] Commission Implementing Decision (EU) 2022/1187 of 7 July 2022 amending Implementing Decision (EU) 2022/493 as regards the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 [2022] JO L184/56, annex I.

reducing tobacco consumption by 2% within five years of its transposition, set at 20 May 2016,[2307] was met, with a smoking prevalence among those aged over fifteen falling from 26% in 2014 to 23% in 2020.[2308] After a peak at 29% in 2017, youth smoking rates fell to from 25% in 2014 to 20% in 2020.[2309] Although it is hard to evaluate the exact contribution that Union rules have made in this regard, these have accompanied the dramatic fall in the use of tobacco that has occurred in Europe, and the developed world more generally, since the 1980s.[2310] Tobacco control policies do work and those that have been put in place in the EU are among the most effective.[2311]

The orientations taken and the type of instruments adopted by the EU are the product of political decisions and compromises involving the weighing of different interests. For various reasons, the EU and its Member States remain reticent to act forcefully in certain areas. However, some of the limits found in EU lifestyle risks policy do not result from a political bargain but can better be explained by the constitutional framework within which this policy is developed. The EU cannot do whatever it wants in relation to lifestyle. This impacts certain regulatory tools more than others. It is this series of question that are addressed in Chapter 7.

[2307] Tobacco Products Directive, art 29(1).
[2308] European Commission, Report on the application of Directive 2014/40/EU (n 1429) 1.
[2309] ibid.
[2310] K Giskes and others, 'Trends in Smoking Behaviour between 1985 and 2000 in Nine European Countries by Education' (2005) 59 Journal of Epidemiology & Community Health 395; Eric A Feldman and Ronald Bayer, 'The Triumph and Tragedy of Tobacco Control: A Tale of Nine Nations' (2011) 7 Annual Review of Law and Social Science 79.
[2311] See Feliu (n 448) 1, concluding that 'European Union Member States with a higher level of implementation of tobacco control policies have both a higher decrease in their smoking prevalence and a higher increase in their quit ratios'. It is important to bear in mind that this is an ecological study, meaning that any causal relationship between tobacco control policies and the chosen outcomes (smoking prevalence and quit ratios) cannot formally be established. However, these results conform with other studies showing a reduction in smoking prevalence and an increase in quit ratios after the adoption of tobacco control policies.

Chapter 7

EU management of lifestyle risks: the difficult balance of objectives and interests

1. Introduction

Through a wide range of measures, the EU seeks to promote a healthier, better life for its citizens: eliminating the use of tobacco products, encouraging more responsible patterns of drinking, and fostering healthier diets. Under this broad common objective, EU lifestyle risks regulation appears as a highly contrasted field, with varying degrees of engagement from the EU and different instruments adopted. Mostly, this does not reflect the relative seriousness of these various risks for human health but the fact that other concerns have been incorporated into the law and policy on lifestyles. Some stronger public health interventions have been discarded on grounds of their negative effects on economic operators, some others due to the opposition of Member States. Despite their usefulness for health promotion, nutrient profiles, front-of-pack nutrition labelling, alcohol health warnings and tobacco plain packaging have not yet been adopted by the EU. They may be in the near future. When managing lifestyle risks, the EU must balance public health with other public and private interests, while not losing track of the objective of ensuring the smooth functioning of the internal market, without which no harmonisation measures can be adopted in that field.

This balancing of competing objectives, values and interests is at the core of the constitutional principles governing the existence and exercise of Union competences: conferral, subsidiarity, proportionality and respect for fundamental rights. These principles set limits to Union action, ensuring that it takes place where necessary and without affecting the rights and interests of Member States and private parties in a disproportionate manner. They allow to understand why the EU acts and why a certain course of action is favoured over another, making the trade-offs and compromises referred to throughout this thesis visible. The main contention of this Chapter is that these fundamental principles of Union law are not always performing well when applied to the EU management of lifestyle risks. This affects the clarity, the sincerity and, ultimately, the legitimacy of Union action in that field. The reason for this is mainly structural and pertains to the centrality of the internal market as a constitutional objective. It also reflects a somewhat narrow vision of what managing lifestyle risks entail.

There are four main points of tension. A first category of problems derives from the dual nature of EU harmonisation in the field and the need to conduct what is primarily a health policy with an internal market legislative competence. This affects, first, the type of measures that can be adopted by the EU. The internal market nature of EU legislation limits the range of options available to the EU legislature to control lifestyle-related health risks. The Court has tried to solve this tension, in an unconvincing manner mostly, at the expense of the principle of conferral and the proper delimitation of powers between the EU and its Member State. A second problem, intimately linked to the first, is the difficulty for Union law make room for flexibility and to accommodate national diversity. Indeed, the conditions for the use of EU internal market powers, which are geared towards the elimination of obstacles stemming from regulatory differences, are inherently hostile towards any attempt at preserving regulatory diversity.

A second category of problems are linked to proportionality and fundamental rights, and the extent to which private interests may constitute a limit on Union action. As regards the rights and interests of economic operators, the main issue is of a conceptual nature. That economic operators may suffer negative consequences from lifestyle risks control measures is neither surprising nor objectionable per se, for it derives from the very nature of the risk that is being regulated. Where these are construed as internal market measures, however, economic operators are negatively affected by interventions from which, on the face of it, they should logically benefit. As regards consumer autonomy, the situation is of a quasi-invisibility. It is not only that health protection is considered as prevailing over the capacity of individuals to make free and informed choices, but also that this trade-off is rarely, if ever, acknowledged.

The judgements rendered by the Court of Justice on the validity of EU lifestyle measures, in the field of tobacco mostly, form the bulk of the materials analysed in this chapter. The analysis goes nonetheless beyond court cases, which are ex post assessments of the compliance of Union legislation with the four principles set out above, and looks into the legislative process, at impact assessments in particular.[2312] Under the Better Regulation framework, '[a]n impact assessment is required for Commission initiatives that are likely to have significant economic, environmental or social impacts or which entail significant spending, and where the Commission has a choice of policy options', [2313] which will usually be the case with initiatives in the field of lifestyles. Impact assessments help determining 'whether Member States alone could resolve [an] issue satisfactorily, whether the EU has the right to act (i.e. a legal basis) and whether it is best placed to do so',[2314] they should also 'inform policymakers of the extent to which different options would meet their objectives, with what benefits, at what cost, with what implications for different stakeholders, and at what risk of unintended consequences'.[2315] They are therefore a key source of information to assess the compliance of a legislative act with the principles of conferral, subsidiarity, proportionality and respect for fundamental rights, aspects which must clearly be featured in the explanatory memorandum accompanying a legislative proposal.[2316]

[2312] An impact assessment 'is about gathering and analysing evidence to support policymaking. It involves verifying the existence of a problem, identifying its underlying causes, assessing whether EU action is needed, and analysing the advantages and disadvantages of available solutions.' See European Commission, 'Better Regulation Guidelines' (Staff Working Document) SWD (2021) 305 final, 30.

[2313] ibid.

[2314] ibid. On the use of impact assessments and empirical data to establish the existence of EU competence: see Paul Craig, 'The ECJ and Ultra Vires Action: A Conceptual Analysis' (2011) 48 Common Market Law Review 395, 411–412; Sibony, 'Data and arguments: empirical research in consumer law' (n 51) 174-175.

[2315] ibid. See also Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making [2016] OJ L123/1, para 12: 'Impact assessments should cover the existence, scale and consequences of a problem and the question *whether or not Union action is needed*. They should map out alternative solutions and, where possible, *potential short and long-term costs and benefits*, assessing the economic, environmental and social impacts in an integrated and balanced way and using both qualitative and quantitative analyses. The principles of *subsidiarity* and *proportionality* should be fully respected, as should *fundamental rights*.' Emphasis added.

[2316] See European Commission, 'Better Regulation Guidelines' (n 2312) 35-36. On the role of impact assessments in the context of competence, proportionality and subsidiarity review by the Court of Justice, see Alberto Alemanno, 'The Better Regulation Initiative at the Judicial Gate: A Trojan Horse within the Commission's Walls

2. Conferral and the limits of the EU regulatory toolbox

A number of gaps can be identified in EU regulation of lifestyle risks, within each of the risk factors regulated as well as between them. In the field of tobacco, forceful action has been taken on cross-border advertising and in relation to certain forms of tobacco products, such as tobacco for oral use and tobacco with a characterising flavour, while only non-binding recommendations have been issued regarding smoke-free environments and other measures such as 'local' advertising rules, restrictions on the use of vending machines or age limits. This does not mainly result from political choices but reflects the limits set by the principle of conferral.

EU lifestyle risks harmonisation measures follow a double objective: that of ensuring the smooth functioning of the internal market while achieving a high level of public health protection. This means that no such measure that does not positively contribute to the internal market can be adopted by the EU. The legislative rhetoric is usually of reconciliation, as it is regarding the proportionality assessment of national measures. For those measures that have survived the application of free movement provisions, the EU must resort to harmonisation measures in order not to leave the market fragmented. Harmonisation would allow to have the best of both worlds: a well-functioning market and an improvement of public health.

On paper, considering especially the obligation contained in Article 114(3) of attaining a high level of protection for health, both objectives can be smoothly pursued together. The single EU rule unifies the market and protects health at the same time. The reality, however, is other. The conditions for recourse to Article 114 TFEU and equivalent legal bases[2317] limits the type of measures that can lawfully be adopted by the EU. These limits have not always been respected by the Union legislator, undermining the legitimacy of EU action in the field.

2.1. The conditions for recourse to Article 114 TFEU

As discussed in Chapter 2, in order to be lawfully adopted under Article 114 TFEU, EU measures must contribute, alternatively, to eliminating obstacles to free movement or appreciable distortions of competition.[2318]

Regarding distortions of competition, the condition that these must be 'appreciable' stems from a willingness to limit the reach of EU powers under Article 114 TFEU. Indeed, as any discrepancy in the regulatory environment affects competition between undertakings,[2319] were the Court to consider the existence of the slightest of these differences as sufficient to warrant

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or the Way Forward?' (2009) 15 European Law Journal 382, 396–399; Alberto Alemanno, 'A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control' (2011) 17 European Public Law 485, 499–504.

[2317] Articles 53(1) and 62 TFEU. See n 583.

[2318] The alternative rather than cumulative nature of these two conditions was confirmed by the Court in *Tobacco Advertising II* (n 26), para 67.

[2319] *Tobacco Advertising* (n 25), para 107. See also Dashwood, 'The Limits of European Community Powers' (n 603) 121; Gareth Davies 'Can selling arrangements be harmonized?' (2005) 30 European Law Review 370, 372.

the use of the EU internal market powers, the reach of that competence would be 'practically unlimited.'[2320]

Little guidance is to be found in the case-law on what constitutes an appreciable distortion of competition. In the *Tobacco Advertising* judgement, the Court considered that the concept did not include restrictions of forms of competition applying to all economic operators in a Member State,[2321] such as a ban on tobacco advertising applicable to all tobacco manufacturers. The Court also ruled that differences in legislation that would put some actors 'at an advantage in terms of economies of scale and increase in profits' would be too remote and indirect to constitute appreciable distortions.[2322] The conclusion would be different if such regulatory discrepancies led a business to relocate its economic activities in another Member State.[2323]

In some judgements, the Court did identify appreciable distortions. In *Titanium Dioxide*, this was the case of differences in legislation affecting the production costs in the titanium dioxide industry,[2324] and, in *Vodafone*, of divergent national laws regarding roaming charges which could significantly affect the production costs of the service provider.[2325] The presence of an appreciable distortion of competition, it seems, cannot be established without 'showing that [an] industry in at least some Member States is particularly disadvantaged'.[2326] It is a concept 'founded in the presence of inequality'.[2327] Hence, 'although vague, the test is not empty'.[2328]

Determining what constitutes an obstacle to free movement is made easier by the symmetry existing between this concept and that of restriction under free movement provisions, Articles 34, 49 and 56 TFEU in particular.[2329] The correspondence between these two concepts would seem logic, since harmonisation seeks to eliminate the barriers that cannot be overcome by negative integration alone.[2330] In dealing with the validity of measures under Article 114 TFEU,

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[2320] *Tobacco Advertising* (n 25), para 107. See also Alexandre Saydé, *Abuse of EU Law and Regulation of the Internal Market* (Hart Publishing 2014) 262: 'Taken to its extreme, regulatory neutrality would confer an infinite scope to Article 114 TFEU.'
[2321] *Tobacco Advertising* (n 25), para 113.
[2322] *Tobacco Advertising* (n 25), para 109.
[2323] ibid, para 110.
[2324] *Commission v Council* (n 563), para 12. See also *Tobacco Advertising* (n 25), para 109.
[2325] *Vodafone* (n 587), para 47. Advocate General Maduro took the view that the risk of possible future differences in national price controls creating obstacles to trade had not been established to the point of justifying the adoption of price control measures under Article 114 TFEU. He believed however that the Union legislature could regulate roaming prices to remove restrictions to free movement arising from the behaviour of private parties. See *Vodafone*, Opinion of Advocate General Poiares Maduro (n 601).
[2326] Davies, 'Can selling arrangements be harmonized?' (n 2319) 373.
[2327] ibid.
[2328] ibid.
[2329] On this 'symmetry thesis', see Somek (n 57) 103-105.
[2330] To this 'symmetry thesis', Alexander Somek opposes the 'asymmetry thesis' defended by Gareth Davies: ibid 105-107. Davies takes the view that the concept of 'obstacle' under Article 114 TFEU is broader than that of 'restriction' under Article 34 TFEU, meaning that selling arrangements, which are not covered by the latter provision, could still be harmonised under Article 114 TFEU: Davies, 'Can selling arrangements be harmonized?' (n 2319). See however the recent seemingly contradictory position adopted by Davies in 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 76: 'in order to understand what it means to remove an obstacle to movement we must have some definition of what such obstacles are, or perhaps of what it means to move freely. These *definitions are found in the case-law on free movement*, those judgments

the Court makes frequent references to its free movement case-law to establish the existence of obstacles to free movement.[2331]

In the case of the free movement of goods, one can therefore rely on the three tests developed by the Court of Justice to identify a measure having equivalent effect to a quantitative restriction: product requirements imposed on a foreign product that has already complied with its home regulation,[2332] selling arrangements that do not 'apply to all relevant traders operating within the national territory and […] affect in the same manner, in law and in fact, the marketing of domestic products and those from other Member States'[2333] and other measures which hinder the access of foreign products to the market of a Member State.[2334] For services, the concept of restriction to free movement covers 'any restriction, even if it applies without distinction to national providers of services and to those of other Member States, when it is liable to prohibit or otherwise impede the activities of a provider of services established in another Member State where he lawfully provides similar services'.[2335]

As established in Chapter 3, the Court of Justice takes a broad view of what constitutes a restriction to free movement, which means that most national measures may be harmonised under Article 114 TFEU. Yet, it should not be forgotten that Article 114 TFEU seeks the *removal* of obstacles to free movement and distortions of competition: '[i]n accordance with Article 114 TFEU, the legislature has competence to *eliminate* obstacles to free movement and to improve the functioning of the internal market. The latter essentially refers to *eliminating* distortions in competition'.[2336] Merely identifying obstacles to free movement or distortions of competition resulting from differences in national legislation is not enough to justify the harmonisation of these national provisions. The proposed EU measure must eliminate these obstacles or distortions. As the following developments will show, it is this condition which is most often overlooked or missing when the Court examines the validity of EU lifestyle measures, resulting in a wrongful appreciation of their compatibility with the requirements of Article 114 TFEU.

2.2. The content of EU harmonisation measures

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in which the Treaty prohibitions on restrictions on movement of persons, services, capital or goods are given direct effect'. Emphasis added.

[2331] See *British American* Tobacco (n 27), para 64; *Tobacco Advertising II* (n 26), para 57. See also Case C-154/04 *Alliance for Natural Health and Others* [2005] EU:C:2005:199, Opinion of Advocate General Geelhoed, para 35: where the Advocate General referred to the 'vitamins cases', such as *Commission v Denmark* (n 872) and *Commission v France* (n 872), rendered under Article 34 TFEU, to establish the existence of obstacles to free movement under Article 114 TFEU. Something similar can be seen in *Tobacco Advertising II* (n 26) 116-119.

[2332] *Cassis de Dijon* (n 612).

[2333] *Keck* (n 669), para 16.

[2334] *Trailers* (n 668), para 37.

[2335] *Säger v Dennemeyer* (n 1261), para 12.

[2336] *Czech Republic v Parliament and Council* (n 587), Opinion of Advocate General Sharpston, para 44, emphasis added. See also *Tobacco Advertising* (n 25), paras 84, 95; *Tobacco Advertising II* (n 26), para 69. Although the case-law has regrettably lost clarity on the matter, this condition still remains good law: see the direct and indirect references to previous cases made in *Philip Morris* (n 28), paras 58 and 81; *Poland v Parliament and Council* (n 587), para 32; Case C-482/17 *Czech Republic* v *Parliament and Council* [2019] EU:C:2019:1035, para 34.

There is little doubt that a wide range of regulatory options are available to the EU legislator under Article 114 TFEU. This is particularly the case of measures harmonising product requirements – rules relating to the designation, composition, packaging or labelling of products – which eliminate discrepancies in national legislation and facilitate the free movement of the products concerned.[2337] These form the bulk of the EU lifestyle risks regulatory apparatus. Here, the 'weight' given to health can be freely set – a given label or limit on the use of an ingredient may be more or less protective of health – while the nature of the measure remains pertinent from a free movement perspective.

Yet not all possible measures fulfil the criteria set for recourse to Article 114 TFEU, either way because the national rules harmonised do not constitute obstacles to free movement or distortions of competition, or because these are not eliminated by the proposed EU measure. Concrete examples of this have arisen, in two ways. In some instances, because of its lack of competence for harmonisation, the EU resorts to non-binding incentive measures which protect public health to a smaller extent. In some others, the lack of competence is disregarded by the Court so as to enable the legislator to adopt stronger health protective measures. In the latter case, the internal market rationale of the measure is disregarded, together with the proper delimitation of powers between the EU and its Member States. A number of measures will be explored, with a focus on the most problematic of all, the enactment of general bans at the EU level.

2.2.1. Products bans

Member States rules prohibiting certain products from being placed on the market clearly constitute obstacles to the free movement of goods,[2338] which the Union may harmonise away under Article 114 TFEU. Harmonisation is however conditioned to the removal of such obstacles, an element which is lacking where the Union itself prohibits an entire class of products. As stated by Advocate General Fennelly, 'a measure whose sole effect is to prohibit an economic activity cannot […] be said to constitute the removal of barriers to trade affecting that activity'.[2339] Any EU wide prohibition of a product can equally not be considered as removing appreciable distortions to competition, but rather as generalising a restriction of forms of competition, following the reasoning of the Court in *Tobacco Advertising*.[2340] This has yet not prevented the EU from banning two different categories of tobacco products from the market: tobacco for oral use and tobacco products containing characterising flavours. A careful analysis of the various judgements where the legality of these bans has been discussed shows that no convincing argument has been put forward, to date, as to how these measures can be considered genuine contributions to the smooth functioning of the internal market.

[2337] *British American Tobacco* (n 27), para 64.
[2338] See *Arnold André* (n 975) para 39; *Swedish Match* (n 975), para 38.
[2339] *Tobacco Advertising*, Opinion of Advocate General Fennelly (n 596), para 113. See also Somek (n 57) 104: 'a prohibition of the sale of certain tobacco products […] cannot be regarded as a measure conducive to Union trade for it effectively eliminates trade in certain products which would have been allowed to persist had standards of negative integration been applied'.
[2340] *Tobacco Advertising* (n 25), para 113.

2.2.1.1. Tobacco for oral use

The legality of the ban on tobacco for oral use was first contested in the *Swedish Match* and *Arnold André* judgements. The Court upheld the ban in both cases, laying down the general principle according to which a measure under Article 114 TFUE 'may consist in […] provisionally or definitively prohibiting the marketing of a product or products',[2341] without explaining however how such a ban fulfils the necessary conditions for the use of that article. The Court rightfully observed that prohibitions affecting tobacco for oral use enacted at the national level constitute obstacles to the free movement of goods,[2342] but fully disregarded the condition that these obstacles be removed by the EU harmonisation measure. The Court's approach was recently confirmed in the *Swedish Match II* case.[2343]

In *Swedish Match* and *Arnold André*, Advocate General Geelhoed offers a more detailed, albeit unconvincing, defence of the ban. Acknowledging that the 'prohibition on selling a product cannot itself improve the conditions for the marketing of that product' – '[i]n fact, the product is excluded from the market'–[2344] he nonetheless considers that the ban on the marketing of tobacco for oral use improves trading conditions for 'related products', insofar as it helps reducing the enforcement costs of the legislation concerning these latter products.[2345] 'In short, if snus is not on the market of the European Union, the effort to control the marketing of other smokeless tobacco products can be reduced.'[2346] It may be the case that monitoring the compliance of a product with certain standards is more consuming of resources than ensuring that this product is not placed on the market in the first place. Yet, Advocate General Geelhoed does not bring any element forward to substantiate this claim, nor does he explain how a reduction in enforcement costs benefits legally marketed products, by removing obstacles to trade from the point of view of the manufacturers or distributors of these products. It is hard not to see in the Advocate General's position an attempt to defend a rule which may very well be justified on grounds of public health, but does not fulfil the criteria set for the use of the Union internal market competence.

This lack of contribution to the internal market also appears from the impact assessment accompanying the Commission's proposal for the TPD, where the possibility of lifting the ban on tobacco for oral use was discussed. Such a move, it was argued, would lead certain Member States to enact bans at the national level which 'could negatively affect the functioning of the internal market if it reintroduces the fragmentation of the market that existed before 1992 [the year where the ban was enacted at the EU level]'.[2347] How, one may ask, can a situation where a product can be traded in some Member States be worse, from the perspective of removing barriers to trade, than a situation where there is no market at all for this product ? The EU

[2341] *Arnold André* (n 975), para 35; *Swedish Match* (n 975), para 34.
[2342] *Arnold André* (n 975), paras 38-40; *Swedish Match* (n 975), paras 37-39.
[2343] *Swedish Match II* (n 1620), paras 55-58.
[2344] Cases C-434/02 *Arnold André* and C-210/03 *Swedish Match* [2004] EU:C:2004:487, Joined Opinion of Advocate General Geelhoed, para 78.
[2345] ibid, para 79.
[2346] ibid.
[2347] European Commission, TPD impact assessment (n 1642), part 1, 62. Following the same logic, the impact assessment considers that banning all STPs from the EU market would bring additional benefits to the internal market if compared to the sole ban on tobacco for oral use, ibid 72.

legislator may very well consider that uniformity, rather than the removal of barriers to trade, is a desirable goal for the internal market, but such are not the criteria set by the Court, which the Court has itself regrettably decided to disregard.

2.2.1.2. Tobacco with a characterising flavour

The EU prohibition on the marketing of tobacco with characterising flavours suffers from a similar defect and was also wrongfully upheld by the Court in *Poland v European Parliament and Council* and *Philip Morris*. In both cases, as it did in *Swedish Match* and *Arnold André*, the Court offered very little by way of justification for the legality of the ban, simply pointing at the obstacles arising from Member States' decisions to ban cigarettes with characterising flavours, without once again paying due concern to the necessity of removing these obstacles to lawfully act under Article 114 TFEU.[2348]

Advocate General Kokott's defence of the measure, albeit more convincing than that deployed by Advocate General Geelhoed, appears equally misguided. According to her, the ban effectively removes obstacles to trade because it 'serves to create uniform trade conditions for all tobacco products throughout the European Union'.[2349] Rather than prohibiting a class of products, the ban would merely constitute a restriction of their composition : 'in other words, tobacco products may in principle still be placed on the market in the European Union, but only without characterising flavours'.[2350] Advocate General Kokott construes the prohibition of characterising flavours as a product requirement. If that argument could be accepted, this would indeed render the measure lawful under Article 114 TFEU.[2351]

Taking such a view presupposes however to accept that flavoured and unflavoured tobacco products are similar enough from the point of view of the consumer, so that banning the former effectively opens up a market segment for the latter. This can be contested and, in any way, would need to be proven. Determining the 'common quality' of the banned and authorised product is crucial for assessing the legality of a ban under Article 114 TFEU.[2352] In this case, using a characteristic flavour significantly alters the taste of a cigarette,[2353] it is hence doubtful that flavoured and unflavoured cigarettes can be considered as similar products. Most importantly, if these two products were indeed similar, a sufficient degree of substitutability would exist between them. It would mean that someone barred from smoking a menthol

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[2348] *Poland v Parliament and Council* (n 587), paras 57-64; *Philip Morris* (n 28), paras 117-124.
[2349] Case C-547/14 *Philip Morris Brands e.a.* [2015] EU:C:2015:853, Opinion of Advocate General Kokott, para 83. This stands in contradiction with paragraph 82, where she mentions 'a class of other products', see also para 65.
[2350] ibid, para 83.
[2351] See also Somek (n 57) 132: 'the prohibition of a certain product may be conducive to removing distortions of competition so that similar products (linked via cross-elasticity, of course) are made better off on the market'.
[2352] Geber (n 951) 168.
[2353] As recognised by Advocate General Kokott herself in *Philip Morris* (n 2349), para 103: 'In short, if characterising flavours facilitate or assist smoking because *they can reduce or camouflage the generally very bitter and even pungent taste of tobacco smoke*, it is not unreasonable to assume that dispensing with such flavours may have the opposite effect and thus contribute to improved health protection.' Emphasis added.

cigarette would switch to a classic cigarette,[2354] which goes against the very rationale of a ban aimed at limiting the overall consumption of tobacco products.[2355] Indeed, this ban can only be useful if a reasonable amount of people quit smoking altogether after it is introduced, or do not become smokers.

The prohibition of characterising flavours thus illustrates very well how market and health can contradict. On the one hand, the ban is enacted in order to stop people from continuing or starting to smoke. On the other hand, its internal market contribution can only be valid if menthol and other cigarettes are similar, in which case any curbing effect on consumption is unlikely to happen. This confusion as to what should be the true objective of the ban actually appears from the text of TPD itself, whose Recital 16 states that: 'products with characterising flavour with a higher sales volume should be phased out over an extended time period to allow consumers adequate time to switch to other products', here as well contradicting the public health rationale of the ban.[2356]

2.2.1.3. Constructive and destructive bans

In the cases of tobacco for oral use and tobacco with characterising flavours, the EU legislator has put 'destructive' bans in place.[2357] This situation must be distinguished from 'constructive' bans, introduced within the same class of products, which can indeed serve to create uniform trading conditions.[2358] An example of a constructive ban in the field of lifestyles, rightfully

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[2354] See, regarding dark-tobacco and light-tobacco cigarettes, the similar observation made by Advocate General Alber in Case C-302/00 *Commission v France* [2001] EU:C:2001:449, para 69: 'The fact that it is unlikely that any smoker might become a non-smoker were one of the two cigarette types no longer available alone demonstrates their substitutability'.

[2355] As accepted by the Court in *Philip Morris* (n 28), para 108 and expressed by Advocate General Kokott in *Philip Morris* (n 2349), para 103: 'It appears perfectly plausible that a prohibition on menthol cigarettes and other flavoured cigarettes, like that introduced by the Union legislature, makes the initiation of tobacco consumption less attractive to adolescents and young adults and, at the same time, makes it easier for habitual smokers — or at least some of them — to escape nicotine addiction. In short, if characterising flavours facilitate or assist smoking because they can reduce or camouflage the generally very bitter and even pungent taste of tobacco smoke, it is not unreasonable to assume that dispensing with such flavours may have the opposite effect and thus contribute to improved health protection.' The same logic underlies the ban of tobacco for oral use: see *Arnold André*, (n 975) para 38; *Swedish Match* (n 975), para 37.

[2356] See also *Planta Tabak* (n 1635), para 47.

[2357] See the difference made by Scott Crosby between constructive and destructive bans in the case of the prohibition of ingredients: Crosby (n 33) 186. See also Anatole Abasquene de Parfourus, '"Breaking through the Foul and Ugly Mists of Vapours"— Regulation of Alternative Tobacco and Related Products by the New TPD and Exercise of EU Competence' (2018) 18 *German Law Journal* 1291, 1302: the author considers the ban of characterising flavours to be a destructive ban.

[2358] See Derrick Wyatt, 'Community Competence to Regulate the Internal Market' in Michael Dougan and Samantha Currie (eds), *50 Years of the European Treaties : Looking Back and Thinking Forward* (Hart Publishing 2009), 117: 'As noted above, the rationale of withdrawal from the market of non-compliant products is to enforce application of the relevant safety standard, and contribute to the elimination of disparities between national rules and their application, and thereby to the free movement of goods between the Member States. Prohibiting non-compliant products as a means of enforcement of a safety standard application of which facilitates the free movement of compliant products is quite different from prohibition outright of a product.' See also Stephen Weatherill 'Protecting the Internal Market from the Charter', in Sybe de Vries, Ulf Bernitz and Stephen Weatherill (eds), *The EU Charter of Fundamental Rights as a Binding Instrument: Five Years Old and Growing* (Hart Publishing 2015) 229.

upheld by the Court of Justice in *Alliance for Natural Health*,[2359] is that contained in Directive 2002/46 on food supplements.[2360] The Directive establishes a list of authorised vitamins and minerals which may be used in the manufacture of food supplements.[2361] Thus doing, it prohibits certain products from being placed on the market, while at the same time opening the market for other similar food supplements.[2362]

Another constructive ban may be found at Article 18 of the TPD, which allows Member States to prohibit the cross-border distance sales of tobacco products. Such a measure may not be removing obstacles to trade as regards the activity of distance selling itself, but serves however, as apparent from Recital 33 of the TPD, to limit access to tobacco products that do not comply with the Directive, hence preventing illegal trade. In this way, it does contribute to the creation of uniform trading conditions for tobacco products and facilitate the smooth functioning of that market. The Court has recognised the contribution of such measure by stating that 'an EU measure adopted on the basis of Article 114 TFEU may incorporate provisions seeking to ensure that requirements aimed at improving the conditions for the functioning of the internal market are not circumvented'.[2363] The Court did not rule explicitly on the validity of the ban on CBDS but seemed to assume in *Pillbox 38* that the stated effects of the measure were present.[2364]

As Derrick Wyatt expressed powerfully, 'the [EU] lawmaker has no legitimate interest in the banning of free-standing products. […] Action at the [EU] level makes no contribution to the internal market in fact; it simply asserts [EU] competence for the sake of an abstract principle; the principle that in a single market it is central authority which decides which products or services may be placed on that market.'[2365] It is, though, this abstract principle that Advocate General Geelhoed defends when writing that 'the primary goal of the internal market provisions of the EC Treaty that one single market appear, that is not fragmented by divergent national rules. This goal does not have as a consequence that all possible products can be sold on that market, even if they harm the health of users.'[2366]

This vision of an internal market where homogeneity matters more than free movement also transpires from the discussion of a possible general ban on all tobacco products, contained in the TPD impact assessment.[2367] This option was not considered feasible, due to 'unreasonable compliance costs' and the likely appearance of an illegal market which would undermine the very objective of stopping the use of tobacco in the European Union. At no point does the

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[2359] Case C-154/04 *Alliance for Natural Health and Others* [2005] EU:C:2005:449.
[2360] Directive 2002/46, arts 3, 4(1) and 15(b).
[2361] ibid, annex I and II.
[2362] Although it must be regretted than neither the Court nor the Advocate General were able in this case to formulate such argument and failed explain why the directive was indeed valid under Article 114 TFEU: see *Alliance for Natural Health* (n 2359), paras 34-39; Case C-154/04 *Alliance for Natural Health and Others* [2005] EU:C:2005:199, Opinion of Advocate General Geelhoed, paras 31-36.
[2363] *Pillbox 38* (n 1662), para 123; see also *Tobacco Advertising* (n 25), para 100; *British American Tobacco* (n 27), para 82.
[2364] *Pillbox 38* (n 1662), para 124.
[2365] Wyatt (n 2358) 119-120.
[2366] *Arnold André* and *Swedish Match*, Joined Opinion of Advocate General Geelhoed (n 2345), para 80.
[2367] European Commission, TPD impact assessment (n 1642), part 1, 49-50.

Commission addresses the question of the existence of an EU competence to enact such a sweeping ban. Yet, one fails to understand how such a wide-ranging prohibition contributes in any way to the removal of obstacles to trade or distortions of competition, and how the internal market, as a place where goods circulate freely, is supposed to benefit from it.

2.2.2. Other measures

Beyond product bans, a range of other policy options appear inaccessible to the EU legislator under Article 114 TFEU. Unlike for product bans however, the EU has refrained from acting, in compliance with the principle of conferral. The limited nature of EU legislative competence has prevented the attainment of a high level of protection of public health.

The prime example of this is the regulation of tobacco advertising, most forms of which are currently prohibited under EU law. National measures restricting or banning certain types of advertising can be considered as obstacles to free movement, in line with the Court's assessment under Article 34 and 56 TFEU (see Chapter 3, Section 5). The various prohibitions on tobacco advertising currently in place at the EU level, on television, radio and in periodicals, appear perfectly lawful under Article 114 TFEU, as these facilitate the free circulation of the medium to which they are associated. They are constructive bans: while restricting advertising activity and hence arguably generalising the presence of obstacles to free movement from the point of view of advertisers and tobacco manufacturers, these bans enable the cross-border movement of magazines and audiovisual programmes by removing the differences in national legislation affecting them, thus providing for a level playing field.[2368]

On the other hand, as the Court ruled in *Tobacco Advertising*, the prohibition of more static forms of advertising, such as the use of posters or advertising spots in cinemas, is not an option available to the EU legislator, since it does not remove obstacles to free movement.[2369] Indeed, contrary to press or audiovisual products, billboards or movie theatres are not mobile once they are installed, which means that diverging national rules on advertising cannot affect their free circulation. A prohibition of these static forms of advertising is a destructive ban, it reduces opportunities for trade without opening a market for any other economic activity. Furthermore, as underlined by the Court in the *Tobacco Advertising* judgement, differences in advertising

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[2368] *Tobacco Advertising* (n 25), paras 96-98; *Tobacco Advertising II* (n 26), para 71. See also TAD, recital 1: 'There are differences between the Member States' laws, regulations and administrative provisions on the advertising of tobacco products and related sponsorship. Such advertising and sponsorship in certain cases crosses the borders of the Member States or involves events organised on an international level […]. The differences in national legislation are likely to give rise to increasing barriers to the free movement between Member States of the products or services that serve as the support for such advertising and sponsorship.'

[2369] See *Tobacco Advertising* (n 25), para 99. See also *Tobacco Advertising*, Opinion of Advocate General Fennelly (n 596), para 113: 'It is apparent to me from the foregoing that the Advertising Directive cannot be regarded as removing barriers to, and thereby facilitating, trade in services whose content is exclusively devoted to the advertising or sponsorship of tobacco products, including both those services which find tangible expression in goods such as printed brochures, leaflets or posters and the service elements of free distribution of tobacco products. The Directive's sole effect, within its extensive sphere of application, is to prohibit trade in the services in question. There are no compensating gains for undertakings active in the production or provision of such services.'

regulation between member states cannot be considered as appreciable distortions of competition.[2370] No possibilities therefore exist for a binding prohibition of static forms of advertising at the EU level,[2371] which led the Court to annul the first version of the Tobacco Advertising Directive, Directive 98/43. The unlawful elements taken away from the first TAD were subsequently included in the non-binding Council Recommendation of 2 December 2002, which covers types of advertising whose prohibition cannot be enacted by the Union: the use of promotional items such as ashtrays, lighters, parasols; the use of billboards, posters and other indoor or outdoor advertising techniques; or the use of advertising in cinemas.[2372]

Retail display bans are another type of measures seeking to limit promotional opportunities for tobacco or other products. The introduction of an EU-wide retail display ban was envisaged by the Commission as part of the revision of the 2001 TPD but was set aside on subsidiarity grounds.[2373] It is yet doubtful that the EU would have the competence to enact such a ban. As discussed in Chapter 3, it is far from obvious that a retail display ban constitutes an obstacle to free movement when enacted at the national level, or, for that matter, an appreciable distortion of competition. In any way, reasoning by analogy with advertising, an EU-wide retail display ban would not remove any of the obstacles created by national bans but, rather, by generalising a ban on a specific promotional technique, would reduce the opportunities for foreign products to penetrate each of the domestic markets.[2374]

The 2002 Recommendation also contains rules regarding other aspects of tobacco control. It recommends that Member States require vendors of tobacco products 'to establish that tobacco purchasers have reached the age for purchase of such products required in national law, where such an age limit exists', and restrain the self-service of tobacco products in shops or restrict the use of tobacco vending machines to places where person under the age limits, usually minors, have no access.[2375] Regarding age limits for the purchase of tobacco products or alcoholic beverages, even if these could be analysed as restrictions on the use of a product prohibited under Article 34 TFEU, hence constituting obstacles to free movement within the meaning of Article 114 TFEU, an EU measure generalising this type of rules would also not be capable of removing obstacles to trade or distortions of competition. The same can be said of a measure prohibiting or restricting the use of vending machines. An EU regulation of this method of sale was also considered during the revision process leading to the adoption of the

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[2370] *Tobacco Advertising* (n 25), paras 108-104.
[2371] See TAD, recital 12: 'Other forms of advertising, such as indirect advertising, as well as the sponsorship of events or activities without cross-border effects, fall outside the scope of this Directive. Subject to the Treaty, Member States retain the competence to regulate these matters as they deem necessary to guarantee the protection of human health.'
[2372] Council Recommendation of 2 December 2002, para 2.
[2373] European Commission, TPD impact assessment (n 1642), part 1, 50.
[2374] For a diverging view, see Alemanno, 'Out of Sight, Out of Mind. Towards a New EU Tobacco Products Directive' (n 33) 217: according to Alemanno, 'display ban measures, as general rules mandating a common standard for the marketing and sale of cigarettes in Europe, would actually remove any possible obstacles emerging from disparities among national rules'.
[2375] Council Recommendation of 2 December 2002, para 1.

TPD and abandoned on grounds of subsidiarity.[2376] Here again, leaving aside the doubts as to the qualification of these national measures as obstacles to free movement or appreciable distortions of competition, it seems that any EU attempt at harmonising these measures would not constitute a removal of obstacles or distortions but a reinforcement of those.[2377]

Finally, another illustration of the constitutional limits to EU action in the field of lifestyle risks is to be found in the regulation of smoke-free environments, a field which remains non-harmonised by the EU and only subject to the 2009 Council Recommendation. As previously discussed, national rules prohibiting smoking in certain public spaces are unlikely to constitute restrictions to the free movement of goods. Assuming that they do, the conclusion should be once again that any EU rule prohibiting the use of tobacco products in determined areas would only constitute a generalisation of the obstacles or distortions present at the national level. Notwithstanding the regulation of smoking in workplaces,[2378] the EU does not have any competence to impose smoke-free environments to Member States, a view which seems to be also shared by the European Commission.[2379] It is not the 'concerted activity [of] the tobacco industry [which] may explain why the EU has yet to take any further action in this area, despite evidence of widespread public support',[2380] but the limits of its competence.

2.3. Interim conclusion

Notwithstanding the legislative and judicial rhetoric of reconciliation, the internal market nature of the EU harmonisation competence limits the range of public health options available to the legislator. Measures that fall straightforwardly within that competence are product requirements, such as information disclosures or warnings, or are those that relate most closely to free movement, like cross-border advertising.[2381] These interventions tend to be situated at the lower end of the regulatory spectrum, they 'provide information' and 'enable choice' rather than 'eliminate' or 'restrict choice'.[2382] This is logical, since these are also likely to be less disruptive for economic operators. A market-making competence, even if it requires the removal of formal obstacles to trade rather than an actual increase in trade, cannot be utilised to eliminate entire swathes of the market.

[2376] European Commission, TPD impact assessment (n 1642), part 1, 50.
[2377] See Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1767.
[2378] The EU has the power to regulate smoking in workplaces under its social policy competence, contained in Article 153 TFEU. See Chapter 2, Section 3.1.
[2379] See Karen Banks, 'The Lisbon Treaty's Competence Arrangement Viewed from European Commission Practice', in Garben and Govaere (n 523) 196-97: 'Some years ago, the competent services of the Commission were convinced that there was a need for binding EU rules on smoking in public places. However, after examination of all possibilities, it was concluded that the most they could propose was a Council Recommendation. This resulted in Council Recommendation of 30 November 2009 on smoke-free environments.'
[2380] Anna Gilmore and Martin McKee, 'Tobacco Control Policy: The European Dimension' (2002) 2 Clinical Medicine 335, 338.
[2381] The EU also has broad powers to enact measures in the field of indirect taxation under Article 113 TFEU, although the unanimity requirement contained in that provision and the wide differences in prices existing between Member States render the adoption of strengthened tax measures on unhealthy commodities unlikely.
[2382] See the 'Nuffield ladder' Chapter 1, Section 6.1.

The current situation is not satisfactory from a health perspective. Ideally, all options should be on the table. It is not to say that product bans and rules regulating the use of cigarettes in the public sphere or the retail environment should necessarily be adopted at the EU level but that deciding whether to adopt these measures or not should be left to political judgement, rather than being foreclosed due to the inadequacy of the current competence framework.

Concluding this section by discussion the limits to EU action may come as a surprise to some. Until now, the discussion has rather been focusing on the absence of limits resulting from the Court's interpretation of Article 114 TFEU.[2383] Yet, as a careful analysis of the various tobacco judgements reveals, the unbound character of this competence proceeds from the Court watering down its own case-law rather than openly renouncing its long-standing *Tobacco Advertising* criteria. The adoption of pure public health measures under the guise of the internal market is not only a problem for the vertical division of powers in the EU, but it also affects the legitimacy of EU lifestyle risks policy. It makes the law conceptually poorer, because measures which have nothing to do with free movement have to be defended as if they were about increasing trading opportunities.[2384]

Public health is not the only value that suffers from this situation. The internal market that emerges from tobacco legislation and comparable regulatory endeavours is a market that makes little sense economically. It is a market which may be 'more perfect in a certain legal formal sense, but [is] in fact less active, and in which even cross-border trade [is] reduced',[2385] a market which pursues regulatory neutrality to an absurd extent.[2386] Although the internal market is primarily a legal rather than an economic concept,[2387] it cannot be dissociated from the economic gains expected from its establishment and its deepening.[2388]

3. Preserving Member State regulatory autonomy

A second limit to the regulation of lifestyles risks at the EU level comes from the necessity to preserve a degree of regulatory autonomy for Member States. 'Tensions between unity and diversity are an inherent feature of the European integration project,'[2389] yet, these are particularly relevant to a field market by cultural and ethical diverseness, where practices,

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[2383] Barents (n 601); Wyatt (n 2358); Stephen Weatherill, 'The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case-law has become a "Drafting Guide"' (2011) 12 German Law Journal 827; Saydé (n 2320) 262. A good example the 'drafting guide' approach referred to by Weatherill can be seen in *Pillbox 38* (n 1662)112, read in conjunction with recital 43 of the TPD.

[2384] Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 85.

[2385] ibid 80.

[2386] On the paradigm of regulatory neutrality in the internal market: see Saydé (n 2320) 235-242.

[2387] Weatherill, *The Internal Market as a Legal Concept* (n 607).

[2388] Saydé (n 2320) 230; see also recently Panu Poutvaraa and others, 'Contribution to Growth: Free Movement of Goods. Delivering Economic Benefits for Citizens and Businesses' (2019) EPRS, accessed 11/05/2023 [https://www.europarl.europa.eu/RegData/etudes/IDAN/2019/631063/IPOL_IDA(2019)631063_EN.pdf]. In the same vein, the Better Regulation Toolbox refers to the following 'Single Market benefits' arising from Union legislation: trade creation, more competitive markets – 'bigger choices, higher quality and lower prices' – and gains in productivity: European Commission, 'Better Regulation Toolbox' (n 103) 207.

[2389] Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology* (n 2) 11.

perceptions and preferences may differ widely and call for a different degree or mode of public intervention.

The following observation by Somek regarding EU tobacco policy holds true for lifestyles more generally:

> If it is true that the weight attributed to health is dependent on cultural norms, the allocation of power for anti-tobacco regulation is not merely a matter of choosing *the adequate level of risk-regulation* with an eye to maximizing its effect; rather, it requires answering the question at which point the *differences in cultural traditions may legitimately prevail* over a federal authority's ambition to legitimize its existence by enhancing what it takes to be the welfare of its subjects.[2390]

Somek puts the finger on two interrelated but separate questions regarding the relationship between cultural diversity and EU lifestyle policy, and, more generally, regarding the space for regulatory autonomy in that field. Cultural diversity may first undermine the pertinence of action undertaken at the EU level, from a public health perspective, raising the question of determining '*the adequate level of risk-regulation* with an eye to maximizing its effect'. A health-based argument can be made for continuous action at the national level, either way by leaving Member State a certain degree of autonomy or by refraining from acting altogether. The second question, clearly laid down by Somek, is 'at which point the differences in cultural traditions may legitimately prevail' over the objective of promoting health at the EU level. Here, even where EU action proves to be the most beneficial for health, the preservation of cultural diversity, as a competing objective, would justify to leave some regulatory space to Member States. To provide a concrete illustration of these two situations, we first take a look at some specific issues that have arisen as regards EU nutrition policy and food information.

The need to preserve national regulatory autonomy may result in two main outcomes, keeping in mind that the protection of a national tradition cannot 'in itself release Member States from their obligations under EU law'.[2391] Either the EU refrains from acting or the EU acts in a way that does not fully displace Member States' capacity to act, the key instruments being respectively subsidiarity and minimum harmonisation.

3.1. Cultural diversity in EU nutrition policy

In 1987, the Commission wrote, regarding the European Cancer Code, that '[a]t European level, however, it would be unrealistic to go into too much detail, especially as regards food. Indeed, eating habits are an *integral part of the culture* of a community and *vary considerably* between countries, regions or even towns'.[2392] In its 2000 Resolution on health and nutrition, the Council acknowledged that '*the diversity of food cultures throughout the European Union constitutes a valuable asset that ought to be respected*, and that it is necessary to take this into

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[2390] Somek (n 57) 94, emphasis added; see also 145.
[2391] Case C-115/13 *Commission v Hungary* [2014] EU:C:2014:253, para 44; Case C-91/18 *Commission* v *Greece* [2019] EU:C:2019:600, para 74.
[2392] European Commission, Europe against cancer' programme: Proposal for a plan of action 1987 to 1989 (1373), 32, emphasis added.

account when drawing up and implementing nutritional health policies, which must therefore be defined first of all at national level'.[2393]

The wide differences existing in national food cultures represent a challenge for the devising and adoption of a nutrition policy at the EU level, both from a health-based and a diversity-based perspective. The regulation of food information provides a good illustration thereof, particularly the attempt to adopt nutrient profiles and a front-of-pack label at the EU level.

As discussed in Chapter 6, one of the reasons behind the difficulty to adopt nutrient profiles for foods common to all Member States, as provided for in the Claims Regulation, is the differences in nutrient intake recommendations and food-based dietary guidelines existing between Member States.[2394] Food-based dietary guidelines are 'policy recommendations in the form of guidelines for healthy eating […] primarily intended for consumer information and education'.[2395] These dietary guidelines vary from country to country and are largely influenced by cultural factors and local patterns of consumptions. In its scientific opinion on the matter, EFSA concluded that it was 'not feasible to establish detailed and effective food based dietary guidelines which could be used at the EU level'.[2396] In that regard, EFSA pointed to a number of factors: diverging public health priorities between countries[2397]; diverging priorities in selecting principal nutrients, 'depending on the country-specific nutrient intake levels and on the impact of the related diseases on morbidity and mortality rates'; and 'wide disparities in dietary/cultural habits and the availability of food products between European Member States'.[2398] Food-based dietary guidelines, the EFSA concluded, 'will fail if the public finds them culturally unacceptable'.[2399] Recommending the intake of a food that is virtually unknown in a given country, or only consumed by a small fraction of the population, even if it is favourable nutritionally, is unlikely to influence consumption and to yield any significant positive health outcome. Whatever their purpose is, the application of nutrient profiles needs to result in a categorisation of foods that fits a country's food-based dietary guidelines.

Nutrient profiles are not only relevant to the Claims Regulation, but also to the upcoming reform of front-of-pack nutrition labelling. Evaluative FoP labels, such as the Nutri-Score, which result in the classification of products along a graded scale, use nutrient profiles in order to determine the relative healthiness of products. A relevant predictor of the effectiveness of a FoP scheme to improve diets is its ability to adequately distinguish between healthy and unhealthy products within and across food groups, and its consistency with dietary

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[2393] Council Resolution of 14 December 2000 on health and nutrition, recital 11, emphasis added.
[2394] EFSA Panel on Dietetic Products, Nutrition and Allergies, 'The Setting of Nutrient Profiles for Foods Bearing Nutrition and Health Claims Pursuant to Article 4 of the Regulation (EC) No 1924/2006' (2008) 6 The EFSA Journal 1, 4. See also Friant-Perrot and Garde (n 95) 142.
[2395] EFSA Panel on Dietetic Products, Nutrition, and Allergies, 'Scientific Opinion on Establishing Food-Based Dietary Guidelines' (2010) 8 The EFSA Journal 1460, 1461.
[2396] ibid 1484; see also Angela Bechthold and others, 'Perspective: Food-Based Dietary Guidelines in Europe—Scientific Concepts, Current Status, and Perspectives' (2018) 9 Advances in Nutrition 544.
[2397] EFSA Panel on Dietetic Products, Nutrition, and Allergies, 'Scientific Opinion on Establishing Food-Based Dietary Guidelines' (n 2395) 1484.
[2398] ibid 1485.
[2399] ibid.

recommendations.[2400] The Nutri-Score has for instance been found to be effective in discriminating the nutritional quality of products in different national contexts and to be consistent with a set of different national dietary guidelines.[2401] Whichever label is chosen by the Commission for a generalisation at the EU level, it will be crucial that it can be applied in all Member States in accordance with the local food-based dietary guidelines, which may constitute an additional obstacle to its adoption.

Cultural diversity in food may therefore affect the EU's ability to act in a manner that is pertinent for public health, where variations in consumption patterns make the adoption of EU-level dietary recommendations, and instruments based thereon, less pertinent. It may also constitute a difficulty in its own right, leading some Member States to oppose EU-level regulation which they see as threat to some of their culinary traditions or traditional products.

A sensitive area of EU food policy is the protection of the traditional food and agricultural products covered by a quality scheme (PDO, PGI, GI, etc., see Chapter 1, Section 5.3), which usually have a great cultural relevance. Yet, these products tend to be high in fat, salt or sugar and to be energy-dense,[2402] meaning that policies that discourage the consumption of HFSS foods are likely not to be beneficial to quality traditional products, at least those whose nutritional composition is not favourable. Further, products benefitting from protection under one of EU quality schemes need to comply with strict requirements as to their composition, their method of production and, for geographical indications, as to the origin of the raw materials and where the production process takes place. Once these products are granted protection, their characteristics are therefore set and cannot be modified at will. This is a fundamental difference with industrial products, whose composition can be reformulated, and which could therefore be less penalised by the application of nutrient profiles. As previously discussed in Chapter 6, a number of Member States opposed the proposal of the Commission on nutrient profiles for fear of a segregation of the market between traditional products and processed foods.

Similar considerations have been expressed regarding FoP nutrition labelling. In 2016, the Council delegations of seven Member States signalled their opposition to the MTL label developed in the United Kingdom (see Table 3),[2403] pointing at the detrimental effect that it

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[2400] Chantal Julia and Serge Hercberg, 'Development of a New Front-of-Pack Nutrition Label in France: The Fivecolour Nutri-Score' (2017) 3 *Public Health Panorama* 4, 715.

[2401] Szabo de Edelenyi and others (n 2176); Louise Dréano-Trécant and others, 'Performance of the Front-of-Pack Nutrition Label Nutri-Score to Discriminate the Nutritional Quality of Foods Products: A Comparative Study across 8 European Countries' (2020) 12 Nutrients 1303; Urška Pivk Kupirovič and others, 'Facilitating Consumers Choice of Healthier Foods: A Comparison of Different Front-of-Package Labelling Schemes Using Slovenian Food Supply Database' (2020) 9 Foods 399.

[2402] Out of 1577 PDO/PGI, more than half (841) belong to the following categories: 'Fresh meat' 'Meat products (cooked, salted, smoked, etc.)' 'Cheeses', 'Oils and fats', 'Chocolate and derived products', 'Bread, pastry, cakes, confectionery, biscuits and other baker's wares': see eAmbrosia [https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/geographical-indications-register/] accessed 11/05/2023.

[2403] Council of the European Union, '"Hybrid" Nutrition Labelling System Recommended in Some Member States: Information from the Delegations of Italy, Cyprus, Greece, Portugal, Romania, Slovenia and Spain' (2016) 6585/16.

would have on EU quality products. They deplored that some of these products 'would get a "red label" in reason of their composition' and therefore risk being shunned by consumers, in contradiction with European quality policy.[2404] In its 2020 report on FoP labelling, the Commission observed that '[e]xperts from a few EU national competent authorities favoured reductive FOP schemes providing nutrient-specific information, based on portion sizes, without evaluating foods and are concerned that under evaluative FOP schemes some traditional products and regional specialities (e.g. cheeses, edible oils, meat products) might display labels that deter consumer purchase'.[2405] Some Member States therefore call for an exemption of PDO, PGI, TSG and single ingredient products, such as olive oil, from any EU FoP label, basing their claim on the necessity to protect the European cultural heritage.[2406]

Member States' reticence towards the adoption of an evaluative FoP label at the EU level has taken a particularly bitter turn regarding Nutri-Score, which they suspect will be the label proposed by the Commission for adoption. Italy in particular strongly opposes the colour-coded label, which it sees as a major threat against its traditional products and its food heritage.[2407] This position is shared by all major stakeholders in the country: professional unions, food industry groups, government, political parties, traditional food consortiums, generalist newspapers, etc.[2408] Although some of the criticisms are aimed at the scientific relevance of the label and its underlying algorithm, resistance mostly arises from a desire to defend the 'Mediterranean diet' and the excellency of Italian cheeses, cured meat, and olive oil against what is perceived as a stigmatising label[2409] and a deliberate 'French' plot to undermine Italian cuisine and traditions.[2410]

This position was clearly laid down in two parliamentary questions recently addressed by Italian MEPs to the Commission:

> The 'Nutri-Score' system is a label on food packaging which classifies foods by calculating a nutritional score based on a five-colour scale, giving the food a generally positive or negative nutritional profile. This system *creates prejudice around food* and disregards the amount consumed and its inclusion in a diet, influencing consumers in their purchases and guiding them *towards lower-quality products*.

[2404] ibid 2.
[2405] European Commission, Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration (n 2160) 17.
[2406] Council of the European Union, 'Non Paper on the "Front of Pack Nutrition Labeling – FOPNL" by Cyprus, Czech Republic, Greece, Hungary, Italy, Latvia and Romania' (2020) 10846/20, 4.
[2407] Fialon, Nabec and Julia (n 30).
[2408] ibid.
[2409] ibid. As pointed out by the authors, though, the products usually singled out as being penalised by the Nutri-Score are actually those whose consumption should be limited as part of the Mediterranean diet: cheese, cured meat, etc.
[2410] Politico, 'Italy claims it's winning the war against French food labels' (2022), accessed 11/05/2023 <https://www.politico.eu/article/italys-war-against-french-food-label-starts-to-pay-dividends/> ; Euractiv, 'France might drop support for Nutri-score, say Italians' (2021), accessed 11/05/2023 <https://www.euractiv.com/section/agriculture-food/news/france-might-drop-support-for-nutri-score-say-italians/>.

> Among the products regarded as negative are extra-virgin olive oil, Parmigiano Reggiano and Grana Padano cheeses and Parma ham – *all symbols of the Mediterranean diet* which continues to be regarded as one of the best diets […].[2411]
>
> The Nutri-score system uses five colours labelled from A to E to indicate whether a food is healthy or unhealthy, based on saturated fat, salt or sugar content for example. It does not, however, indicate recommended intake as part of a balanced diet. *As a result, many PDO/PGI 'Made in Italy' products* (including Grana Padano, Parmigiano Reggiano, Parma ham or extra-virgin olive oil) *are considered unhealthy* and labelled with a red D or E sticker, while certain fizzy drinks are given green B stickers to denote healthy foods. This colour-coded labelling system […] *penalises traditional labelling with geographical indications*. Italian producer associations regard the Nutri-score system as discriminatory, since it gives distorted and incomplete information regarding nutritional values, *arbitrarily classifying as dangerous many Mediterranean food products*.[2412]

Similar arguments have been voiced to oppose plans by the Commission, as parts of the Beating Cancer Plan, to propose the extension of the mandatory indication of ingredients and the nutrition declaration provided for in the Food Information Regulation to alcoholic beverages, and the introduction of health warnings on the packaging of those products.[2413] The idea that wine, a flagship European product with so much cultural value, could be labelled as unhealthy creates strong resistance. This led Margaritis Schinas, EU Commissioner in charge of the 'European way of life', to clarify that wine was 'part of who we are and of our way of life', and that '[c]ertainly the European Union will not ban wine, and we will not label wine as being something that is toxic'.[2414]

What is at play here has been very well identified and described by Chalmers as regards the regulation of food safety in the EU, whose words perfectly fit the current debate surrounding the Nutri-Score:

> One of the paradoxical features of EU law is that its trans-national legal norms lead to the reterritorialisation of conflicts along national lines. *Conflicts* about food safety *that would otherwise seem internecine to individual societies become recast as conflicts between the European Union* and [EU] law, on the one hand, *and individual Member States and national law*, on the other.[2415]
>
> Whilst, within a national context, this competition will take place between different agencies or between governmental and non-governmental actors, disputes within a European Union context reconfigure this contest. *Battlelines become aligned along national and Union contours with different actors either supporting the position of Union or of national institutions*.[2416]

[2411] European Parliament, 'Nutri-Score and food labelling schemes: Mediterranean diet and high-quality agri-food products at risk' (2019) Question for written answer by MEP Luisa Regimenti, emphasis added, accessed 11/05/2023 <https://www.europarl.europa.eu/doceo/document/P-9-2019-004347_EN.html>.
[2412] European Parliament, 'Nutri-score labelling: misleading and discriminating against top-quality 'Made in Italy' food products' (2019) Question for written answer by MEP Mara Bizzoto, emphasis added, accessed 11/05/2023 <https://www.europarl.europa.eu/doceo/document/E-9-2019-004318_EN.html>.
[2413] European Commission, 'Europe's Beating Cancer Plan' (n 23) 10.
[2414] Euractiv, 'EU goes easy on alcohol in cancer plan' (2021), <https://www.euractiv.com/section/agriculture-food/news/eu-goes-easy-on-alcohol-in-cancer-plan/> accessed 11/05/2023.
[2415] Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (n 43), emphasis added.
[2416] ibid, emphasis added; see also Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life' (n 43)

Wine is toxic though, and Parma ham and Parmigiano Reggiano contain a lot of salt and fat. Their traditional nature and great cultural relevance should not be raised as an obstacle to the provision of appropriate information to consumers regarding the health risks associated with their consumption. What can be seen though is a resistance to fully accept the hazardous nature of those products which goes beyond the preservation of cultural practices, or market shares, but goes directly to the question of risk perception. Wine, traditional cheeses or meat preparations are perceived positively and the idea that a public authority, a European one for that matter, could decide to label these products as unhealthy is anathema to a lot of consumers and manufacturers. These positions may be regretted but cannot be dismissed out of hand, for not only they can lead to political deadlock, as we have seen with the non-adoption of nutrient profiles, but they can also undermine the EU's effort to promote healthier lifestyles in the population. The effectiveness of labels is based on their acceptance, liking and trust on the part of consumers. Introducing Nutri-Score in Italy would be plainly ineffective, and perhaps even counter-productive, if the vast majority of consumers decided to ignore it or go against it.

These disagreements may be dealt with at a political level. This has for instance been the case with smokeless tobacco products. Sweden obtained an opt-out from the prohibition of tobacco for oral use because it could not accept an EU ban on this product that is so widely used on its territory. In other Member States, other forms of smokeless tobacco products, such as chewing or nasal tobacco, where exempted from the ban precisely on grounds of their traditional nature.[2417] Beyond these types of specific exemptions, it is important to identify how EU law must or may accommodate these differences and concerns, and which tools it has at its disposal.

3.2. 'To act or not to act':[2418] subsidiarity and lifestyle risks

On some occasions, differences in patterns of consumptions or diverging political priorities regarding which risks to tackle and how may justify regulation at the national rather than the EU level, on ground of effectiveness or simply because the value of the product or activity controlled is considered to be too important for the risks to be addressed supranationally.

In such circumstances, subsidiarity appears to be a key instrument to safeguard national regulatory autonomy. Subsidiarity is for instance referred to in the EU Alcohol Strategy as one of the main reasons justifying why alcohol should remain firmly within the ambit of Member States, on grounds of the 'different cultural habits related to alcohol consumption'.[2419] Subsidiarity was also put forward to explain why the EU should refrain from legislating in the field of gambling.[2420]

The role that subsidiarity may play in the field of lifestyle risks remains however unclear. Is it just a buzzword, used conveniently to justify a lack of ambition from the EU and the Member States, or does it really constitute a brake on the EU's involvement in the matter? Answering

[2417] Council Directive 92/41, recitals. See also Tobacco Products Directive, recital 32.
[2418] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1766.
[2419] European Commission, EU Alcohol Strategy (n 1502) 1.
[2420] European Council in Edinburgh, Conclusions of the Presidency (n 1545) 28.

this question requires first to clearly define subsidiarity, arguably one of the most misunderstood principles of European Union law.

3.2.1. The meaning of subsidiarity

According to the principle of subsidiarity, enshrined in Article 5(3) TEU, in areas which do not fall within its exclusive competence, 'the Union shall act only if and in so far as the objectives of the proposed action *cannot be sufficiently achieved* by the Member States, […] but can rather, by reason of the scale or effects of the proposed action, *be better achieved* at Union level'.[2421] Subsidiarity may be understood as a principle of preference for local action and is hence intimately linked to federalism, as briefly discussed in Chapter 2. Action at the higher level of government should only take place if there is a good reason for it.

Subsidiarity is usually construed as entailing a two-stage test: a 'negative' test of national incapacity to achieve the set objectives of the given measure in a satisfactory manner – 'cannot be sufficiently achieved' – and a 'positive' test requiring for the EU to be able to achieve these objectives in a better way – 'be better achieved'.[2422] Only if these two conditions are met should the EU endeavour to act. The Protocol on the application of the principles of subsidiarity and proportionality, annexed to the TEU and TFEU, provides guidance to assess compliance with those conditions and lays down procedures for the judicial and political control of subsidiarity. Political control consists primarily in the so-called 'Early Warning Mechanism', whereby national parliaments can send reasoned opinions on draft legislative acts, which may result in the revision of the Commission's proposal.[2423] The Court of Justice is tasked with the judicial review of subsidiarity, and must verify 'both compliance with the substantive conditions set out in Article 5(3) TEU and compliance with the procedural safeguards provided for by that protocol'.[2424]

[2421] Art 5(3) TEU, emphasis added.
[2422] See Case C-358/14 *Poland v Parliament and Council* [2015] EU:C:2015:848, Opinion of Advocate General Kokott, para 142; *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 275; *Pillbox 38*, Opinion of Advocate General Kokott (n 24), para 165.
[2423] For further details and discussions on the 'Early Warning Mechanism', see Davor Jancic, 'The Game of Cards: National Parliaments in the EU and the Future of the Early Warning Mechanism and the Political Dialogue' (2015) 52 Common Market Law Review 939; Tomasz Jaroszyński, 'National Parliaments' Scrutiny of the Principle of Subsidiarity: Reasoned Opinions 2014–2019' (2020) 16 European Constitutional Law Review 91.
[2424] *Philip Morris* (n 28), para 217.

Subsidiarity has generated considerable debate in the academic community and the political sphere.[2425] 'The word that saves Maastricht',[2426] introduced at a time of existential fear over the seemingly unstoppable expansion of EU powers, seems to have failed to prevent the EU from expanding its reach in a growing number of fields, which explain why frequent political efforts are made to revive it.[2427] If general discussions on the meaning of subsidiarity and its role in the Union legal order go well beyond the scope of this work, it is still necessary to clarify some of the terms of this debate to understand the role that subsidiarity has played and can play in the field of lifestyle risks.

Subsidiarity, as it can be read from Article 5(3) TEU, is essentially a 'technocratic' principle. It is about how best to achieve a given policy objective and not about discussing the pertinence of that objective in the first place. Crucially, understood in that way, subsidiarity is *not* about whether a given objective should be pursued by the EU at the expense of Member States' interests.[2428] Subsidiarity 'takes as its starting point that all levels are united in wishing to achieve certain goals and that none has any other interests or objectives in conflict with these'.[2429] It is concerned with regulatory efficiency rather than respect for Member States' autonomy.[2430] Where it is felt by one or several Member States that action at the EU level would unduly interfere with a sensitive interest, the application of Nutri-Score to traditional food for instance, subsidiarity stricto sensu, as laid down in Article 5(3) TEU, cannot play a role.

Yet, subsidiarity is often understood in a different way, as encapsulating the idea that the EU should not meddle too much in Member States' internal affairs or citizens' daily lives, that it should not act on trivial matters in areas that are thought to be better left to Member States.

[2425] See e.g. Roger Van den Bergh, 'The Subsidiarity Principle in European Community Law: Some Insights from Law and Economics' (1994) 1 Maastricht Journal of European and Comparative Law 337; George A Bermann, 'Proportionality and Subsidiarity' in Catherine Barnard and Joanne Scott (eds), *The Law of the Single European Market: Unpacking the Premises* (Hart Publishing 2002); Gareth Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time' (2006) 43 Common Market Law Review 63; Mattias Kumm, 'Constitutionalising Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union' (2006) 12 European Law Journal 503; Schütze, 'Subsidiarity after Lisbon: Reinforcing the Safeguards of Federalism?' (n 480); Groussot and Bogojević (n 480); Paul Craig, 'Subsidiarity: A Political and Legal Analysis' (2012) 50 Journal of Common Market Studies 72. As put by Schütze: '"[three] correcting words of the legislator and entire libraries are turned into maculature." Worse: three additional words and entire libraries will be filled again! Libraries have literally been filled since the introduction of the "principle of subsidiarity" into the European legal order.'

[2426] Deborah Z Cass, 'The Word That Saves Maastricht? The Principle of Subsidiarity and the Division of Powers within the European Community' (1992) 29 Common Market Law Review 1107.

[2427] See most recently the work of the 'Task Force on Subsidiarity, Proportionality and "Doing Less More Efficiently"' created in 2017 by the President of the European Commission Jean-Claude Juncker. The 2018 final report of the Task Force may be accessed at <https://ec.europa.eu/info/sites/default/files/report-task-force-subsidiarity-proportionality-and-doing-less-more-efficiently_en.pdf>.

[2428] Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time' (n 2425) 78; Schütze, 'Subsidiarity after Lisbon: Reinforcing the Safeguards of Federalism?' (n 480) 533.

[2429] Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time' (n 2425) 78.

[2430] 'This makes it a principle of delegation, rather than one of protecting national autonomy. It simply does not address the question of conflicts of interest or policy, nor of the value of local autonomy, diversity and decentralisation.': Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 87.

This question, one may say, is already addressed by the very existence of an EU act and the fact that Member States have given it support so that it becomes law.[2431] Subsidiarity is often used as an umbrella term to refer to all Union law principles or instruments which somewhat embody the necessity to leave sufficient regulatory space to Member States.[2432] In that sense, it has much to do with the principles of conferral and proportionality contained in Articles 5(2) and 5(4) TEU and the respect for national identities and fundamental structures of Member States enshrined in Article 4(2) TEU.[2433] This broader, more political understanding of subsidiarity is legitimate, but is less amenable, if at all, to judicial review and less pertinent for any legal discussion.

Unfortunately, public debate, policy and legislative practice, even judicial review at times, have tended to obfuscate the difference between these two understandings of subsidiarity. As very well said by Davies, '[t]he public discourse around subsidiarity in the EU tends to use it as a shorthand for the general safeguarding of decentral choices, when this is not in fact its function, thereby adding a further potentially disillusioning layer of deception to speech about the EU'.[2434] The Court itself, although very well aware that its review is restricted to subsidiarity *stricto sensu*, as contained in Article 5(3) TEU, is not immune from this confusion, when Advocate General Kokott defines for instance subsidiarity as the EU's political institutions 'limit[ing] their action to regulating important matters in the common European interest'.[2435]

Although subsidiarity has found only limited application in the field of lifestyle risks and is, for the reasons just outlined, unlikely to constitute a powerful tool for those opposing EU involvement in the matter, there is a clear potential and need for greater engagement with that principle. Doing so would both clarify the justification for Union action and increase its legitimacy.

3.2.2. Subsidiarity, health and judicial review

Subsidiarity under Article 5(3) TEU constitutes a limit to EU action in the field of lifestyles where it appears that the objective of a proposed measure could adequately be achieved at the national level or, at the very least, that acting at the EU level does not bring additional benefits with regard to the fulfilment of that objective. Where it is considered that a piece of EU

[2431] See Craig, 'Subsidiarity: A Political and Legal Analysis' (n 2425) 81: 'The very fact of [an EU legislative act's] enactment attests to the fact that sufficient Member States […] believed that action at EU level was required'. See also ibid 83.

[2432] Alemanno and Garde write for instance that '[a]nother manifestation of the principle of subsidiarity in EU policy, and EU lifestyle policy more specifically, is the use the EU has made of a broad range of harmonization techniques allowing for a degree of diversity between Member States to co-exist with harmonized EU standards': Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1767.

[2433] For a discussion on the links existing between subsidiarity and national identity, see Somek (n 57) 145; Barbara Guastaferro, 'Coupling National Identity with Subsidiarity Concerns in National Parliaments' Reasoned Opinions' (2014) 21 Maastricht Journal of European and Comparative Law 320. Under Article 4(2) TEU : 'The Union shall respect the equality of Member States before the Treaties as well as their national identities, inherent in their fundamental structures, political and constitutional, inclusive of regional and local self-government.'

[2434] Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 87.

[2435] *Pillbox 38* (n 1662), para 163.

legislation, or a specific provision contained therein, does not conform to these conditions, a claim may be brought forward for breach of the principle of subsidiarity.

This limits the claims that parties opposing a piece of EU lifestyle risks regulation can formulate. Since this policy follows the double objective of ensuring the smooth functioning of the internal market and protecting public health, arguing for a breach of subsidiarity requires to show that action at the national level is adequate for the achievement of at least one of these two objectives. Because it is hard to see how Member States can contribute to the internal market objective on their own – it is precisely their uncoordinated activities which give rise to obstacles to free movement or distortions or competition in the first place, creating a need for harmonisation – non-compliance with the principle of subsidiarity may hence only be raised as regards the health objective pursued.

This appears from several of the judgements handed down on the validity of the TPD, where applicants have unsuccessfully argued that action at the national level would have been sufficient to achieve the health objective pursued by the Directive.[2436] In *Poland v Parliament and Council*, Poland and Romania claimed in particular that 'the significant differences' existing in the consumption of tobacco products between Member States rendered the effect resulting from their prohibition 'essentially *local in nature*', 'so that *action undertaken at the level of the Member States* in which the consumption of the products is significant *would have been more effective*'.[2437] In *Swedish Match II*, the plaintiff sustained that 'the general and absolute prohibition on the placing on the market of tobacco products for oral use deprives Member States of any discretion in their legislation and imposes a uniform body of rules, with no consideration of the *individual circumstances* of the Member States'.[2438]

Since no clear explanation was given as to why local circumstances put into question the attainment of the health objective pursued by the TPD, the Court could have rejected these claims for lack of substantiation. It focused instead on the impossibility for Member States alone to contribute to the internal market objective, ruling that:

> *Even if the second of those objectives [health] might be better achieved at the level of Member States*, the fact remains that pursuing it at that level would be liable to entrench, if not create, situations in which some Member States permit the placing on the market of tobacco products containing certain characterising flavours, whilst others prohibit it, thus *running completely counter to the first objective* of Directive 2014/40, namely the improvement of the functioning of the internal market for tobacco and related products.
>
> The *interdependence of the two objectives* pursued by the directive means that the EU legislature could legitimately take the view that it had to establish a set of rules for the placing on the EU market of tobacco products with characterising flavours and that, because of that interdependence, *those two objectives could best be achieved at EU level*.'[2439]

[2436] See *Philip Morris* (n 28), para 214; *British American Tobacco* (n 27), para 74.
[2437] *Poland v Parliament and Council* (n 587), para 106, emphasis added.
[2438] *Swedish Match II* (n 1620), para 64, emphasis added.
[2439] *Philip Morris* (n 28), paras 221-22, emphasis added; see also *Poland v Parliament and Council* (n 587), paras 117-118; *Swedish Match II* (n 1620), paras 68-69.

Considering that the EU will always be comparatively better placed that Member States to act for internal market purposes[2440] – '[t]he removal of obstacles to cross-border trade in the European internal market, which is the focus of interest in Article 114 TFEU, is a prime example of action which cannot, *as a rule*, be sufficiently realised at national level' – [2441] the Court, by analysing both objectives taken together, severely limits the possibility for Member States or other claimants to contest the validity of EU measures in the field of lifestyles. Indeed, since Member States alone cannot, by definition, take action to remove obstacles to trade or distortions of competition trough harmonisation,[2442] a successful subsidiarity claim would require to show that a measure adopted at the EU level is fully incapable of meeting its stated health objective, an unlikely prospect. Hence, the internal market nature of lifestyle risks legislative acts effectively prevents any health-based subsidiarity claim from successfully being made. For the Court, following an alternative approach – requiring that the EU is better placed to achieve each of the objectives considered separately – would mean weighing the relative importance of these two objectives, which is precisely what it has refrained from doing since its ruling in *Tobacco Advertising*, so as to respect the legislator's intention to pursue both objectives simultaneously (see Chapter 2, Section 3.2).[2443]

In *Poland v Council*, Advocate General Kokott considered that '[a] stricter judicial review of subsidiarity may be necessary where an EU measure exceptionally affects matters of national identity of the Member States', within the meaning of Article 4(2) TEU.[2444] She doubted however that 'problems relating to the manufacture, sale and consumption of menthol cigarettes [could] seriously to be regarded as a matter of national interest'.[2445] Regardless of whether that latter point is true – it seems that having the Court take a stance on what constitutes a *national* interest somewhat defeats the purpose – what this stricter judicial review of subsidiarity could entail remains to be seen, especially vis-à-vis the fulfilment of the internal market objective.

The Court's reluctance to assess the achievement of the health objective as part of its control of subsidiarity can be regretted. Understanding the extent to which action at Union level is necessary for health purposes would enhance its legitimacy and acceptability, in a field where

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[2440] See *British American Tobacco* (n 27), para 182; *Poland v Parliament and Council* (n 587), paras 117-118; *Swedish Match II* (n 1620), paras 68-69.; see also Case C-491/01 *British American Tobacco* [2002] EU:C:2002:476, Opinion of Advocate General Geelhoed, para 285.

[2441] *Poland v Parliament and Council* (n 2422), Opinion of Advocate General Kokott, para 154, emphasis added. That being said, although 'a strong presumption of added value for action at Union level' exists 'where the EU measure in question has the aim of resolving problems with a cross-border dimension, in particular eliminating obstacles to trade and thus improving the functioning of the European internal market […], an internal market dimension cannot automatically lead to the conclusion that the positive component of the subsidiarity test must be considered to be satisfied', '[o]therwise the principle of subsidiarity in internal market matters would be deprived of much of its practical effectiveness': ibid 164. See for a more detailed discussion: ibid 165-168; *Vodafone*, Opinion of Advocate General Poiares Maduro (n 601), paras 27-36.

[2442] It seems therefore 'plausible to conclude', with Davies, 'that subsidiarity has no relevance to those functional competences whose aim is to create the uniformity necessary for an internal market': Davies 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time' (n 2425) 75. See also Somek (n 57) 134, 144.

[2443] See also *Poland v Parliament and Council*, Opinion of Advocate General Kokott (n 2422), para 157.

[2444] ibid, para 148.

[2445] ibid, para 166; see also 148.

health is clearly the main political objective. If it was shown that EU action was preferrable on internal market grounds alone, this would not necessarily lead to the annulment of the relevant piece of legislation but could stimulate the discussion at the political level regarding its pertinence. For Advocate General Kokott, where 'national, regional or local features are central to [an] issue', 'this tends to suggest that intervention should be at the level of the Member States and that the matter should be addressed by the authorities which have greater proximity and expertise in respect of the action to be taken'.[2446] Lifestyle risks are an issue where, precisely, such infra-European features are likely to play an important role.[2447]

The prohibition of tobacco for oral use, whose compliance with the principle of subsidiarity was at stake in *Swedish Match II*, provides a good example. As in other judgements, at no point did the Court address the question of subsidiarity from a health perspective,[2448] although this could have offered an interesting discussion of the scientific underpinnings of the ban and its pertinence for public health. As discussed in Chapter 1, and referred to by the Court in its judgement,[2449] uncertainty remains as to the effectiveness of this form of tobacco when used as a cessation aid and the role that it can play to reduce exposure to health risks in the population, following a harm reduction strategy. Interestingly enough, the report of the scientific committee that had informed the adoption of the ban indicates that 'the association between patterns of smokeless tobacco use and smoking cessation differs between populations and *is likely to be affected by cultural, societal and other factors*', therefore concluding that 'it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco if it were made available in an EU country where it is now unavailable'.[2450] Some countries may benefit from lifting the ban – this could be the case, for instance, of countries neighbouring Sweden, where consumers are familiar with the product – while, in others, public health may be better served by continuing to prohibit the product from being placed on the market. In such case, a ban enacted at the national level would be more effective from a health point of view, even if, indeed, that would mean accepting that obstacles to free movement arise from this divergence in legislation. The absence of any discussion on this point is even more regrettable since, as discussed in the previous section, the prohibition of tobacco for oral use does not make any valid contribution at all to the internal market.

Reasoning by analogy, the regulation of e-cigarettes could also be an area where differences amongst countries make action at the national level more effective. A recent study showed for instance that a majority of British smokers attempting to quit did so with the aid of e-cigarettes, a proportion that greatly exceeds that of the other European countries surveyed.[2451] In a British

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[2446] ibid, para 152.
[2447] See in that regard recital 20 of the TPD: 'the responsibility for regulating the ingredients of tobacco for oral use, which requires in-depth knowledge of the specific characteristics of this product and of its patterns of consumption, should, in accordance with the principle of subsidiarity, remain with Sweden'.
[2448] *Swedish Match II* (n 1620), paras 68-69. The Advocate General did not address subsidiarity in his opinion.
[2449] *Swedish Match II* (n 1620), paras 41-45.
[2450] SCENIHR (n 166) 12, emphasis added.
[2451] Sophia Papadakis and others, 'Quitting Behaviours and Cessation Methods Used in Eight European Countries in 2018: Findings from the EUREST-PLUS ITC Europe Surveys' (2020) 30 European Journal of Public Health iii26, iii28.

context then, carefully regulated advertising may yield better public health outcomes than the large prohibition decided at the EU level. It is true, according to the Court, that 'the subsidiarity principle is not intended to limit the EU's competence on the basis of the situation of any particular Member State taken individually'.[2452] Yet, if it was established that preferences regarding the use of e-cigarettes as a cessation aid varied greatly among Member States in general,[2453] this would open the floor to a successful health-based subsidiarity claim, at the expense once again of the internal market objective.

Perhaps inadvertently, this is exactly what the impact assessment accompanying the proposal for the Trans Fat Regulation showed, as regards the limitation of TFAs in food. It was observed that 'legal measures and voluntary initiatives taken by Member States so far differ, as different national views in relation to acceptable levels exist',[2454] which means that Member States had been able to deal with the public health issue at stake on their own, according to local preferences. Hence, unsurprisingly, the only convincing reason for pursuing action at the EU level was the need to provide a level playing field for economic operators and ensure the proper functioning of the internal market.[2455]

This is not to say that Member States are necessarily better placed than the EU to act in these two cases, or in lifestyle risks matters in general. To establish this would require the performance of proper studies, the outcome of which could then be discussed by the Court. Impact assessments are the adequate forum for such an evaluation to be done, yet, regrettably, these remain generally very elusive as regards compliance with the principle of subsidiarity.

In the TPD impact assessment, subsidiarity analysis covers no more than a page and barely addresses its public health dimension.[2456] The main argument put forward to justify the need for Union action is that '[o]nly a harmonised approach at EU-level can remove obstacles to cross-border trade' and 'ensure that industry is not obliged to adapt at different times to 27 national regimes'.[2457] The only health-based argument made revolves around the difficulty for Member States to act unilaterally due to regulatory avoidance when other countries adopt different rules. It appears for instance 'almost impossible for a Member State to enforce restrictions on tobacco internet sales if such sales are unregulated in other Member States',[2458]

[2452] Case C-508/13 *Estonia v Parliament and Council* [2015] EU:C:2015:403, para 53.
[2453] In that regard, recent Eurobarometer data shows a relative homogeneity amongst Member States in the use of e-cigarettes as a cessation aid, which concerns in most EU countries less than a tenth of smokers who stopped or tried to stop smoking: see European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 114.
[2454] European Commission, Trans Fat impact assessment (n 2178), part 1, 25.
[2455] ibid.
[2456] European Commission, TPD impact assessment (n 1642), part 1, 45-46.
[2457] ibid 45.
[2458] ibid. For a similar line of reasoning as regards excise duties, see European Commission, 'Impact assessment accompanying the document: Proposal for a Council Directive amending Council directive 95/59/EC, 92/79/EEC and 92/80/EEC on the structure and the rates of excise duty applied to manufactured tobacco' (Tobacco Excise Duties Directive impact assessment) (Staff Working Document) SWD (2008) 2266, 12: 'Although the existence of the current EU minimum rates limits the divergences in national excise duty rates on tobacco products, it has not been sufficient to prevent the persistence of significant divergences, despite the increasing attention paid by Member States to the achievement of health objectives in this field. These divergences entail substantial cross

a valid point which would have deserved to be further unpacked. This neglect of subsidiarity is logically reflected in the TPD Proposal itself[2459] and the relevant recitals of the directive,[2460] the latter constituting, in Advocate General Kokott's own words, 'not exactly a shining example of the frequently invoked technique of "better regulation", to which the EU institutions have for some time been committed'.[2461]

Similar shortcomings can be seen from the Food Information Regulation impact assessment, where the subsidiarity check is almost all about the internal market objective and the harmonisation brought by the regulation. A reference is made to the fact that 'uniform action will ensure Community wide minimum standards for consumers and thereby reduce inequity for citizens across the EU',[2462] once again a potentially good argument to justify action at the Union level, unfortunately lacking further refinement. A more systematic reference to subsidiarity does feature in the most recent impact assessments or legislative evaluations,[2463] in line with the new impetus on subsidiarity and proportionality at the EU level.[2464] It is the case for instance of the impact assessment accompanying the 2018 revision of the AVMSD, although a misunderstanding of what subsidiarity really entails, a discussion of the added value of Union action, seems to be persisting.[2465]

Even if an impact assessment usually contains elements allowing the Court to perform its control of subsidiarity, in the absence of a devoted and sufficiently worked out 'subsidiarity section',[2466] the lack of a proper subsidiarity review in an impact assessment and the resulting failure on the legislator's part to clearly expose the reason warranting Union action to the public

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border shopping and smuggling, which creates distortions of competition in the tobacco market, lead to losses in budgetary resources
for those Member States applying a relatively high excise duty and undermines the health policy objectives.' See also European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787) 103-104.

[2459] European Commission, TPD proposal (n 1430) Explanatory Memorandum, 11.

[2460] TPD, recital 60 : 'Since the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.'

[2461] *Poland v Parliament and Council*, Opinion of Advocate General Kokott (n 2422), para 177.

[2462] European Commission, Food Information Regulation impact assessment (n 466) 23. See also European Commission, Food Information Regulation Proposal (n 2176), explanatory memorandum 9: 'uniform action ensures Community wide minimum standards reducing inequity for citizens across the EU'.

[2463] See e.g. European Commission, 'Study assessing articles 32 and 36 of Council Directive 2008/118/EC' (n 1787) 103-104; European Commission, Trans Fat impact assessment (n 2178), part 1, 24-26.

[2464] See European Commission, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'The principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking' COM (2018) 703 final.

[2465] See European Commission, 'Impact assessment accompanying the document: Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services in view of changing market realities' (Staff Working Document) SWD (2016) 168 final, 22, 31, 36, 41, 46.

[2466] See *Poland v Parliament and Council* (n 587), para 123; *Poland v Parliament and Council*, Opinion of Advocate General Kokott (2422), paras 180-183.

should be sanctioned by the Court.[2467] It is not primarily the responsibility of parties opposing a piece of EU legislation to come up with arguments establishing a breach of subsidiarity but that of the EU legislator to explain why it thinks that this principle is being complied with. Subsidiarity functions as a presumption in favour of national action, which should only be superseded if good reasons exist for it.

Even where the EU decides not to act on subsidiarity grounds, it fails to clearly lay down the reasons justifying its choice. The EU Alcohol Strategy, which mentions several times subsidiarity, refers in this regard to 'different cultural habits related to alcohol consumption' without explaining why these differences put Union action into question: how, for instance, these would affect the effectiveness of EU health warnings on alcoholic beverages or binding restrictions on advertising directed to minors. The Commission has failed to lay down a convincing argument as to why the market for alcoholic beverages should be treated so distinctly from the market for tobacco products or that of other foodstuffs.[2468] In that case, subsidiarity appears to be 'instrumentalised' more than anything else.[2469]

The Commission also considered the adoption of a ban on tobacco vending machines during the revision of the TPD and discarded the idea over 'subsidiary concerns'.[2470] The reason was that 13 Member States had already banned tobacco vending machines and the remaining others had set up restrictions to limit access to young people under the legal age for purchasing. It was felt that Member States were able to address the problem on their own. What is interesting here is that uncoordinated national action of this kind, which leads to a fragmentation of the market, is precisely the argument usually put forward by the EU to justify the need for harmonisation from an internal market perspective. Most Member States had tobacco control laws in place before the EU stepped in and, in the absence of EU action, would have most certainly adopted stringent regulatory measures over the course of time. Yet, subsidiarity did not seem to play a role there. This example shows again how the EU fails to produce a general discourse as to why and in which circumstances action in lifestyles is necessary at the Union level.

3.3. 'To act but not always exhaustively':[2471] flexible forms of harmonisation

When confronted to the need to accommodate diversity, the EU is not only faced with the binary choice of acting or not acting, it may also choose to legislate in a way that does not fully displace Member States' capacity to act. In an area such as lifestyles, where significant

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[2467] See Paul Craig, 'Subsidiarity: A Political and Legal Analysis' (2012) 50 Journal of Common Market Studies 72, 78 : 'If the verification or justification for EU action contained in the Impact Assessment appear merely formal, scant or exiguous, then the ECJ should not hesitate to so conclude, thereby indicating that the enhanced role accorded to subsidiarity in the Lisbon Treaty will be taken seriously.'

[2468] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1770.

[2469] Bartlett and Garde, 'EU Public Health Law and Policy – on the Rocks? A Few Sobering Thoughts on the Growing EU Alcohol Problem' (n 1906) 394.

[2470] European Commission, TPD impact assessment (n 1642), part 1, 50.

[2471] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1767.

variations in circumstances and preferences exist, minimum harmonisation represent an appealing regulatory option, allowing to accommodate diversity while guaranteeing to all citizens a minimum floor of health protection. Minimum harmonisation may serve various purposes.[2472] It allows Member States to move at a difference pace and to achieve different levels of protection, in accordance with the severity of the public health problem faced in each country or the level of support for public intervention existing in the population. It is also a cautionary tool, in an area where scientific uncertainty persists regarding certain risks, where the effects of regulatory instruments are not always well-known and where policy experimentation may therefore appear desirable. The argument could even be made that, from a health point of view, minimum harmonisation always represents the best option, 'as it would be counterproductive to set a ceiling to the level of protection that can be applied across the EU'.[2473]

Unlike for other legal bases, such as those in the field of social policy,[2474] public health,[2475] consumer protection[2476] or environment,[2477] where minimum harmonisation is required under the TFEU, there is no 'constitutionalisation' of minimum harmonisation in the internal market.[2478] The legislator remains free as to which method to use.[2479] Article 114 TFEU does provide for mechanisms permitting Member States to maintain or introduce further requirements in certain circumstances,[2480] under its paragraphs (4) to (10), but these clauses allow for derogation in a way that is conceptually different from minimum harmonisation.[2481]

Minimum harmonisation is therefore not mandatory under Article 114 TFEU. What remains uncertain however, something on which the Court has failed to give a clear answer until now, is the extent to which minimum harmonisation should be an available option under that provision. After all, a measure purporting to eliminate obstacles to free movement and distortions of competition seems to be failing that purpose if it allows Member States to enact more stringent measures, thereby recreating the obstacles and distortions that it sought to eliminate in the first place. Regarding tobacco excise duties, it appears for instance that the

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[2472] See ibid 1767–1769.
[2473] Sacha Garben, 'Article 169 TFEU' in Kellerbauer, Klamert and Tomkin (n 524) 1460. The argument was made as regards consumer protection but is equally applicable to public health.
[2474] Art 153(2)(b) TFEU.
[2475] Art 168(4)(a) TFEU.
[2476] Art 169(4) TFEU.
[2477] Art 193 TFEU.
[2478] Nina Boeger, 'Minimum Harmonisation, Free Movement and Proportionality' in Syrpis (n 599) 65–66.
[2479] Case C-270/12 *United Kingdom v Parliament and Council* [2014] EU:C:2014:18, para 102; see also Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (n 608) 196.
[2480] Article 114(4) to (10) TFEU.
[2481] These provisions permit a derogation from the legislative act itself rather than constituting a derogation allowed under that act. The role of Article 114(4) to (10) TFEU is not explored further for two reasons. First, to the knowledge of the author, no decisions have been rendered by the Commission pursuant to these paragraphs in a matter related to lifestyle risks. Second, as extensive studies of these provisions have shown, their potential for allowing regulatory diversity remains limited: see Ellen Vos and Maria Weimer 'Differentiated integration or uniform regime? National derogations from EU internal market measures', in Bruno de Witte, Andrea Ott and Ellen Vos (eds), *Between Flexibility and Disintegration : The Trajectory of Differentiation in EU Law* (Edward Elgar Publishing 2017); Weimer (n 2), see especially 143-179.

minimum rate currently in place is insufficient to eliminate most of the distortions of competition that result from diverging national rates.[2482] More generally, 'the harmonized standard should not be set at a level so low that it becomes meaningless both from an internal market point of view and from a public health perspective'.[2483] From a public health perspective, it is a matter of political choice, of the level of ambition that the EU sets for itself. From the point of view of the internal market, however, it is first and foremost a legal matter, a question of competence and of compliance with the requirements of Article 114 TFEU.

3.3.1. Some clarifications and early debates

To address this issue, an important conceptual and terminological distinction must first be drawn between *minimum* harmonisation and *partial* harmonisation, the former term being often improperly used to refer to the latter. These two concepts apply to two separate dimensions of an EU legislative act, its scope and its intensity,[2484] dimensions which are sometimes conflated by the Court itself.[2485]

The scope of a legislative act, on the one hand, determines what this act covers and what it leaves unregulated. It is an issue of *partial* harmonisation: certain aspects of a policy area or of a given product are not subject to harmonisation.[2486] 'Matters found to lie outside the legislative field of a harmonization measure remain non-harmonized and thus within the residual powers of the Member States.'[2487] The Union is not required to fully harmonise every product or service that it regulates, even less every policy area in which a measure is adopted. Tobacco, alcohol and food advertising are for instance partially harmonised matters in EU law, to a different degree.

The intensity of an EU act, on the other hand, concerns the possibility, or not, granted to Member States to adopt a requirement that differs from the one prescribed in that act, usually to reach a higher standard of protection. Two main options exist.[2488] Either the EU measure is of total harmonisation, in which case Member States are deprived of any possibility to act within its scope, or it is of *minimum* harmonisation, in which case Member States are allowed

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[2482] European Commission, 'Evaluation of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco' (n 1746) 20.
[2483] Alemanno and Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1769.
[2484] Piet Jan Slot, 'Harmonisation' (1996) 21 European Law Review 378, 388–389; Stephen Weatherill, 'Pre-Emption, Harmonisation and the Distribution of Competence to Regulate the Internal Market' in Catherine Barnard and Joanne Scott (eds), *The Law of the Single European Market : Unpacking the Premises* (Hart Publishing 2002) 52–63; Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (n 608) 194–196.
[2485] See Slot (n 2484) 389.
[2486] For some elements on partial harmonisation and its different meanings: see Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (n 608) 195 and footnote 14. See also Case C-779/18 *Mikrokasa v XO* [2019] EU:C:2019:1146, Opinion of Advocate General Hogan, paras 48-50.
[2487] Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (n 608) 194–195.
[2488] Leaving aside optional harmonisation: see Schütze (n 608) 197-198.

to adopt a standard stricter than the one set at EU level. In the latter case, 'Member States are, to some extent, allowed to preserve their traditional "ways of life"'.[2489]

In the remainder of this section, the terms minimum and total harmonisation will hence be used to refer to issues pertaining to the intensity of an EU act, while partial harmonisation will be used when referring to its scope. Both methods, minimum and partial harmonisation, raise important constitutional questions as regards their legality under Article 114 TFEU. The Irish plan to introduce new health warning labels on alcohol, matters that are currently unregulated under EU law and left outside the scope of the Food Information Regulation, will for instance hinder the free movement of products that have been lawfully marketed under the Regulation.

Union measures must remove obstacles to free movement or distortions of competition in order to be lawfully adopted under Article 114 TFEU, which seems prima facie to eliminate minimum harmonisation from the equation. If an EU act allows for future divergences in national law, its contribution to free movement appears rather tenuous.[2490] 'As minimum harmonisation introduces more political diversity into the internal market, the key question remains to what extent such diversity continues to be accepted even if it impinges on the economic objective to harmonise regulatory standards in the internal market, so as to optimise conditions for undistorted competition and free trade.'[2491]

The answer to that question must vary depending on whether the stricter national standard applies to all products or agents or only to domestic ones. While under a 'thick' version of minimum harmonisation a Union act allows Member States to impose stricter rules to all actors falling under its jurisdiction, domestic and foreign alike, under a 'thin' version these national rules only apply to domestic actors.[2492] Considering that internal market measures are adopted to facilitate free movement, the thin conception seems to be better in line with the requirements of Article 114 TFEU, although it may lead to reverse discrimination for domestic agents.[2493]

Strikingly enough considering the importance of this question for EU legislation, the Court of Justice has not offered a clear and straightforward answer to date. In early judgements, the Court interpreted the harmonisation effect of internal market measures 'thickly' or 'thinly', depending on whether or not the legislative act under review contained a clause prohibiting Member States to apply their stricter requirements to foreign goods or services complying with

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[2489] Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (n 608) 198.
[2490] See Josef Weinzierl and Jonas Weissenmayer, 'News from minimum harmonisation: how the tobacco advertising cases shape the law of the internal market' (2016) European Law Blog, accessed 11/05/2023 [https://europeanlawblog.eu/2016/10/04/news-from-minimum].
[2491] Boeger (n 2478) 62.
[2492] Boeger (n 2478) 63. According to Weatherill, in cases where 'thin' minimum harmonisation is used, that latter term 'is a misnomer insofar as it is intended to refer to a standard which Member States must introduce but may surpass *even if to do so is to create obstacles to cross-border trade*': Stephen Weatherill, 'Supply of and demand for internal market regulations: strategies, preferences and interpretation' in Niamh Nic Shuibhne (ed), *Regulating the Internal Market* (Edward Elgar Publishing 2006) 47, emphasis added.
[2493] See regarding Directive 89/622 on the labelling of tobacco products: Case C-11/92 *The Queen v Secretary of State for Health, ex parte Gallaher and Others* [1993] EU:C:1993:262, paras 20-22.

the act.[2494] For measures that did not include such a free movement clause, the Court considered that Member States could enforce their stricter standards on both domestic and foreign actors.[2495]

The first blow to minimum harmonisation came with the *Tobacco Advertising* judgement, where the Court partially based its decision to annul the directive at stake on the directive's failure to ensure the free movement of products in conformity with its provisions.[2496] The Court seemed to consider that allowing Member States to apply stricter standards to foreign products would jeopardise the removal of obstacles to free movement intended by the directive. This was confirmed in subsequent judgements.[2497] In *Tobacco Advertising II*, the Court observed for instance that:

> [U]nlike Directive 98/43 [the annulled Tobacco Advertising Directive], Article 8 of [Directive 2003/33] provides that the Member States are not to prohibit or restrict the free movement of products which comply with the Directive.[2498]
>
> In preventing the Member States in this way from opposing the provision of advertising space in publications intended exclusively for professionals in the tobacco trade, Article 8 of the Directive *gives expression to the objective* laid down in Article 1(2) *of improving the conditions for the functioning of the internal market*.[2499]

A number of commentators considered that *Tobacco Advertising* should be construed narrowly, that the solution found in that judgement was highly contextual and should not be interpreted as generally precluding recourse to 'thick' minimum harmonisation under Article 114 TFEU.[2500] In *Philip Morris*, however, the Court not only clarified and confirmed the position

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[2494] Michael Dougan, 'Minimum Harmonization after *Tobacco Advertising* and *Laval Un Partneri*', in Mielle Bulterman and others (eds), *Views of European Law from the Mountain: Liber Amicorum for Piet Jan Slot* (Kluwer Law International 2009) 5. Such a clause was for instance present in Directive 89/622, art 8(1); see *Gallaher* (n 2493).

[2495] See e.g *Buet* (n 1169).

[2496] *Tobacco Advertising* (n 25), para 101-104. The Court based its decision on the fact that Article 5 of Directive 98/43/EC read as follows, '[t]his Directive shall not preclude Member States from laying down, in accordance with the Treaty, such stricter requirements concerning the advertising or sponsorship of tobacco products as they deem necessary to guarantee the health protection of individuals', and that the directive contained no free movement clause.

[2497] See also regarding Directive 2002/46 on food supplements: *Alliance for Natural Health and Others,* Opinion of Advocate General Geelhoed (n 2362), para 37; regarding Directive 2001/37: *British American Tobacco* (n 27), para 74. Article 13(1) of Directive 2001/37 reads: 'Member States may not, for considerations relating to the limitation of the tar, nicotine or carbon monoxide yields of cigarettes, to health warnings and other indications or to other requirements of this Directive, prohibit or restrict the import, sale or consumption of tobacco products which comply with this Directive'.

[2498] *Tobacco Advertising II* (n 26), para 73, emphasis added. The Court further adds: '[t]his article consequently precludes Member States from impeding the movement within the Community of publications intended exclusively for professionals in the tobacco trade, inter alia by means of more restrictive provisions which they consider necessary in order to protect human health with regard to advertising or sponsorship for tobacco products'. This is another illustration of the opposition between health and the internal market as regards the degree of harmonisation.

[2499] ibid, para 74, emphasis added.

[2500] Dougan, 'Minimum Harmonization after *Tobacco Advertising* and *Laval Un Partneri*' (n 2494) 8-11; see also Boeger (n 2478) 73; Weinzierl and Weissenmayer (n 2490).

adopted in *Tobacco Advertising*, but seemed to go one step further by denying all possibility for the EU legislator to adopt internal market measures of a minimum harmonisation nature.

3.3.2. The TPD, plain packaging and the Philip Morris judgement

Under Article 24 of the TPD, entitled 'Free movement':

> 1. Member States may not, *for considerations relating to aspects regulated by this Directive*, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.
>
> 2. This Directive shall not affect the right of a Member State *to maintain or introduce further requirements*, applicable to all products placed on its market, in relation to the *standardisation of the packaging of tobacco products*, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. […]
>
> 3. A Member State may also *prohibit a certain category* of tobacco or related products, *on grounds relating to the specific* situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. […][2501]

Judging from Article 24(1), the TPD appears to be a measure of partial and total harmonisation. Member States are prevented from enacting further measures that would restrict or prohibit the marketing of products complying with the directive, but only for considerations relating to aspects regulated by the directive, which implies that some of these products' aspects are not covered by it. Article 24(2) and (3) seem to bring derogations to the principle contained in the first paragraph, allowing (i) a Member State to maintain or introduce further requirements in relation to the standardisation of the packaging, or plain packaging, of tobacco products or (ii) to prohibit a certain category of products on grounds relating to the specific situation in that Member State.

As discussed in Chapter 6 (Section 3.4.1), Article 24(2) was placed in the TPD so as not to prevent Member States to introduce plain packaging at the national level, given that the EU legislator had decided not to adopt this stringent tobacco control measure. This is a clear illustration of the benefits of minimum or partial forms of harmonisation. The EU was allowed to adopt other measures related to the labelling and packaging of tobacco products – harmonising the size and shape of packets, introducing health warnings – without restraining those of the Member States that wished to go further in terms of public health protection.[2502] Crucially, Article 24(2) allowed to build an evidence base that would inform a potential future adoption by the EU. From a public health and national regulatory autonomy perspective, Article 24(2) TPD is therefore a good provision.

This, however, is notwithstanding the impact that it may have on the internal market, for Article 24(2) TPD implies that a manufacturer placing tobacco products on the market of one Member

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[2501] Emphasis added.

[2502] Support for plain packaging varies significantly between Member States. A majority of the population supports the measure in 13 Member States, while in the remaining 14 others a majority is opposed. Support spans from 72% (Ireland) to 28% (Portugal). See European Commission, 'Attitudes of Europeans towards tobacco and electronic cigarettes' (n 159) 219-220.

State allowing traditional packaging, where colours and trademarks are apparent, will have to repackage its products in order to penetrate the market of another Member State where plain packaging is in force. One may therefore question the compatibility of such a provision with the conditions for recourse to Article 114 TFEU, the removal of obstacles to trade or appreciable distortions of competition. A similar question arises from Article 24(3) TPD, the 'safeguard clause'[2503] which allows Member States to prohibit the placing on the market of products regulated under the TPD. Here again, the removal of obstacles operated by the directive seems temporary, at best, if the products concerned can unilaterally be prohibited by Member States.

In *Philip Morris*, the court sought to reconcile Article 24(2) and (3) TPD with the requirements of Article 114 TFEU. Regarding Article 24(2) TPD, a provision not devoid of ambiguity,[2504] the Court considered that two interpretations could be made. It could be interpreted as permitting 'Member States to maintain or introduce further requirements *in relation to all aspects* of the packaging of tobacco products, including those which have been harmonised by the directive'.[2505] This, however, 'would amount, in essence, to *undermining the harmonisation* effected by the directive' since 'the consequence of such an interpretation would be to permit Member States to *replace the requirements* relating to packaging which have been harmonised by the directive *with other requirements*, introduced at national level'.[2506] 'Such an interpretation', the Court adds, *'would render Article 24(2) of Directive 2014/40 incompatible with Article 114 TFEU*'.[2507] For the Court, Member States that wish to derogate from the requirements set in the TPD should follow the procedure set out in Article 114(4) TFEU and following.[2508] In a momentous statement, the Court thus openly rejects the use of minimum harmonisation under Article 114 TFEU, both, it seems, in its 'thick' and 'thin' versions.[2509]

The other possible interpretation, the one favoured by the Court, was to make of Article 24(2) TPD a clause of partial harmonisation. 'Article 24(2) of Directive 2014/40 may also be interpreted as meaning that it permits Member States to maintain or introduce further requirements *only in relation to aspects* of the standardisation of the packaging of tobacco products *which have not been harmonised* by the directive',[2510] in line with the general scheme of the directive.[2511] Understood in this way, Article 24(2) TPD still fails to guarantee the free circulation of products that comply with the directive.[2512] The Court considered that such

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[2503] On the use of 'safeguard clauses' in EU legislation, see Slot (n 2456) 394–395.
[2504] See *Philip Morris* (n 28), para 69.
[2505] ibid, para 71, emphasis added.
[2506] ibid, para 71, emphasis added.
[2507] ibid, para 72, emphasis added.
[2508] *Philip Morris* (n 28), para 71. See Stephen Weatherill, 'The Fundamental Question of Minimum or Maximum Harmonisation' in Sacha Garben and Inge Govaere (eds), *The Internal Market 2.0* (Hart Publishing 2021) 274.
[2509] According to Weatherill, only the thick version is rejected by the Court: ibid. Yet, the Court objects here to the substitution of national requirement for EU requirements generally, without making a reference to whom national requirements apply.
[2510] *Philip Morris* (n 28), para 73, emphasis added.
[2511] ibid, paras 74-77.
[2512] ibid, para 79.

'partial harmonisation' was yet compatible with article 114 TFEU since, 'whilst it does not eliminate all obstacles to trade, it does eliminate some'.[2513] This means 'that manufacturers of tobacco products throughout the internal market are able to use cigarette packets which have a uniform basic design and are required to adapt that design to the specificities of their respective national laws, regulations and administrative provisions only in certain details (colours, for example), but no longer in every respect'.[2514]

The Court's interpretation of Article 24(2) TPD appears formally correct from an internal market point of view, although one may seriously doubt that this was really what the legislator had in mind, considering that this interpretation renders Article 24(2) largely redundant with Article 24(1).[2515] By ensuring that standards do not diverge at least in relation to some aspects of the product concerned, partial harmonisation, unlike minimum harmonisation, does bring benefits to the internal market.[2516] In practice though, such a 'piecemeal'[2517] approach can still raise questions. If the harmonisation of a product was so limited that marketing it in several member States still required separate production processes for the manufacturer, the removal of obstacles to trade or appreciable distortions of competition affecting production costs would again be quite hypothetical. The presence of economies of scale would be far from certain.[2518] This is where impact assessments could play a role, by gathering the necessary evidence.

In *Philip Morris*, the Court also dealt with the legality of Article 24(3) TPD under Article 114 TFEU. As recognised by the Court itself, 'it is true that by permitting the Member States to prohibit a certain category of tobacco or related products even though they comply with the requirements of Directive 2014/40, Article 24(3) of the directive is capable of impeding the free movement of those products'.[2519] This, following the reasoning taken regarding Article 24(2), should render Article 24(3) incompatible with Article 114 TFEU. Here again, the Court managed to uphold the validity of that provision by construing it as a partial harmonisation clause. According to the Court, the lawfulness of tobacco products is an aspect which is not covered in the directive:[2520]

> Article 24(3) of Directive 2014/40, read in conjunction with paragraph 1 of that article, thus seeks to *delineate the scope of the directive* by clarifying that tobacco and related products which comply with the requirements laid down by the directive *may move freely* on the internal

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[2513] ibid, para 81.
[2514] *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 119.
[2515] Indeed, if Article 24(2) covers 'aspects of the standardisation of the packaging of tobacco products which have not been harmonised by the directive', then Article 24(1) alone is sufficient for allowing Member States to act.
[2516] We disagree here with Weinzierl and Weissenmayer (n 2490) who consider that the 'overall harmonising effect [of minimum harmonisation] is identical to that of partial harmonisation: both do not eliminate all obstacles to trade, but they do eliminate some.'
[2517] Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 79.
[2518] Contrary to what was argued by the Court in *Philip Morris* (n 28), para 103. See also *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 98.
[2519] *Philip Morris* (n 28), para 87.
[2520] ibid, para 90.

> market, *provided that those products belong to a category of tobacco products or related products which is, as such, lawful* in the Member State in which they are marketed.[2521]

This, one may object, is stretching the logic of partial harmonisation to an absurd extent, considering especially that the lawfulness of tobacco products *is* a matter regulated in the directive, first and foremost regarding tobacco for oral use.

Advocate General Kokott favoured another interpretation of that provision:

> Article 24(3) of the Directive *may not be interpreted* so broadly that it effectively gives the Member States *carte blanche permanently to ban*, on public health grounds, the placing on the market of certain products covered by the Directive, *thereby unilaterally invalidating the free movement of those products*. The argument put forward by the Parliament and the Commission that, on the basis of Article 24(3) of the Directive, individual Member States are permitted for example to prohibit completely the placing on the market of cigarettes cannot therefore be accepted. Such *unilateral national prohibitions* are possible only in respect of products which have *not* been the subject of harmonisation in Directive 2014/40.[2522]

Yet, according to Kokott, 'this does not mean, however, that Article 24(3) of the Directive would be unlawful and would thus have to be annulled'.[2523] She considers the obligation made in Article 24(3) TPD that the Member State concerned only acts on grounds relating to its specific situation, taking into account the level of protection achieved in the directive, and subject to the control of the Commission, as providing sufficient guarantee to ensure its compatibility with Article 114 TFEU.[2524] Her argument, it seems, is that these strict conditions ensure that only few cases will arise, which has indeed been the case.[2525] Yet, legally, nothing prevents Member States from having recourse to Article 24(3) TPD with respect to any tobacco products covered by the directive. Moreover, a similar interpretation could have been made as regards Article 24(2) TPD – allowing its application to aspects covered by the directive because the procedure provided for in that article provides the necessary safeguards to ensure that derogations do not multiply – which was however not the reasoning adopted by the Court of Justice.

3.3.3. Philip Morris and the future of minimum harmonisation

Philip Morris is an important judgement. It provides a textbook example of the difficulty of reconciling provisions that have primarily a public health purpose, ensuring that Member States remain in capacity to adopt more stringent tobacco control measures, with their stated and required objective, which is to contribute to the smooth functioning of the internal market by

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[2521] ibid, para 91, emphasis added. See also *Swedish Match II* (n 1620), paras 73-74.
[2522] *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 125, emphasis added.
[2523] ibid, para 126.
[2524] ibid, paras 127-128.
[2525] Three decisions have been rendered so far under this provision, the Commission has accepted national measures in all three cases: see European Commission, Commission Implementing Decision concerning national provisions notified by Finland prohibiting the placing on the market of certain categories of smokeless tobacco products, C(2016) 4592 final; European Commission, Commission Implementing Decision concerning national provisions notified by Austria prohibiting the placing on the market of chewing tobacco, C(2016) 7685 final; European Commission, Commission Implementing Decision concerning national provisions notified by Greece prohibiting the placing on the market of chewing and nasal tobacco, C(2020) 1066 final. In none of these cases does the Commission seem to apply the condition that Member States only act on grounds related to their 'specific situation' particularly strictly.

removing obstacles to free movement or distortions of competition. In order to uphold provisions such as Article 24(2) and (3) TPD, without openly renouncing to its case-law regarding the validity of measures adopted under Article 114 TFEU, the Court is led to make interpretations that do not appear fully convincing. Legislating in the field of health with an internal market competence presents limits, a conclusion already drawn from the analysis contained in the preceding section.

This tension is also apparent in the Audiovisual Media Services Directive, whose Article 3(1) provides that 'Member States shall ensure freedom of reception and shall not restrict retransmissions on their territory of audiovisual media services from other Member States for reasons which fall within the fields coordinated by this Directive'. Under Article 4(1) AVMSD, 'Member States remain free to require media service providers *under their jurisdiction* to comply with more detailed or stricter rules *in the fields coordinated by this Directive*', and, provided a number of strict substantive and procedural conditions are met, may extend these rules to services providers established in other Member States.[2526]

Such 'thin' minimum harmonisation, although it sits awkwardly with the interpretation of Article 24(2) TPD adopted in *Philip Morris*,[2527] does ensure the free movement of audiovisual media services coming from other Member States, at the expense, though, of public health. Under Articles 3(1) and 4(1) AVMSD, a Member State may prohibit alcohol advertising on television with regard only to operators established on its territory. In the case of two neighbouring countries sharing a language, where cross-border transmission tends to be a common phenomenon, France and Belgium for instance, or Germany and Austria, this can undermine the stricter advertising policy chosen by one of the two countries.[2528] 'Isn't it paradoxical', as rightfully written by Amandine Garde, 'that Member States may be significantly better off in the absence of existing EU rules purporting to protect public health?'[2529]

As the AVMSD example shows, from a public health perspective, minimum harmonisation does seem to be the best option: 'the aim of achieving a high level of protection within the Union would always be better served by allowing Member States to go beyond the federal compromise represented in European legislation'.[2530] One could even make the argument that recourse to minimum harmonisation is required by the various health mainstreaming clauses

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[2526] See AVMSD, art 4(2)-(5), emphasis added. This possibility seems to have been used only once, by Sweden, whose request was ultimately rejected. See European Commission, 'Reporting on the application of Directive 2010/13/EU "Audiovisual Media Services Directive" for the period 2014-2019' (n 1893) 6.
[2527] Article 4(1) AVMSD does allow Member States to 'replace requirements […] which have been harmonised by the directive with other requirements, introduced at national level', a situation which, after *Philip Morris*, should lead to its incompatibility with Articles 53(1) and 62 TFEU. See *Philip Morris* (n 28), paras 71-72. As ruled in *Tobacco Advertising*, the conditions for recourse to Articles 53(1) and 62 TFEU are similar to those for recourse to Article 114 TFEU. See above note …
[2528] Bartlett and Garde, 'Time to Seize the (Red) Bull by the Horns' (n 34) 514.
[2529] Garde, 'Harmful Commercial Marketing and Children's Rights: For a Better Use of EU Powers' (n 1853) 845.
[2530] Schütze, 'Classifying EU Competences: German Constitutional Lessons?' (n 556) 48. The argument was made as regards environmental protection but equally applies to public health.

contained in the TFEU and the Charter, which all refer to a 'high level of protection'.[2531] Ideally, minimum harmonisation should also be construed in a 'thick' manner, since having to accept foreign products or services offering a lesser degree of protection can act as a powerful deterrent for Member States to adopt a stricter regime.[2532]

Such is not the logic of the internal market and of Article 114 TFEU, as *Philip Morris* timely reminded us of. The difference between that provision and other 'social' legal bases, where minimum harmonisation is constitutionally required, was also highlighted in the recent *Octapharma* case, dealing with the respective scopes of application of Directive 2001/83 on the Community code relating to medicinal products and Directive 2002/98 on the quality and safety of human blood.[2533] In its judgement, the Court held the following:

> It should be recalled that, though their objective is the protection of human health, Directives 2001/83 and 2002/98 were not adopted on the basis of the same articles of the FEU Treaty. Thus, Directive 2001/83 is based on Article 114 TFEU, the object of which is the establishment and functioning of the internal market, whereas Directive 2002/98 is based on Article 168 TFEU, which provides for a high level of human health protection. Article 168(4) (a) TFEU does, it is true, provide that the Member States cannot be prevented from maintaining or introducing more stringent protective measures […].
>
> However, in cases where that directive is not applicable, it must be stated that *the same possibility is not provided* for by Directive 2001/83 or *by Article 114 TFEU*. It follows that the possibility for a Member State to maintain or introduce in its territory more stringent protective measures is available only in the areas which come within the scope of Directive 2002/98.[2534]

Although both directives pursue a similar objective of health protection in neighbouring fields, the choice of legal basis affects the capacity of Member States to enact stricter, more protective rules. This shows again that using Article 114 TFEU to pursue health objectives is not without consequences.

A similar logic applies in consumer protection, where Article 169 TFEU only protects Member States' right to maintain or adopt stricter standards in cases where the EU adopts measures 'which support, supplement and monitor the policy pursued by the Member States'.[2535] The Court made clear that this constitutional minimum harmonisation clause was not applicable to consumer protection legislation adopted under Article 114 TFEU.[2536] Consumer protection is actually an area where the over-reliance on total harmonisation for internal market purposes has led to insufficiencies in the level of protection granted to consumers. For some, '[t]he

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[2531] See in the area of consumer protection: Stephen Weatherill, 'Maximum versus Minimum Harmonization: Choosing between Unity and Diversity in the Search for the Soul of the Internal Market' in Niamh Nic Shuibhne and Laurence W Gormley (eds), *From Single Market to Economic Union – Essays in Memory of John A Usher* (Oxford University Press 2012) 186-187 and 199.

[2532] Michael Dougan, 'Minimum harmonization and the internal market' (2000) 37 Common Market Law Review 867; Weatherill, 'Supply of and demand for internal market regulations: strategies, preferences and interpretation' (n 2492) 47.

[2533] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [2003] OJ L33/30.

[2534] Case C-512/12 *Octapharma v ANSM* [2014] EU:C:2014:149, para 43-44, emphasis added.

[2535] Article 169(2)(b) and (4) TFEU.

[2536] Case C-52/00 *Commission v France* [2002] EU:C:2002:252, para 15.

balance between internal market and consumer protection objectives has swung too much in favour of market integration by the overstatement of the case for maximum harmonisation'.[2537] This has been justified by the need to preserve the level playing-field of the internal market, effectively brushing aside consumer protection concerns.[2538]

If one was to take seriously the Court's unambiguous rejection of minimum harmonisation, in its 'thick' version at least, this would have considerable repercussions on the EU acquis, in the field of lifestyles, consumer protection, and beyond.[2539] As previously discussed, doubts exist as regards the validity of Article 4(1) AVMSD post-*Philip Morris*. A similar interrogation arises if looking at the provisions of the Food Information Regulation. Its Article 38 provides that '[a]s regards the matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorised by Union law', adding that 'such measures shall not give rise to obstacles to free movement of goods, including discrimination as regards foods from other Member States'. This reads like a typical clause of partial and total harmonisation, similar to Article 24 TPD. At the same time, Articles 39 to 44 of the regulation permit Member States, for a number of aspects harmonised under the directive, to adopt national measures applicable to all products, domestic and imported alike. Here as well, it seems that such provisions allow Member States to 'replace the requirements relating to [aspects] which have been harmonised by the directive with other requirements, introduced at national level',[2540] 'an interpretation [that] would render [these provisions] incompatible with Article 114 TFEU'.[2541] In the field of consumer law, where a number of legislative acts adopted un Article 114 TFEU are of a minimum harmonisation nature, a blanket application of *Philip Morris* would also have dramatic consequences.

Should *Philip Morris* be extended to other legislative acts than the TPD and to other fields of law where recourse to Article 114 TFEU is widespread? Nothing from the judgement indicates that the solution found was particularly contextual. The conclusion made regarding Article 114 TFEU and minimum harmonisation does seem to have a broader relevance. Yet, as it has been rightfully observed, in recent years, 'there is no hint […] that the Court finds anything constitutionally troubling in a measure of harmonisation which leaves room for stricter rules to be selected by Member States which will lead to obstacles to trade even where the terms of the Directive have been met'.[2542] In *Buhagiar* for instance, the Court's Grand Chamber declared, regarding Directive 91/477/EEC on control of the acquisition and possession of weapons,[2543] an act based on Article 114 TFEU, that:

[2537] Geraint Howells, Christian Twigg-Flesner and Thomas Wilhelmsson, *Rethinking EU Consumer Law* (1st edition, Routledge 2017) 326.
[2538] ibid.
[2539] See Weinzierl and Weissenmayer (n 2490).
[2540] *Philip Morris* (n 28), para 71.
[2541] *Philip Morris* (n 28), para 72.
[2542] Weatherill, 'The Fundamental Question of Minimum or Maximum Harmonisation' (n 2480) 275–276. For an overview of that case-law, see ibid 274-278.
[2543] Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons [1991] OJ L256/5.

> Directive 91/477 […] was adopted as an 'accompanying measure for the internal market' which, whilst ensuring a high level of safety for European citizens, contributes to the creation of conditions enabling controls at the borders between Member States to be abolished by establishing a *minimum harmonised framework* relating to the acquisition and possession of firearms for civilian use and their transfer between Member States.[2544]

The radical approach to minimum harmonisation and the internal market that *Philip Morris* invites us to take is not satisfactory if viewing the internal market in an embedded way, where non-market values and interests have to be integrated, and Member State autonomy somewhat accommodated. Full homogeneity is probably not an ideal perspective, if only a feasible one, for the Union internal market.[2545] Yet, it belongs to the Court to clearly explain how a measure that does not ultimately ensure the free movement of goods or services can be validly adopted under Article 114 TFEU, by clarifying what the conditions set for recourse to that provision entail. Regulatory diversity should indeed be cherished and protected, but not at the expense of a proper delimitation of the Union and Member States' respective powers, and of proper judicial review. If the internal market is to remain a place of diversity, then harmonisation itself should perhaps be interrogated, since, as observed by Saydé, choosing harmonisation is already choosing against regulatory diversity.[2546] 'Conversely, whenever regulatory competition is—consciously or not—adopted as paradigm of economic integration, a positive harmonisation by Union legislature is unlikely.'[2547]

3.4. Interim conclusion

Looking at EU lifestyle risks regulation from the perspective of Member States regulatory autonomy, the conclusion is broadly the same as that drawn in the preceding section: the internal market nature of this area of the law affects the ability to conduct a policy which is responsive to other interests, be it health, cultural diversity or the value of local regulation per se. It neutralises health-based subsidiarity claims and seriously puts into question the validity of minimum harmonisation as a mode of legislation. As regards this latter point, *Philip Morris* is in a way a judgement comparable to *Tobacco Advertising*: an isolated reminder that Article 114 TFEU should only be used to adopt measures genuinely contributing to the internal market, followed by a stream of cases which, without formally renouncing this principle, simply decide to ignore it.

As Van den Bergh rightly observes:

> Over-emphasizing the market integration goal carries the risk that the arguments favouring centralization are overstated and the benefits of decentralization do not get the careful consideration they deserve. The market integration argument is not hospitable to the potential disadvantages of centralization: fewer preferences of EU citizens can be satisfied, information

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[2544] Case C-267/16 *Buhagiar v Minister for Justice* [2018] EU:C:2018:26, para 49, emphasis added.
[2545] See Weatherill, 'Supply of and demand for internal market regulations: strategies, preferences and interpretation' (n 2492) 47-49; Dougan, 'Minimum Harmonization after *Tobacco Advertising* and *Laval Un Partneri*' (n 2494) 17-18.
[2546] Saydé (n 2320) 261.
[2547] ibid 262.

> advantages at lower levels of government get lost and the beneficial effects of regulatory competition cannot be achieved.[2548]

By deliberately framing their practice and their review around the narrow internal market objective, the legislator and the Court prevent a more holistic discussion from taking place, that would lay down more clearly why EU action is needed, and under which circumstances local diversity in practices and preferences justify to refrain from taking action at the EU level. This is sorely missing at the moment, which may backfire when it is felt that the EU is overstepping, like the Nutri-Score issue illustrates.

4. Proportionality and the rights and interests of economic operators

Economic operators are those most directly impacted by lifestyle risks regulations. They are usually the addressee of rules which purports to restrain their business opportunities, limit consumption and, ultimately, may lead to a loss of revenue. This raises the question of the proportionality of EU lifestyle policy and the possible limits resulting from the application of that principle: under which circumstances, if ever, a useful public health measure may be discarded on grounds of its disproportionate effect burden on economic operators.

Under the principle of proportionality, enshrined in Article 5(4) TEU, 'the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties'. As discussed in Chapter 4, proportionality 'as a constitutional principle enables courts to reconcile conflicting rights and norms by considering their relative value'.[2549] Article 5(4) TEU does not refer to any specific right or interest but, as we shall see, proportionality has only been applied in the field of lifestyles risks to protect economic operators. Some authors have argued for using proportionality to protect the autonomy of Member States, in part to offset what they perceive as the lack of teeth of subsidiarity under Article 5(3). Following this approach, the Court 'should ask whether the importance of [an EU] measure is sufficient to justify its effect on the Member States'.[2550] Although it seems that proportionality can be read in this way from Article 5(4) TEU, as protecting not only individual rights from undue encroachment but also that of the Member States, this is not how it has been applied by the Court. No discussion of Member States autonomy has taken place as regards proportionality in the field of lifestyle risks.[2551]

Proportionality, as applied to EU lifestyle risks measures, confronts the objectives pursued by the Union legislator with that of economic operators whose interests are adversely affected. In that way, it bears much resemblance with the proportionality assessment of national measures

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[2548] Van den Bergh (n 468) 963.
[2549] Sauter, 'Proportionality in EU Law: A Balancing Act?' (n 1069) 441.
[2550] Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time' (n 2425) 83; Kumm (n 2397) 519–524; Schütze, 'Subsidiarity after Lisbon' (n 480). Schütze defends the application of a 'federal proportionality' test, although under the formal heading of subsidiarity and article 5(3) TEU. Kumm advocates for an integrative 'subsidiarity and proportionality framework'.
[2551] For an isolated reference to Member States' interests under proportionality, see European Commission, TPD Proposal (n 1430) 11-12, emphasis added: 'Under the principle of proportionality, the content and form of the Union action shall not exceed what is necessary to achieve the objectives of the Treaty (Article 5(4) TEU). This proposal provides an appropriate level of margin for implementation by the Member States. *It fully respects responsibilities of the Member States* to organise, finance and deliver health services and medical care.'

derogating free movement, analysed in Chapter 4. This allows to draw useful comparisons between the application of that principle to measures adopted by the EU and the national legislator. A notable difference lies in the nature of the test applied. While both types of measures, national and EU, are scrutinised as regards their suitability and necessity, the Court in the latter case also assesses proportionality stricto sensu. It is established case-law that that the principle of proportionality for EU acts requires that:

> [A]cts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is necessary in order to achieve those objectives; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and *the disadvantages caused must not be disproportionate to the aims pursued*.[2552]

This section investigates how economic operators' rights and interests are taken into account in the making EU lifestyle risks regulation and to which extent these provide a limit to the measures that can be adopted. Thus doing, it also analyses the role played by proportionality as a principle of good governance, which requires the legislator to lay down the reasons motivating its policy choices and to provide elements to justify these choices.

4.1. Economic interests v internal market

EU legislation in the field of lifestyles follows the double objective of facilitating the smooth functioning of the internal market and protecting public health. Proportionality must therefore be assessed in relation to these two objectives. The interests of economic operators are thus not only pitted against public health requirements, as it is the case when assessing the proportionality of national measures, but also against the interests of the internal market. This constitutes a major conceptual reconfiguration. Under free movement rules, companies are seen as the beneficiaries of an unfettered market where obstacles to the free circulation of goods or services are eliminated. Under internal market legislation, a measure which purports to lift the obstacles to trade existing in a given market may at the same time be detrimental to the companies which are active on that same market.

To better understand how an internal market measure adopter under Article 114 TFEU may be, all things considered, detrimental to economic operators, it is useful to look at the costs incurred by these operators laid down in the legislative impact assessments. For a first category of direct impacts, EU harmonisation may give rise to costs but also to cost savings. Changes in packaging and labelling rules may for instance require the design of a new label or to adapt

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[2552] *Philip Morris* (n 28), para 165; *Pillbox 38* (n 1662), para 48; *Poland v Parliament and Council* (n 587), para 78, emphasis added; see also *British American Tobacco* (n 27), para 122; *Arnold André* (n 975), para 45; *Swedish Match* (n 975), para 47; *Swedish Match II* (n 1620), para 35; *Planta Tabak* (n 1635), para 51. For a clear outline of the three sub-tests, see Case C-151/17 *Swedish Match AB v Secretary of State for Health (Swedish Match II)* [2018] EU:C:2018:241, Opinion of Advocate General Saugmandsgaard Øe, para 29 : 'In this regard, I would point out that, according to settled case-law, that principle requires, in the first place, that acts of the EU institutions be appropriate for attaining the legitimate objectives they pursue ('suitability test'). In the second place, those acts cannot exceed the limits of what is necessary for that purpose: when there is a choice between several appropriate measures, the least onerous must be favoured ('necessity test'). In the third place, the disadvantages caused must not be disproportionate to the aims pursued ('test of proportionality in the strict sense').'

printing machines.[2553] Regulation generally implies administrative costs: getting familiar with the requirements stemming from a new set of rules, collecting the necessary data, complying with a notification procedure, etc.[2554] A the same time, companies are also expected to benefit from regulation at the *EU* level. Complying with a single set of rules rather than 27 regulatory regimes leads to cost saving.[2555] Regarding the introduction of a harmonised reporting format for ingredients in tobacco products, the TPD impact assessment concluded for instance that '[t]he costs for introducing such a system on a mandatory basis would therefore be marginal and largely off-set by the savings generated by the use of one single format across the EU'.[2556] Overall, as far as these direct impacts were concerned, the TPD was considered to be beneficial to cigarettes and RYO tobacco manufacturers, because of the cost savings resulting from greater harmonisation.[2557]

The most substantial costs for companies are likely to belong to a second category of indirect impacts, resulting from a reduction in the consumption of the products or activities regulated. Lifestyle risks measures, if effective, lead to a loss of revenue for the operators concerned with possible consequences on employment. The TPD impact assessment estimated that the measures contained in the legislative proposal would lead to a reduction of the consumption of cigarettes and RYO tobacco of around 2% within a five-year period after transposition of the directive,[2558] resulting in a decrease of revenue for the tobacco industry of 76 million euros per year and a loss of 1500 jobs.[2559]

If considering the overall impact of the TPD on economic operators, the impact assessment concluded that the indirect costs incurred by cigarettes and RYO tobacco manufacturers 'might outweigh the benefits from the [direct] cost savings referred to above'.[2560] Arguably, the more restrictive the regulation is, and thus able to meet its public health objective, the most certain it is that it will result in an overall loss for economic operators, all costs and benefits considered. The cost savings arising from a total ban on tobacco products would for instance be far outweighed by the loss of revenue for tobacco companies. Yet, in order to justify recourse to the internal market competence to enact such a ban, it needs to be framed as a measure benefitting the internal market. This, as discussed above, is a difficult endeavour.

That being said, the fact that an internal market measure may have negative consequences for economic operators does not mean that this measure should not be adopted under the Union

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[2553] European Commission, Food Information Regulation impact assessment (n 466) 30-32; European Commission, TPD impact assessment (n 1642), part 1, 86-87.
[2554] Regarding food labelling, see European Commission, Food Information Regulation impact assessment (n 466) 32. Regarding the setting-up of a notification and age verification system for CBDS and regarding the EU tracking and tracing system: see European Commission, TPD impact assessment (n 1642), part 1, 104-105 and 108-109, respectively.
[2555] 'In many cases, the main benefit of internal market harmonisation/rules lies in cost savings following the replacement of 27 different national rules and procedures that companies and citizens face with one harmonised EU regime or by creating a 28th (EU) regime': European Commission, 'Better Regulation Toolbox' (n 103) 205.
[2556] European Commission, TPD impact assessment (n 1642), part 1, 99.
[2557] ibid 120-121.
[2558] ibid 113-114.
[2559] ibid 115. Regarding jobs, the impact assessment still concludes in a net gain of 2,200 jobs due to expenditure in other industries.
[2560] ibid 122.

internal market competence. The concepts of obstacle to free movement or distortion of competition under Article 114 TFEU are formal ones – restrictions by object, if adopting the vocabulary of competition law – as it is the case for restrictions under Article 34 or 56 TFEU. The Court does not require for a national measure to lead to an actual reduction in trade volume to qualify it as a restriction, as it does not require that an EU internal market measure is conducive to more cross-border trade. An effective EU health warning does bring benefits to the internal market, understood as a place where companies compete on a level-playing field, while ultimately being detrimental to those same companies.

Assessing the proportionality of an EU lifestyle risks measures vis-à-vis its internal market objective potentially leads to an interesting confrontation of interests: how much of these benefits to the internal market are worth the negative consequences incurred by businesses? This question is however never directly addressed in the case-law. Internal market-based proportionality review of EU acts appears overall to be a relatively new practice.[2561]

As regards suitability, the EU legislator must demonstrate that the measure adopted constitutes an appropriate mean to achieve both of the objectives pursued, market and health. This, one may think, places a greater constraint on the EU legislator, which has to justify its measures with regard not to one but two objectives, unlike it is the case for the national legislator. It offers more possibilities of challenges. Yet, by definition, a measure which fulfils the requirement for the use of Article 114 TFEU and contributes to the smooth functioning of the internal market is appropriate for the achievement of that same objective. In judgements rendered on the validity of EU lifestyle risks measures, suitability with regards to the internal market objective is therefore usually not discussed at length. Where EU measures clearly fulfil the conditions for recourse to Article 114 TFEU, this practice is not problematic. It is the case for instance of product requirement rules, such as the rules on e-cigarette liquids and containers, cartridges and tanks discussed in *Pillbox 38*, whose legality under Article 114 TFEU was never challenged.[2562] In cases where it wrongfully concludes that a measure can lawfully be adopted under Article 114 TFEU, such as the bans on tobacco for oral use and tobacco with characterising flavours, the Court logically applies the same reasoning when scrutinising proportionality and comes to the same conclusion.[2563] Hence, from the point of view of the internal market objective, the discussion of suitability does not bring much. At this stage, the consequences on economic operators are not yet addressed, as suitability is only concerned with the objective of a measure.

Regarding necessity, business interests and the internal market are once again not frontally pitted against one another. The discussion usually revolves around the existence of less restrictive measures which would be equally effective to achieve the public health objective. At times however, the internal market objective comes into play. It such cases, it represents an

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[2561] It is for instance absent from *British American Tobacco* (n 27); *Arnold André* (n 975); *Swedish Match* (n 975). See also Alemanno and Garde (n 31) 1776.
[2562] *Pillbox 38* (n 1662), paras 85, 112.
[2563] *Poland v Parliament and Council* (n 587), para 81; *Philip Morris* (n 28), para 172; *Swedish Match II* (n 1620), paras 55-58.

extra hurdle to be passed for plaintiffs, for these must identify a less restrictive measure which is suitable to the achievement of both the market and health objectives. This can be seen in *Philip Morris*, where the applicants argued that the organisation of targeted information campaigns on the danger of tobacco products with characterising flavours constituted a suitable and less restrictive alternative to the ban of the said products.[2564] The Court did not have to discuss the merits of the measures with regards to public health, arguably rather limited if compared to a ban, but simply observed that such information campaigns were unlikely 'to remove divergences between national rules relating to the placing on the market of such products and thus improve the conditions for the functioning of the internal market'.[2565] The Court also analysed in that same judgement the proportionality of various other TPD provisions on the labelling and packaging of tobacco products, relating to the integrity, position and dimension of the health warnings provided for in the Directive; to the shape of unit packets of cigarettes and to the minimum number of cigarettes per unit packet.[2566] The applicants in the main proceedings argued that less restrictive measures existed, in the form, for example, of a 'requirement that health warnings must be fully visible and not be distorted by packet shapes',[2567] to which the Court replied that it was 'sufficient to observe' that such a measure 'is not aimed at removing differences between the Member States' rules on the labelling and packaging of tobacco products and it is therefore not appropriate for the purpose of achieving the objective of improving the functioning of the internal market'.[2568]

Finally, in the handful of cases where the 'pure' proportionality of EU lifestyle measures has been assessed, this has always been in relation to their public health objective.[2569] The alleged benefits brought to the internal market by a measure are never openly put into balance with the costs faced by economic operators. Upholding the proportionality of a ban would for instance require to demonstrate how the foregone revenues for companies are somewhat compensated by increased business opportunities for other companies, benefits to other products or reduced costs.

This balancing exercise appears in some ways in the TPD impact assessment. As regards STPs, several options were considered, including a general a ban on this form of tobacco products. The overall conclusion was that a comprehensive ban on STPs would bring the most positive impacts both for health and the internal market, under the doubtful assumption, shared by the Court, that prohibiting an entire category of products is the best option from the point of view of the internal market.[2570] The option was finally not chosen, on grounds of the negative consequences on economic operators and the limited additional benefits to public health to be expected.[2571] Here there is a clear incongruence between the interests of STP companies and a measure presented as benefiting the internal market. Once again, these benefits are formulated

[2564] *Philip Morris* (n 28), para 182.
[2565] ibid.
[2566] TPD, arts 8(3), 9(3), 10(1)(g) and 14.
[2567] *Philip Morris* (n 28), para 193.
[2568] ibid, para 198.
[2569] See *Poland v Parliament and Council* (n 587); *Philip Morris* (n 28); *Swedish Match II* (n 1620).
[2570] European Commission, TPD impact assessment (n 1642), part 1, 74 and part 5, 3.
[2571] ibid.

in an abstract way, without any precise explanation as to *who* is gaining from a total ban on STPs.

4.2. Economic interests v health

On most occasions, the suitability and necessity of EU lifestyle measures is assessed with regard to their public health objective, like it is the case for national measures. According to the Court, 'the EU legislature must be allowed *broad discretion*' in an area such as the regulation of lifestyle risks, 'which entails political, economic and social choices on its part, and in which it is called upon to undertake *complex assessments*'. [2572] The legality of a measure adopted in that area can therefore only be affected if the measure is *manifestly* inappropriate or goes manifestly beyond what is necessary with regards to the objective sought, or leads to manifestly disproportionate consequences.[2573] Regarding EU measures, '[t]he judicial review of compliance with the principle of proportionality is thus attenuated with regard to its three constituent elements'.[2574]

Contrary to national measures, where judicial practice does not always conform to the proclaimed stance that Member States are provided with a 'measure of discretion',[2575] an analysis of the Court's case-law does support the view that the EU legislator benefits from a wide margin of discretion when adopting lifestyle risks control measures. A first indication of this, although it does not in itself demonstrate the lightness of judicial review, is that no piece of EU lifestyle risks legislation, or part thereof, has ever been annulled for breach of the principle of proportionality.

Regarding suitability, the Court's review of EU measures is quite reminiscent of that of national measures. It is limited to establishing a reasonable degree of connection between the measure and its health objective. This can be seen in *Pillbox 38*, where the Court considered that the rules contained in Article 20(3)(a) and (b) of the TPD, setting a maximum volume for e-cigarettes refill containers, cartridges and tanks, and a maximum nicotine concentration for e-liquids, '*make it possible* to limit the risks linked to exposure to nicotine' and are therefore appropriate for ensuring a high level of protection of human health.[2576] In the same judgement, the Court observed that the various bans on e-cigarettes advertising result in 'consumers – not least young people who are particularly sensitive to advertising – [being] confronted with fewer commercial inducements to purchase and consume electronic cigarettes with the result that they are less exposed to the identified or potential risks to human health to which those products

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[2572] *Poland v Parliament and Council* (n 587), para 79; *Pillbox 38* (n 1662), para 49; *Philip Morris* (n 28), para 166, emphasis added. See also *British American Tobacco* (n 27), para 123; *Arnold André* (n 975), para 46; *Swedish Match* (n 975), para 48; *Swedish Match II* (n 1620), para 36; *Planta Tabak* (n 1635), para 52.
[2573] See *Poland v Parliament and Council* (n 587), paras 79, 89, 96; *Pillbox 38* (n 1662), para 75; *Philip Morris* (n 28), paras 166, 177, 184, 190.
[2574] *Swedish Match II* (n 1620), Opinion of Advocate General Saugmandsgaard Øe, para 29.
[2575] *Visnapuu* (n 703), para 118; see also *Heinonen* (n 501), para 43; *Ahokainen* (n 869), paras 32-33; *Rosengren* (n 817), para 39; *Scotch Whisky* (n 612), para 35.
[2576] *Pillbox 38* (n 1662), para 86, emphasis added.

could give rise'.[2577] The link between advertising and increased consumption, and hence the likely negative effect of a restriction of the former on the latter, is accepted by the Court, as it has been the case for national measures. Finally, an EU measure is also deemed 'appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a *consistent and systematic manner'*.[2578] In *Swedish Match II*, the Court rejected the claim that the EU showed inconsistency in prohibiting tobacco for oral use from being placed on the market while allowing trade in other, more harmful forms of tobacco, like cigarettes,[2579] a position that echoes the one adopted by the Court in *Commission v France*[2580] and by Advocate General Tizzano in *Rosengren*.[2581]

The difference in the standard of review applied to EU and national measures is most visible as regards necessity. Whereas the Court, in the latter case, often discusses at length the existence of alternative measures to that adopted by Member States, this is largely absent from the case-law on the validity of EU measures.

This appears for instance from the judgements dealing with the validity of the ban on tobacco for oral use.[2582] In *Swedish Match* and *Arnold André*, the Court simply observed that, as 'apparent from the preamble to the [2001 TPD]', 'the prohibition of the marketing of tobacco products for oral use was *the only measure that appeared appropriate* to cope with the real danger that those new products would be used by young people'.[2583] It further noted that '*no other measures* aimed at imposing technical standards on manufacturers […] or at regulating the labelling of packagings of the product and its conditions of sale, in particular to minors, *would have the same preventive effect* in terms of the protection of health, inasmuch as they would let a product which is in any event harmful gain a place in the market'.[2584] Something similar can be seen in *Swedish Match II*, where the Court held that less restrictive measures, such as health warnings and the prohibition on flavoured tobacco, did not appear to be equally appropriate as regards the protection of public health, without entering into any detailed discussion of these measures' respective merits.[2585] What appears is that the harmful nature of the product is in itself enough to justify the ban, a measure which, by definition, cannot be matched by other measures in terms of effectiveness, provided it is complied with. This approach is not the one taken by the Court vis-à-vis national measures, if one considers for instance the *Van der Veldt* case on salt limit for bakery products.

Another interesting point of comparison is the suitability of age limits. In *Rosengren*, the Court considered that requiring consumers to simply declare in a document that they have reached the legal age for purchasing alcoholic beverages was as effective as a system where age is

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[2577] ibid, para 113.
[2578] *Swedish Match II* (n 1620), para 59, emphasis added.
[2579] ibid, paras 59-60.
[2580] *Commission v France* [2004] (n 896), para 33.
[2581] *Rosengren*, Opinion of Advocate General Tizzano (n 817), para 73.
[2582] It may also be seen in *Tobacco Advertising II* (n 26), para 147.
[2583] *Arnold André* (n 975), para 47; *Swedish Match* (n 975), para 49, emphasis added.
[2584] *Arnold André* (n 975), para 55; *Swedish Match* (n 975), para 57, emphasis added.
[2585] *Swedish Match II* (n 1620), para 50.

actually controlled by staff members in the shops belonging to the State monopoly.[2586] In a number of judgements regarding EU measures, though, the Court refused to consider age limits as a suitable alternative to more stringent measures, such as the prohibition of cross-border distance sales and the ban on tobacco containing characterising flavours, arguing that these could be 'easily circumvented'.[2587]

An aspect of the Court's proportionality assessment which could have resulted into a greater scrutiny of the EU legislator's choices, if compared to that of the national legislator, is the review of the proportionality *stricto sensu*. Indeed, as previously explained, the third limb of the proportionality test is potentially the most intrusive one, as it requires to leave aside the more 'technocratic' concepts of suitability and necessity and to perform a more political assessment: whether the expected benefits of a well-calibrated measure are worth the detrimental effects suffered by some parties, economic operators in our case. Pure proportionality is however not systematically discussed in lifestyle risks judgements, depending on whether an alleged breached thereof is raised by the claimant.[2588] That conclusion holds true regarding the proportionality review of Union acts in general.[2589] Further, where the Court does perform a pure proportionality analysis, it does not take the form of a genuine balancing act, whereby the health benefits expected from EU measures would be openly confronted to the losses suffered by economic operators.

This can be seen in *Poland v Parliament and Council* and *Philip Morris* regarding the alleged disproportionate effect of the ban on tobacco with characterising flavours. In the first of these two cases, Poland argued in particular that 'the social and economic costs of the prohibition on the placing on the market of mentholated tobacco products, in terms of lost jobs and revenue, [were] disproportionate to any advantages arising from that prohibition'.[2590]

In both judgements, the Court observed that, notwithstanding its broad legislative power, the EU legislature 'must base its choice on objective criteria and examine whether objectives pursued by the measure chosen are *such as to justify even substantial negative economic consequences* for certain operators',[2591] a requirement deriving from Article 5 of the Protocol on the application of the principles of subsidiarity and proportionality, under which 'legislative acts must take account of the need for any burden falling upon economic operators to be *minimised and commensurate* with the objective to be achieved'.[2592] The Court upheld the validity of the ban at issue, considering that the EU legislature had 'weighed up, on the one

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[2586] *Rosengren* (n 817), para 56.
[2587] *Poland v Parliament and Council* (n 587), para 93; *Pillbox 38* (n 1662), para 127; *Philip Morris* (n 28), para 181.
[2588] Alberto Alemanno and Amandine Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 163.
[2589] See Craig, *EU Administrative Law* (n 130) 644 : 'although the Union Courts do not always make reference to this aspect of the proportionality inquiry, they do so when the applicant presents arguments directed specifically to it'.
[2590] *Poland v Parliament and Council* (n 587), para 73.
[2591] *Poland v Parliament and Council* (n 587), para 97; *Philip Morris* (n 28), para 185, emphasis added.
[2592] *Poland v Parliament and Council* (n 587), para 98; *Philip Morris* (n 28), para 186, emphasis added.

hand, the economic consequences of that prohibition and, on the other, the requirement to ensure […] a high level of human health protection',[2593] by ensuring that '*the negative economic and social consequences* of the prohibition on the placing on the market of tobacco products with a characterising flavour *were limited*'.[2594] The decisive element was, in the eyes of the Court, the delayed application of the ban for tobacco products whose EU-wide sales volumes represented 3% or more of total sales[2595] and the fact that the ban would only result 'in a decrease in cigarette consumption in the European Union of 0.5 to 0.8% over a five-year period'.[2596]

In *Swedish Match II*, the Court simply observed, regarding the prohibition of tobacco for oral use, that, regardless of the considerable potential for growth existing in that market, 'the economic consequences deriving from the prohibition on the placing on the market of such products remain[ed], in any event, uncertain' since this form of tobacco had been banned in the EU for more than two decades already.[2597]

In these three judgements, the Court did not really put into balance health and the interests of economic operators. It did not seek to determine whether a certain number of saved lives on one side are worth the financial losses on the other but seemed content with the fact that the negative economic consequences flowing from the two bans at stake were limited or uncertain. This begs the question of whether the Court would have reached a different conclusion had the consequences not been 'limited'. If the EU legislator were to introduce a ban on cigarettes, would the Court annul it on grounds of its disproportionate impact on tobacco companies? It is doubtful, since the Court considers that 'the objective of protection of health takes precedence over economic considerations, the importance of that objective being such as to justify even substantial negative economic consequences'.[2598] As expressed by the Court's Advocate Generals:

> [T]he protection of human health *has considerably greater importance in the value system under EU law than such essentially economic interests* (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), with the result that health protection may justify even substantial negative economic consequences for certain economic operators.[2599]
>
> In my view […] provided that it passes the first two elements of the proportionality test, a measure which is intended to protect public health *must necessarily comply* with its third element in so far as *the private interests of economic operators must take a back seat in matters concerning the general interest of public health*.[2600]

[2593] *Poland v Parliament and Council* (n 587), para 102; *Philip Morris* (n 28), para 190.
[2594] *Poland v Parliament and Council* (n 587), para 99; *Philip Morris* (n 28), para 187, emphasis added.
[2595] *Poland v Parliament and Council* (n 587), para 100; *Philip Morris* (n 28), para 188.
[2596] *Poland v Parliament and Council* (n 587), para 101; *Philip Morris* (n 28), para 189.
[2597] *Swedish Match II* (n 1620), para 54.
[2598] *Swedish Match II* (n 1620), para 54.
[2599] *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 179; *Poland v Parliament and Council*, Opinion of Advocate General Kokott (n 2422), para 130, emphasis added; see also *Tobacco Advertising*, Opinion of Advocate General Fennelly (n 596), para 165.
[2600] *Swedish Match II*, Opinion of Advocate General Saugmandsgaard Øe (n 2553), para 87.

The Court's assessment should rather be construed as requiring that adequate consideration be given to the interests of economic operators in the decision-making process, even if health is ultimately given precedence in a way that is particularly detrimental to them.

This is part of a broader move towards a 'process-oriented review', where '[i]nstead of second-guessing the merits of the substantive choices made by the EU legislator, the ECJ prefer[s] to make sure that law-makers ha[ve] done their work properly: the EU legislator ha[s] to show before the ECJ that it ha[s] taken into consideration all the relevant interests at stake'.[2601] In that regard, the Court ruled in *Spain v Council* that:

> [E]ven though [judicial review of proportionality] is of *limited scope*, it requires that the Union institutions which have adopted the act in question must be able to show before the Court that in adopting the act they actually exercised their discretion, which presupposes the *taking into consideration of all the relevant factors and circumstances* of the situation the act was intended to regulate.
>
> It follows that the institutions must at the very least be able to produce and *set out clearly and unequivocally the basic facts* which had to be taken into account as the basis of the contested measures of the act and on which the exercise of their discretion depended.[2602]

Although this judgment should not be interpreted as imposing a general obligation on the Union legislature to perform an impact assessment for each act adopted,[2603] impact assessments do play a key role in the Court's proportionality review, for they allow to understand why the legislator favoured a particular policy option over another, how this option contributes to the achievement of the objective sought and what are the main impacts to be expected from its adoption. These function as an 'aid to the Court',[2604] whose latest case-law in the field of lifestyle features a more systematic reference to these documents.[2605] Impact assessments are useful for the assessment of proportionality in its entirety but may prove to be particularly instrumental as regards proportionality stricto sensu, which requires to balance the costs and benefits of legislation.[2606]

Greater reliance on impact assessments as instruments of judicial review is however conditional to all Union institutions committing to the use of this regulatory tool. The Commission conducts an impact assessment for all its legislative proposals that are likely to have significant economic, environmental, or social impacts, which may be subsequently amended by the co-legislators. Under the Interinstitutional Agreement on Better Law-Making,

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[2601] Koen Lenaerts, 'The European Court of Justice and Process-Oriented Review' (2012) 31 Yearbook of European Law 3, 7.
[2602] Case C-310/04 *Spain v Council* [2006] EU:C:2006:521, paras 122-123, emphasis added. The Court ultimately annulled the contested provision.
[2603] Alemanno, 'The Better Regulation Initiative at the Judicial Gate' (n 2316) 398.
[2604] Alemanno, 'The Better Regulation Initiative at the Judicial Gate' (n 2316); Alemanno, 'A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control' (n 2316).
[2605] *Philip Morris* (n 28), para 189, *Poland v Parliament and Council* (n 587), para 101, *Pillbox 38* (n 1662), para 57, *Swedish Match II* (n 2553), para 41-45.
[2606] Alberto Alemanno and Amandine Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' (n 31) 163. See Case T-13/99 *Pfizer Animal Health v Council* [2002] EU:T:2002:209, para 410, where the General Court ruled that 'a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management'.

the European Parliament and the Council should carry out an impact assessment in relation to their substantial amendments to the Commission's proposal, 'when they consider this to be appropriate and necessary',[2607] although this is rarely done in practice. It was estimated that, while the Commission produced over 700 impact assessments between 2007 and 2014, the European Parliament assessed the impact of around 20 of its amendments over the same period, and the Council assessed none.[2608] Further, the co-legislators rarely begin their discussion of a Commission's proposal with a review of its impact assessment.[2609]

In *Pillbox 38*, the Court recalled its position that the impact assessment accompanying a legislative proposal 'is not binding on either the Parliament or the Council' which remain 'free to adopt measures other than those which were the subject of that impact assessment'.[2610] As rightfully stated by Advocate General Kokott, '[i]f the law-making EU institutions were limited to adopting only provisions which were specifically the subject of an impact assessment by the Commission, the freedom enjoyed by the Parliament and the Council would be restricted appreciably and the legislative procedure would be rendered largely meaningless'.[2611] Hence, 'the mere fact that [the EU legislature] adopted a different and, as the case may be, more onerous measure than the measures envisaged by the Commission […] is not such as to demonstrate that it manifestly exceeded the limits of what was necessary in order to achieve the stated objective'.[2612]

That the Union legislator may depart from the Commission's proposal and its impact assessment suffers no contestation. Yet, as the legislator rarely performs any additional assessment when adopting substantial amendments, this result in a lack of data and arguments available to the parties and the Court when reviewing proportionality. This was the case in *Pillbox 38*, where Article 20 TPD on e-cigarettes had been added to the directive during the legislative procedure. Although the absence of any formal assessment of its impacts did not affect the validity of that provision, the Court did take into account a number of procedural elements to uphold its proportionality: that 'during the legislative process, the Parliament, the Council and the Commission took account of the available scientific evidence and the opinions of the interested parties' and organised 'a number of consultations and meetings […] precisely in order to collect the necessary information on the options available to the EU legislature'.[2613] This may be interpreted as a signal from the Court that the non-binding nature of the

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[2607] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, para 15.
[2608] Communication from the Commission to the European Parliament, the Council, the European Economic and social committee and the committee of the regions, 'Better Regulation for Better Results - An EU Agenda', COM (2015) 215 final, 8.
[2609] ibid. Regarding the TPD impact assessment, see the meagre appraisal from the European Parliament : European Parliament Research Service, 'Manufacture, Presentation and Sale of Tobacco and Related Products: Initial Appraisal of the Commission's Impact Assessment' (2013), accessed 11/05/2023 <https://www.europarl.europa.eu/thinktank/en/document/IPOL-JOIN_NT(2013)507501>.
[2610] *Pillbox 38* (n 1662), para 65.
[2611] *Pillbox 38*, Opinion of Advocate General Kokott (n 24), para 72.
[2612] *Pillbox 38* (n 1662), para 65.
[2613] ibid, para 66.

Commission's impact assessments does not exempt the legislator from gathering the necessary information and evidence before adopting a significant amendment.

The limited nature of the Court's review seems appropriate. In general, 'Courts should be wary of substituting their judgment for that of the primary decision-maker under the guise of proportionality',[2614] especially in an area such as lifestyle risks, where regulation entails the performance of complex assessments and the balancing of various political, economic and social concerns. 'The rationale for this reading of proportionality is an admixture of concerns relating to [both] legitimacy and expertise.'[2615] Yet, the same considerations should apply as regards national legislatures and the Court's review of Member State measures derogating free movement, even more so, one might argue, since the Court of Justice is less familiar with the dealings of a *national* legislator and the *national* circumstances that have prompted the adoption of a particular measure. More generally, 'deployment of proportionality against national measures inevitably raises issues, or at least concerns, of federalism', as a 'national measure subject to proportionality review under [Union] law is presumably a measure that, by reason of subject matter, falls within Member State competence'.[2616] It is arguably even less justifiable for the Court to adopt a strict standard of review and limit the adoption of public health measures at the national level in areas where the Union has itself refrained from acting, like it is the case for alcohol.

That national measures are subject to a more intense scrutiny from the Court than that applied to EU measures can be observed in all areas of EU law, as it has been abundantly observed and discussed among scholars.[2617] This difference in standard of review has usually been justified, or at least explained, by the different function that proportionality would serve in these two cases – a balance between a private and public interest for EU measures and a balance between an EU and a national interest for national measures – [2618] and the centrality of the four freedoms of movement for European integration.[2619] Yet, if these observations may undoubtedly have descriptive value, the Court likely sees its role as an agent of EU (economic) integration and shows therefore less deference towards the national legislator,[2620] it is not sure that they should have prescriptive value. After all, if the protection of human health has 'considerably greater importance in the value system under EU law' than mere economic interests, there is no reason to give less standing to health in the review of the legality of national measures. Conversely,

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[2614] Craig, *EU Administrative Law* (n 130) 653.
[2615] ibid.
[2616] Bermann (n 2425) 76.
[2617] See e.g. Maduro (n 665) 78; Tridimas, 'Proportionality in Community Law: Searching for the Appropriate Standard of Scrutiny' (1072) 66; Craig, *EU Administrative Law* (n 130) 682–683.
[2618] Tridimas, 'Proportionality in Community Law: Searching for the Appropriate Standard of Scrutiny' (n 1072) 66.
[2619] ibid 67; Craig, *EU Administrative Law* (n 130) 682–683.
[2620] According to Poiares Maduro, the Court is more concerned with '*State* intervention than with *public* intervention in the market': Poiares Maduro, *We The Court: The European Court of Justice and The European Economic Constitution* (n 665) 78.

proportionality in the case of EU measures acts 'as the guardian of individual rights'[2621] and these rights should be taken seriously.

Interestingly enough, it has also been argued that the Court's stricter approach as regards restrictions of free movement provisions was warranted by their 'fundamental right' nature. Whereas proportionality for national measures seeks to protect a 'fundamental principle or value', it only serves as regards EU measures as a tool to ensure the 'rationality' of the legislator.[2622] Hence, a useful comparison of the proportionality review for both categories of measures would require to only consider situations where the Court is called upon to assess an alleged breach of a fundamental right by the Union legislature.[2623] Yet, as will appear from the subsequent developments, the case-law on lifestyle risks does not support the claim that the Court's review becomes more intense in cases involving fundamental rights.

4.3. A stronger scrutiny for fundamental rights?

Public health measures affecting a product or an activity may not only lead to a loss of revenue, but are also liable to restrict the freedom of economic operators to conduct their business or to disseminate information, in which case they constitute limitations of their fundamental rights. These rights are protected by Articles 11 and 15 to 17 of the Charter: freedom of expression and information, freedom to choose an occupation and right to engage in work, freedom to conduct a business, and right to property, respectively.

Fundamental rights are generally not absolute. Under Article 52(1) CFR, any lawful limitation thereof 'must be provided for by law and respect [their] essence', and must comply with the principle of proportionality, meaning that the limitation is 'necessary and genuinely meet[s] objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others'.[2624] The 'crucial issue' for the present purpose is whether an assertion on the part of economic operators that one of their fundamental rights has been breached 'changes the nature of the proportionality inquiry undertaken by the EU Courts',[2625] bearing in mind that EU lifestyle measures restricting these economic rights usually protects other rights, the right to health especially.[2626] Do fundamental rights provide an additional layer of protection for

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[2621] Tridimas (n 1072) 67.

[2622] Bermann (n 2425) 75-76. According to the Court, 'the principles of free movement of goods and freedom of competition, together with freedom of trade as a fundamental right, are general principles of community law of which the court ensures observance. the above-mentioned provisions of the directive should therefore be reviewed in the light of those principles': *ADBHU* (n 625), para 9.

[2623] Tor-Inge Harbo, 'The Function of the Proportionality Principle in EU Law' (2010) 16 European Law Journal 158, 173–174.

[2624] Article 52(1) CFR.

[2625] Craig, *EU Administrative Law* (n 130) 658.

[2626] Alemanno and Garde, ''The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (n 31) 1783: 'These other rights include the right to life, the right to a clean environment and the right to information, as mentioned above, but also the right to (nutritious) food, the right to education and the principle that all actions concerning children shall be taken in their best interest.' For a discussion of tobacco

economic operators if compared to non-rights-based proportionality claims of the kind described above ?

The Court does tend 'to construe limits to such rights strictly, with the consequence that there will be a searching inquiry into the suitability and necessity elements of proportionality'.[2627] The margin of discretion is reduced. This was most clearly expressed in *Digital Rights Ireland*, where the Court held that:

> With regard to judicial review of compliance with [proportionality], *where interferences with fundamental rights are at issue, the extent of the EU legislature's discretion may prove to be limited, depending on a number of factors*, including, in particular, the area concerned, the nature of the right at issue guaranteed by the Charter, the nature and seriousness of the interference and the object pursued by the interference.
>
> In the present case, in view of the important role played by the protection of personal data in the light of the fundamental right to respect for private life and the extent and seriousness of the interference with that right caused by Directive 2006/24, *the EU legislature's discretion is reduced, with the result that review of that discretion should be strict*.[2628]

Such is not the case however, where economic rights are at stake, as the lifestyle risks case-law of illustrates very well. In none of these judgements did the claim that a fundamental right was breached led to a greater scrutiny from the Court or a change in the final outcome if compared to the standard review of proportionality.[2629] This may be explained by two factors. First, economic rights are in general given a lesser standing than other rights deemed more fundamental or worthy of protection. Economic rights are 'not absolute' but must be considered in relation to their 'social function',[2630] meaning that they may 'be subject to a *broad range* of interventions on the part of public authorities which may limit the exercise of economic activity in the public interest'.[2631] Only 'a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed' constitutes an unlawful limitation thereof.[2632] Second, in the present case, economic rights have to be put into balance with the protection of human health, an important public interest to protect which, as we have seen, is given greater importance in EU law's value system.

That economic rights are given a lesser standing appears particularly clearly from cases where an alleged breach of Article 11 CFR or Article 10 ECHR on the freedom of expression and

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control under the ECHR, see Amandine Garde and Brigit Toebes, 'Is There a European Human Rights Approach to Tobacco Control?' in Gispen and Toebes (n 507) 83–84.

[2627] Craig, *EU Administrative Law* (n 130) 656.

[2628] Joined Cases C-293/12 and C-594/12 *Digital Rights Ireland and Seitlinger and Others* [2014] EU:C:2014:238, paras 47-48, emphasis added.

[2629] This appears most clearly from *Neptune Distribution*, where the Court, regarding an alleged breach of Article 11 CFR, applied the exact same standard of scrutiny as for non-rights-based proportionality review, stating that 'the EU legislature must be allowed a broad discretion in an area such as that involved in the present case, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments' : Case C-157/14 *Neptune Distribution* [2015] EU:C:2015:823, para 76.

[2630] *British American Tobacco* (n 27), para 149; *Neptune Distribution* (n 2629), para 66; *Pillbox 38* (n 1662), para 157; *Swedish Match II* (n 1620), para 72.

[2631] *Pillbox 38* (n 1662), para 158, emphasis added.

[2632] *British American Tobacco* (n 27), para 149; see also *Deutsches Weintor* (n 2049), para 54.

information is claimed. This freedom applies to the dissemination by an economic operator of commercial information, in the form of advertising[2633] or other promotional means: the use, for instance, of terms such as 'light' 'mild' and 'low-tar' on the packaging and labelling of tobacco products, prohibited by Article 13(1) TPD,[2634] or the use of claims, regulated by the Claims Regulation.[2635] Rules contained in the AVMS Directive also contain restrictions of commercial information.[2636] The Court has made clear that insofar as a restriction on the freedom of information concerns activities of a commercial nature, the EU legislator must be recognised a higher degree of discretion.[2637] As it did in *Karner*, the Court ruled in *Tobacco Advertising II* that, when interfering with 'the commercial use of freedom of expression in a field as complex and fluctuating as advertising', the EU legislator should be recognised a 'certain amount of discretion', judicial review being therefore limited 'to an examination of the reasonableness and proportionality of the interference'.[2638]

In *Tobacco Advertising II*, the Court found that the prohibitions on tobacco advertising and sponsorship contained at Articles 3 and 4 of the TAD, 'even assuming' that they had the effect of indirectly weakening freedom of expression, did not impair journalistic freedom of expression and did not affect the 'editorial contributions of journalists'.[2639] It therefore concluded that the EU legislator had not exceeded the limits of its discretion by adopting such measures.[2640] Thus doing, the Court drew a clear line between mere advertising and what constitutes a 'higher' version of the freedom of expression, such as the activity of journalists.

In *Neptune Distribution* and *Philip Morris*, the Court reviewed, respectively, the restrictions on the use of claims contained in the Claims Regulation and the prohibition of various promotional features on the packaging and labelling of tobacco products, contained at Article 13(1) TPD. In both judgements, the Court concluded that the prohibitions contained in these provisions respected the essence of the freedom of information and expression inasmuch as these, 'far from prohibiting the communication of all information about the product', only prohibited the inclusion of certain elements and features.[2641]

In a number of cases, the Court was called upon to assess the compatibility of EU lifestyle measures with the freedom to choose an occupation and right to engage in work, the freedom to conduct a business, and the right to property, now enshrined in Articles 15 to 17 of the Charter. In *British American Tobacco*, the Court considered that the 2001 TPD provisions on health warnings and the use of favourable descriptors – the latter would be strengthened in Article 13(1) TPD – constituted a lawful interference with the intellectual property rights of

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[2633] *Philip Morris* (n 28), para 147; *Tobacco Advertising II* (n 26), para 155.
[2634] *Philip Morris* (n 28), para 147.
[2635] *Neptune Distribution* (n 2629), para 65.
[2636] See AVMS Directive, recitals 16 and 60; Directive 2018/1808, recital 60.
[2637] *Philip Morris* (n 28), para 155-156.
[2638] *Tobacco Advertising II* (n 26), para 155; see also *Karner* (n 671), para 51.
[2639] *Tobacco Advertising II* (n 26), para 156.
[2640] ibid, para 157.
[2641] *Philip Morris* (n 28), para 151. See also *Neptune Distribution* (n 2629), para 71.

tobacco manufacturers, namely the use of their trademarks.[2642] A similar conclusion was drawn in *Planta Tabak* regarding Article 13(1) TPD.[2643] In *Swedish Match*, the Court recognised that the ban on tobacco for oral use was 'capable of restricting the freedom of manufacturers of such products to pursue their trade or profession',[2644] a freedom recognised as a general principle of EU law at that time, but considered that it did not constitute a restriction of their right to property.[2645] According to the Court, '[n]o economic operator can claim a right to property in a market share, even if he held it at a time before the introduction of a measure affecting that market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances'.[2646] On the basis of the public health objective pursued by the ban, the Court found no disproportionate interference with the freedom to pursue a trade or profession.[2647] In *Pillbox 38*, the Court considered that Article 20(5) of the TPD, prohibiting a range of advertising and promotional means for e-cigarettes, constituted a proportionate interference with the freedom to conduct a business and the right to property.[2648] In *Deutsches Weintor*, finally, the Court examined an alleged breach of Articles 15 and 16 CFR by Article 4(3) of the Claims Regulation prohibiting the use of food claims for alcoholic beverages. It concluded that 'compliance with those freedoms [was] assured in the essential respects'[2649] since '[f]ar from prohibiting the production and marketing of alcoholic beverages, the legislation at issue merely controls, in a very clearly defined area, the associated labelling and advertising'.[2650]

In all these judgements, the Court attempted to strike a 'fair balance' between economic rights and the protection of health, enshrined in Article 35 of the Charter and other horizontal clauses of the TFEU,[2651] ruling invariably in favour of public health. In *Philip Morris* the Court insisted in particular that '*human health protection* — in an area characterised by the proven harmfulness of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic — *outweighs the interests* put forward' by the various tobacco industry operators, claimants in the main proceedings.[2652]

None of the solutions adopted in these various judgements gives much cause for concern on substance. Considering the importance of the public interest at stake, with regard to tobacco consumption especially, such restrictions on the rights of economic operators appear largely justified and proportionate. What can be criticised, however, is that the standard of review

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[2642] *British American Tobacco* (n 27), paras 149-153.
[2643] *Planta Tabak* (n 1635), paras 91-100.
[2644] *Swedish Match* (n 1620), para 72.
[2645] ibid.
[2646] ibid.
[2647] ibid, para 73.
[2648] *Pillbox 38* (n 1662), paras 156-165.
[2649] *Deutsches Weintor* (n 2049), para 56.
[2650] ibid, para 57
[2651] *Deutsches Weintor* (n 2049), para 47 ; *Neptune Distribution* (n 2629), paras 73, 75 ; *Philip Morris* (n 28), paras 153-154. The Court refers to arts 9, 114(3) and 168(1) TFEU.
[2652] *Philip Morris* (n 28), para 156, emphasis added.

adopted in these judgements is virtually the same as that used for non-rights-based proportionality claims, even in situations where the measure under review is a far-reaching restriction, as a total ban on advertising or a ban on an entire class of products. As put by Craig:

> There are […] principled arguments for more vigorous scrutiny in cases concerned with rights. It might well be accepted that such rights cannot be regarded as absolute, but *the very denomination of certain interests as EU rights* means that any interference should be kept to a minimum.[2653]

Where the Court in *Tobacco Advertising II* seems to doubt that a quasi-general ban on tobacco advertising constitutes a restriction on the freedom of expression,[2654] it fails to fully pay due respect to the importance of that right, this regardless of whether the restriction is ultimately considered justified and proportionate.

The weakness of economic rights in this context may appear even more surprising as regards the freedom to conduct a business and the other economic freedoms laid down in Articles 15 and 17 of the Charter. Indeed, these rights, one may argue, 'form[…] part of the EU's economic constitution according to which Member States have undertaken to commit to a specific form of political economy and market within the European Union'[2655] and are 'intrinsically linked to the realisation of an internal market and to the four fundamental freedoms',[2656] freedoms which, as we have seen, do enjoy a particularly great standing in the EU legal order. That EU law provisions adopted under an internal market label are frontally opposed to the rights which underpin the very foundation of that internal market, at least as far as free movement provisions are concerned, is not fully satisfactory on a conceptual level. The internal market as a site of harmonisation may be understood more broadly than a place for unfettered trade, but it cannot completely turn its back to its raison d'être, without making of the internal market the quasi-infinite category which the Court precisely opposed in *Tobacco Advertising*.

4.4. Evidence requirement and standard of review

A last question regarding the application of proportionality to EU lifestyle measures is that of the standard of proof that must be met by the EU legislator and the judicial review of the evidence adduced. Here as well, the Union legislator is granted a broad margin of discretion, and the Court's case-law is largely devoid of the requirements featuring in some free movement cases to produce a particular piece of evidence meeting specific standards. The Court considers that:

> As regards the assessments of *highly complex scientific and technical facts* […], it must be recalled that the Courts of the European *Union cannot substitute their assessment* of that material for that of the legislature on which the FEU Treaty has placed that task. The EU legislature's *broad discretion*, which implies *limited judicial review* of its exercise, applies not

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[2653] Craig, *EU Administrative Law* (n 130) 659, emphasis added.
[2654] ibid, para 156.
[2655] Nils Wahl, 'The Freedom to Conduct a Business: A Right of Fundamental Importance for the Future of the European Union' in Fabian Amtenbrink and others (eds), *The Internal Market and the Future of European Integration: Essays in Honour of Laurence W. Gormley* (n 665) 276.
[2656] ibid 275.

only to the nature and scope of the measures to be taken but also, to some extent, to *the finding of the basic facts*.'[2657]

The application of a limited *standard of judicial review* is not specific to lifestyle risks and can be seen in other areas of EU law involving the assessment of complex facts, such as food and feed safety[2658] or competition law.[2659] This limited review, however, as expressed in the aforementioned quote, concerns the Court's appraisal of the quality or the strength of the evidence justifying a measure adopted by the EU legislator. This does not say anything about the *standard of proof*: what kind of evidence, if at all, must be presented to support the adoption of a measure and prove its compliance with the principle of proportionality. In that way, the Court's control as regard evidence is the exact opposite of that applied to national measures, for which the Court gives guidance as to the kind of evidence to be adduced by national authorities but has never taken a clear stance on what the intensity of its review should be. This may reflect a greater confidence from the Court in the process of gathering evidence at the EU level, with which it is undoubtedly more familiar, than that in place at the national level.

In that regard, a striking feature of the Court's case-law regarding the proportionality of EU measures is the absence of the general requirement applicable to national measures that 'the reasons which may be invoked […] by way of justification [for their adoption] must be accompanied by *appropriate evidence* or by an analysis of the appropriateness and proportionality of the restrictive measure adopted by that State, and *specific evidence* substantiating its arguments'.[2660] This is especially visible in the Court's early lifestyle case-law, largely devoid of any discussion on proof and any reference to specific pieces of evidence.[2661] This has changed in most recent judgements, *Philip Morris*, *Poland v Parliament and Council*, *Pillbox 38* and *Swedish Match II* in particular. Yet, regrettably,[2662] no general principle emerges from these cases as regards the applicable standard of proof, the Court's

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[2657] *Swedish Match II* (n 1620), para 37, emphasis added; see also *Philip Morris*, Opinion of Advocate General Kokott (n 2349), paras 102-103.

[2658] See Case T-13/99 *Pfizer Animal Health v Council* [2002] EU:T:2002:209, para 393 : 'It is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions, on which the Treaty confers sole responsibility in that regard.'

[2659] See Joined Cases C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P *Aalborg Portland A/S* [2004] EU:C:2004:6, para 279 : 'Examination by the Community judicature of the complex economic assessments made by the Commission must necessarily be confined to verifying whether the rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of appraisal or misuse of powers.' On evidence and judicial review in competition law, see Castillo de la Torre and Gippini Fournier (n 1027) 275–288.

[2660] *Scotch Whisky* (n 612), para 54; see also *ANETT* (n 675), para 50.

[2661] See *British American Tobacco* (n 27), *Tobacco Advertising II* (n 26). Regarding *Tobacco Advertising II*, see Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' (n 1319) 121–122. See however a brief reference to evidence in *Swedish Match* (n 975), paras 50-54.

[2662] As rightly put by Paul Craig, '[t]here may be disagreement as to what the standard of proof ought to be in any particular case. It is, nonetheless, right and proper for the reviewing court to determine the standard of proof required for the establishment of facts by the primary decision-maker.': Craig, *EU Administrative Law* (n 130) 470.

more systematic flagging of relevant pieces of evidence does give a feeling that legislative acts cannot be based on a vacuum.

Coming back to the question of judicial review and the appropriate standard of scrutiny, an equilibrium must be found between the necessary respect for the legislator's prerogative and expertise, considering especially the risk, as discussed in Chapter 4, of the Court misunderstanding or mismanaging the evidence produced, and the importance for the Court of discharging its obligations and ensure that a sufficient evidence base exists for the adoption of restrictive measures. Even in complex cases involving a degree of uncertainty, the Court 'must […] ensure that the reasoning supporting the rules […] adopted is convincing, that is, that it is based on objective factors amenable to judicial review'.[2663] It cannot fully escape 'scrutinising the adequacy of the informational basis of contested measures'[2664], 'to ensure that decision-makers have the right type and quality of information at their disposal to make decisions that are consistent with the goal sought and the relevant legal norms'.[2665] To do so, as previously discussed, the Court increasingly relies on the evidence contained in impact assessments.[2666]

Overall though, the Court refuses to get embroiled in scientific controversies and to openly evaluate the quality of the evidence produced, which seems like a reasonable course of action. This appears especially in cases where claimants rely on 'partisan expert evidence'[2667] contradicting that put forward by the European Commission. In such cases, evidence coming from internationally recognised sources is favoured, as it provides the Court with a greater sense of certainty and objectivity compared to studies presented by parties, which may have been selected purportedly to offer a partial account of the state of scientific knowledge. In *Pillbox 38* for instance, confronted to the 'multiple scientific studies and reports' produced by the parties,[2668] which contained contradicting evidence, the Court chose to rely heavily on the WHO 'ENDS report' to set its position regarding the health risks of e-cigarettes and the effectiveness of different regulatory options.[2669]

In cases regarding the TPD, frequent references are made to various document emanating from the FCTC, guidelines or decisions of the conference of the parties, which also provide the Court

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[2663] Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' (n 1319) 126. See also the remarks made by the referring national court in *Technische Universität München*, 'The more difficult the technical questions to be decided the more immune from challenge the Commission' s decision would be. It is questionable whether such a restriction of the legal protection of [EU] citizens is compatible with the constitutional principle guaranteeing effective legal protection which is recognized by [EU] law.': Case C-269/90 *Technische Universität München* [1991] EU:C:1991:317, Opinion of Advocate General Jacobs, para 11.

[2664] Ellen Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' in Mark Dawson, Bruno De Witte and Elise Muir, *Judicial Activism at the European Court of Justice* (Edward Elgar Publishing 2013) 163.

[2665] ibid. On this 'catalyst' function of courts: see Joanne Scott and Susan Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance Narrowing the Gap: Law and New Approaches to Governance in the European Union' (2006) 13 Columbia Journal of European Law 565.

[2666] See above n.

[2667] Barbier de la Serre and Sibony (n 1011) 964.

[2668] *Pillbox 38* (n 1662), para 50.

[2669] ibid, para 51-53.

with this type of trustworthy source of evidence. In *Philip Morris* and *Poland v Parliament and Council*, the Court extensively used the Partial guidelines for implementation of Articles 9 and 10 of the FCTC,[2670] dealing with the regulation of the contents of tobacco products and the regulation of tobacco product disclosures. According to the Court:

> Whilst it is correct that the FCTC guidelines do not have binding force, they are intended, in accordance with Articles 7 and 9 of the FCTC, to assist the Contracting Parties in implementing the binding provisions of that convention.
>
> Furthermore, those guidelines are based on *the best available scientific evidence* and the experience of the Parties to the FCTC, as can be seen from section 1.1 of the guidelines, and have been adopted by consensus, including by the European Union and its Member States, as is stated in recital 7 of Directive 2014/40.[2671]

These guidelines should therefore 'be recognised as being of *particularly high evidential value*'.[2672]

In these two judgement, the guidelines provided the Court with the evidence needed in order to uphold the ban on characterising flavours in tobacco products, justified by the fact that these flavours 'have certain similar, objective characteristics and similar effects as regards initiating tobacco consumption and sustaining tobacco use'[2673] and that 'menthol, amongst other flavours, contributes to promoting and sustaining tobacco use and, because of its palatability, renders tobacco products more attractive to consumers'.[2674] Since the guidelines recommended to prohibit ingredients such as menthol in tobacco products, the Court found this ban to necessary to the protection of human health.[2675] The guidelines were also used by the Court to establish the proportionality of the TPD combined health warnings.[2676] In *Pillbox 38*, similarly, the Court relied on the decision of the Conference of the Parties to the FCTC on e-cigarettes to assess the proportionality of the relevant rules contained in the TPD.[2677] The FCTC's documents are therefore used not only to establish the presence of health risks but also to assess the suitability and necessity of the measures adopted to address these risks.

This extensive reliance on FCTC documents is warranted given the nature of the evidence contained, resulting from a collaborative work of international experts, and the fact that the EU is a party to the FCTC and is bound by its provisions. The fact that a measure is supported by the FCTC should constitute as a strong presumption of its proportionality. It should not, however, lead the Court to refrain altogether from conducting its own assessment, thus delegating its judicial role to a body of scientific experts. This was for instance done in *Pillbox 38*, where the Court simply stated that:

[2670] The guidelines can be retrieved at <https://www.who.int/fctc/treaty_instruments/adopted/article_9and10/en/> accessed 11/05/2023.
[2671] *Poland v Parliament and Council* (n 587), paras 45-46; *Philip Morris* (n 28), paras 111-112; emphasis added.
[2672] *Poland v Parliament and Council* (n 587), para 85; *Philip Morris* (n 28), para 175; emphasis added.
[2673] *Poland v Parliament and Council* (n 587), para 48.
[2674] *Poland v Parliament and Council* (n 587), para 85; *Philip Morris* (n 28), para 175.
[2675] *Poland v Parliament and Council* (n 587), para 90; *Philip Morris* (n 28), para 178.
[2676] *Philip Morris* (n 28), paras 204-208.
[2677] *Pillbox 38* (n 1662), paras 59, 61 and 114.

> [A]s concerns, secondly, the necessity of [the prohibition of electronic cigarettes advertising], it should be noted that, by its decision […], the Conference of the Parties to the FCTC urged "[the p]arties to consider banning or restricting advertising, promotion and sponsorship of [electronic nicotine delivery systems]".
>
> In those circumstances, it is not apparent that, by adopting Article 20(5) of Directive 2014/40, the EU legislature manifestly exceeded the limits of what is necessary in order to achieve the objective pursued by that directive.[2678]

Finding an equilibrium between effective judicial protection granted to those adversely affected by EU legislation, requiring a certain degree of oversight, and respect for the legislator's complex choices is a difficult endeavour, in particular in cases involving scientific uncertainty, where the EU legislature must take account of the precautionary principle. According to that principle:

> [W]here there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.
>
> Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures. [2679]

By definition, the precautionary principle involves a relaxation of the evidential requirement, since health risks need not to be proven with 'sufficient accuracy in the current state of scientific research'.[2680] Yet, this does not result in an absence of judicial review.

Uncertainty and precaution were central to the *Swedish Match II* and *Pillbox 38* cases, dealing respectively with the prohibition on tobacco for oral use and the rules applicable to electronic cigarettes. These two areas of tobacco control present similar features. In both cases, uncertainty remained as to the relationship between the consumption of these two products and that of cigarettes, acting as cessation aids or gateway products, and hence as to the effect of control measures on public health. Essentially, as explained in further details in Chapter 1 (Section 4.1), the debate opposes 'two distinct strands of tobacco control' : the approach defended by the EU to '*reduce the supply and consumption* of tobacco products', the endgame strategy, in other words, and an alternative 'harm reduction' approach, which would seek to '*reduce the harmful effects* of tobacco' without necessarily aiming at eradicating their consumption.[2681] In both *Swedish Match II* and *Pillbox 38*, the claimants essentially argued that by reducing access to an alternative to traditional tobacco products which is less harmful, removing it entirely from the market in the case of tobacco for oral use, the measures adopted by the EU failed to adequately protect public health.[2682]

[2678] ibid, paras 114-115.
[2679] *Pillbox 38* (n 1662), para 55; *Swedish Match II* (n 1620), para 38.
[2680] *Pillbox 38*, Opinion of Advocate General Kokott (n 24), para 64.
[2681] *Swedish Match II*, Opinion of Advocate General Saugmandsgaard Øe (n 1553), para 27.
[2682] *Pillbox 38* (n 1662), para 47; *Swedish Match II* (n 1620), para 46.

In *Pillbox 38*, as previously mentioned, a 'heated debate' opposed the parties to the proceedings.[2683] While the claimant stressed the limited risk of harm involved with the use of e-cigarettes and its potential as a cessation aid, EU institutions and intervening governments pointed at the addictiveness of the product, at the presence of established health risks, such as poisoning, at the existence of a possible gateway and normalisation effect and, finally, at the lack of certainty regarding the role of e-cigarette as a cessation aid.[2684] The Court refrained from conducting any assessment of the evidence submitted by the parties and to endorse one view of the other.[2685] It simply acknowledged, on the basis of the aforementioned WHO report, the existence of uncertainty,[2686] and ruled that, 'in deciding to devote specific rules to the placing on the market of electronic cigarettes and refill containers, […] the EU legislature did not manifestly infringe the limits of its discretion in the matter'.[2687]

In *Swedish Match II*, the claimants similarly criticised the pertinence of the ban on tobacco for oral use. They relied especially on 'recent scientific studies' demonstrating 'that the consumption of snus tends to replace, rather than be additional to the consumption of tobacco products for smoking, and that it has no 'gateway effect' to the latter products'.[2688] Here again, the Court did not assess the validity of the evidence used by the Commission, in the light of these new studies, and simply stated that:

> Given that, if the prohibition on placing on the market tobacco products for oral use were to be lifted, the positive effects would be uncertain with respect to the health of consumers seeking to use those products as an aid to the cessation of smoking and, moreover, there would be risks to the health of other consumers, particularly young people, requiring the adoption, in accordance with the precautionary principle, of restrictive measures, Article 1(c) and Article 17 of Directive 2014/40 cannot be regarded as being manifestly inappropriate to the objective of ensuring a high level of public health.[2689]

These two judgements call for a number of observations to be made. First, as done in some of the free movement cases analysed in Chapter 4, the precautionary principle is here applied in relation to the effect of certain policies and not as regards the existence of certain health risks. What was at stake was not the harmful nature of tobacco for oral use and e-cigarettes, although some uncertainty remains as regards the latter, but the pertinence of the measures adopted by the EU to reduce the overall exposure to risk in the population, taking into account the relationship between the consumption of these two products and that of cigarettes. Second,

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[2683] *Pillbox 38* (n 1662), para 50.
[2684] ibid.
[2685] The same degree of caution was not adopted by Advocate General Kokott, who held that 'in assessing the lawfulness of Directive 2014/40, and in particular the proportionality of the provisions on e-cigarettes contained in Article 20 thereof, it is ultimately immaterial whether the health risks mentioned by the Union legislature — which seem very plausible to me personally — can be proven with sufficient accuracy in the current state of scientific research': *Pillbox 38* (n 24), Opinion of Advocate General Kokott, para 64. One may question the pertinence of having the Advocate General's personal opinion on a highly complex and debated scientific matter expressed in this way.
[2686] *Pillbox 38* (n 1662), paras 51-54.
[2687] ibid, para 61.
[2688] *Swedish Match II* (n 1620), para 46; see also *Swedish Match II*, Opinion of Advocate General Saugmandsgaard Øe (n 2553), paras 43-57.
[2689] *Swedish Match II* (n 1620), para 49.

these two judgements provide an illustration of the 'uncertainty paradox' described by Van Asselt and Vos.[2690] While scientific uncertainty is acknowledged, the Court still analyses the evidence produced as providing a certain sense of certainty, about the uncertain, and a sufficient base for the adoption of the contested measures. This was clearly done in *Pillbox 38* with the WHO report on e-cigarettes, thus ignoring the salient political judgements that have been central to the adoption of the rules regarding tobacco for oral use and e-cigarettes. The choice by the Commission and the legislator to pursue an endgame strategy, with the risks entailed from a harm reduction perspective, is perfectly legitimate but would deserve to be laid down more clearly in a case where science alone does not suffice to justify the adopted measures. The Court's approach risks leading to a situation where 'regulators [are] encouraged even more to cast around science to explain a political decision',[2691] instead of articulating their normative preferences and choices more clearly.[2692] A third and interrelated observation is that scientific uncertainty regarding the effect of certain policy options is even more likely to arise once the choice is made to act at the EU level, as previously discussed regarding subsidiarity. If the effectiveness of tobacco for oral use or e-cigarettes as cigarette replacements is contingent upon national preferences and habits, then the diversity of these preferences and habits is likely to be an obstacle to reaching certainty at the EU level.

4.5. Interim conclusion

Overall, the Court has adopted an appropriate level of scrutiny as regards the proportionality assessment of EU lifestyle risks measures. While being respectful of the legislator's prerogative, it allows to understand how public health may benefit from the measures adopted and to identify the main impacts befalling economic operators. In this regard, the Court's increasing level of engagement with evidence is to be commanded. Through comparison, the Court's approach in the case of EU measures comes to underline the rather strict and disparate nature of that adopted as regards national measures. It offers lessons to reinforce the latter's predictability and acceptance.

In so doing, the Court broadly endorse the stance taken by the EU legislator that, as regards tobacco in particular, reaching a high level of public health protection justifies to limit, even substantially, the rights and interests of economic operators. While this is not objectionable in itself, the fact that a proportionality assessment through the prism of fundamental rights does not result in a greater degree of scrutiny is problematic, for it puts into question the standing recognised to these rights in the EU legal order.

Finally, what appears most striking in the proportionality review of EU lifestyle risks measures is not so much what is present, but what is absent. Although, these measures follow a double objective, they are rarely assessed with regard to what should be, legally, their main objective:

[2690] Marjolein B A van Asselt and Ellen Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 Journal of Risk Research 313.
[2691] Vos (n 2664) 164.
[2692] Van Asselt and Vos (n 369) 332. In that regard, the analysis of Advocate General Saugmandsgaard Øe in *Swedish Match II* appears more complete: see *Swedish Match II*, Opinion of Advocate General Saugmandsgaard Øe (n 1553), paras 61-63.

that of contributing to the establishment and functioning of the internal market. This is especially interesting in the case of lifestyle risks, where economic operators are presented as those having the most to lose from EU regulation.

5. Consumer autonomy: the neglected rights and interests

The law on lifestyle risks is quite unique in that it is primarily aimed at altering individual choices that have little or no bearing on others. It mostly seeks to prevent self-harm. Unlike consumer law, little of it is devoted to prohibiting or regulating truly unfair and exploitative practices. Unlike environmental law, to take another field where consumer choices may be restricted, it does not seek to protect interests that go beyond that of the individual.[2693] This paternalistic trait of EU lifestyle risks regulation is further reinforced by the fact that it does not act forcefully, if at all, in areas where lifestyles do generate harm to others: second-hand smoking, drink-driving, interpersonal violence. Moreover, EU lifestyle risks regulation is increasingly behaviourally informed, which, as discussed in Chapter 1 (Section 6.2), raises specific ethical questions.

Against this background, one may expect the law to reflect this state of affairs and questions of autonomy to be hotly debated in the policy-making process or to appear prominently in litigation on the validity of EU lifestyle measures. The opposite is true. Unlike is the case for economic operators, whose rights and interests are duly taken into account in the decision-making process and judicial review, the consumer perspective appears rather absent from the regulatory discussion on lifestyle risks. This question surfaces in some of the EU strategies and programmes adopted in the field. The EU Nutrition Strategy or the Commission Communication on public health of 1993, for instance, stress the responsibility of individuals regarding their lifestyles. Yet, in the concrete designing of EU measures and their evaluation by the Court of Justice, this dimension is surprisingly absent. Where it is present, a monolithic vision of the consumer emerges, that of a consumer who is lightly impacted by regulation, unlike businesses, and whose interests are aligned with that of the legislator, in need of protection and benefitting from a policy that furthers their health.

This can be appraised from two different perspectives. The restrictive impact of EU lifestyle risks measures on consumer autonomy may be envisaged as creating ‘costs’, to be identified and integrated in the impact assessment process, and as limitations on some of the fundamental protected in the Union legal order.

5.1. Costs to consumers in impact assessments

Despite being enacted to benefit consumers, to protect consumers from harm, lifestyle risks measures may also adversely impact consumers in various ways. Consumers are heterogenous and have various interests. Article 169 TFEU on consumer protection refers to ‘protecting the

[2693] It is not to say that a society may not have interests in having a healthy population, but that health is always primarily an individual quality.

health, safety and *economic interests* of consumers, as well as promoting their *right to information*'.[2694] A measure restricting available options may benefit consumers from a health and safety point of view but may be detrimental from the perspective of freedom of choice. As expressed by the 'Better regulation toolbox', a policy option's significant impacts on consumers involve their ability to access retail goods and services, and whether the option affects the 'prices, quality, availability or choices of consumer goods and services'.[2695] Further, a number of EU interventions in the field of lifestyle seek to prevent the transmission of information rather than promote it.

Yet this detrimental effect is only rarely acknowledged in impact assessments accompanying the various legislative proposals or ex post evaluations. Lifestyle interventions are framed above all as policies that benefits health and the internal market, without actual direct references made regarding impacts on consumers. The TPD impact assessment does mention the restricting effect of bans on consumer choice,[2696] but at no point is this aspect considered relevant when discussing the relative merits of different policy options involving a ban.[2697] The section discussing the overall impacts of the preferred options is almost silent regarding consumers, mentioning only that 'the envisaged revision focuses on discouraging young people from taking up tobacco consumption and allowing adult consumers to take informed decisions',[2698] largely ignoring the fact that most of the TPD provisions do not aim at allowing consumers to take informed decisions but at restraining the appeal of tobacco products or their access to the market.

This absence somewhat affects the truthfulness of the discussion. All policies that seek to alter behaviour, even if beneficial on balance, entail costs due to the forgone benefits that consumers drew from their previous course of action.[2699] This is the case for consumers who alter their conduct to comply with a mandate or a ban but may also be the case when the provision of information reach its goal and lead to a change in behaviour.[2700] Further, even considering that lifestyle interventions benefit consumers as a whole, they still make some individuals worse off, because consumers are heterogeneous.[2701] Those that wish to abandon smoking or adjust their drinking patterns may welcome measures nudging or coercing them in that direction, some others may regret the influence on their choices resulting from it. Moreover, consumers are affected by a range of other costs: judgment and decision-making costs, incurred when measures 'lead consumers to pay greater attention to their choices, process more information,

[2694] Emphasis added.
[2695] European Commission, 'Better Regulation Toolbox' (n 103) 292.
[2696] See European Commission, TPD impact assessment (n 1642) 60, 63, 85 and 93.
[2697] See as regards STPs: ibid, 74-76; as regards the ban on characterising flavours: ibid, 103-104.
[2698] ibid 119.
[2699] Avishalom Tor, The Private Cost of Behavioral Interventions' (2023) 72 Duke Law Journal 1673.
[2700] ibid 10-11.
[2701] ibid 11.

engage in a more thorough deliberation, or even simply make a choice they would have avoided',[2702] or, in the case of behavioural regulation, emotional or psychological costs.[2703]

The costs involved with information requirements or restrictions, the EU's preferred type of intervention, appear particularly overlooked. Cass Sunstein identifies for instance different types of costs resulting from the mandatory labelling of health information: 'a small cognitive tax', resulting from reading and processing the information present on the label, a 'hedonic tax' on all consumers, regardless of their ultimate choices – those who resist the change are negatively affected from knowing that their action is harmful and those who adapt their behaviour still learn something that inflicts pain – and a general 'consumer welfare loss' resulting from the forgone enjoyment involved in the consumption of unhealthy products.[2704] Pictorial or health warnings of the sort used in the TPD, meant to induce fear or disgust, are particularly likely to give rise to the 'hedonic tax' referred to by Sunstein, because they work through the negative affect they generate, a cost imposed on all cigarette consumers, including the majority that does not change its behaviour and thus does not benefit from the intervention.[2705]

None of these costs is ever acknowledged in EU legislation on lifestyle risks. This appears from the TPD and Food Information Regulation impact assessments, where the following observations are made regarding labelling:

> The proposed measure would improve consumer protection across the EU, including providing assistance to smokers wishing to quit (e.g. quit lines, web sites), protecting consumers from misleading information on the health impact of smoking (replacement of TNCO levels) and providing appropriate information (strengthened labelling). At the same time, it is expected that the measures would affect neither the range of products available on the EU-market nor their quality.[2706]
>
> The provision of nutrition information is beneficial for consumers, as a means to compare different products on the basis on their nutritional quality, and to make better informed choices about the prepackaged food they purchase.[2707]

Whichever form they take, provision of factual information, use of fear-inducing messages or prohibition of information, measures are invariably presented as benefitting consumers. The TPD impact assessment does refer to the 'strong emotional reactions' and the 'negative reactions' resulting from exposure to pictorial health warnings, but as a positive contribution due to the effect on consumption. In the recent evaluation of the Claims Regulation, the absence of EU-level nutrient profiles is presented as giving rise to public health costs for citizens and

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[2702] ibid 19.
[2703] ibid 12-13, 19.
[2704] Cass R Sunstein, *The Cost-Benefit Revolution* (The MIT Press 2018) 124–126. Regarding the 'cognitive tax', see also Zamir and Teichman (n 110) 176.
[2705] Tor, 'The Private Costs of Behavioural Interventions' (n 2699) 1693.
[2706] European Commission, TPD impact assessment(n 1642), part 1, 88.
[2707] European Commission, Food Information Regulation impact assessment (n 466) 40.

consumers, without any mention of any possible benefits.[2708] The use of claims on HFSS foods does however benefits some consumers, those for instance who are determined to purchase such foods and would like to arbitrate between products on the basis of other health-related characteristics. These would be deprived of that possibility if the use of claims on HFSS foods were to be prohibited.

A proper identification of the costs to consumers and citizens involved with the regulation of lifestyle risks would have several benefits. It could help identifying measures which are truly disproportionate on account of their aggregate effect on consumers, measures which are for instance over-inclusive, 'targeting a small minority while imposing costs on autonomy for the majority'.[2709] Most importantly making these costs more visible would allow the proportionality control to be more inclusive. Claimants may raise points linked to the disproportionate effect of certain measures on consumers, forcing the Court to discuss proportionality from this perspective, a perspective which is entirely absent at the moment. At the level of true proportionality especially, what is presented is a binary opposition between health and the interests of economic operators. In *Swedish Match II*, for instance, Advocate General Oe does refer to the necessity to 'take full account of the interests involved, 'including the interests of *individuals* negatively affected by that measure' but only refers subsequently to the '*negative economic consequences* for certain operators'.[2710]

5.2. Fundamental rights

The binary and somewhat oversimplified vision of what lifestyle risks regulation entails for society and the different actors involved is reflected in discussion on fundamental rights. EU measures are almost solely construed as protecting the rights of consumers, without any regard for the restrictive aspect thereof. That people's fundamental rights can be negatively affected by interventions aiming at protecting public health should not appear as controversial. For a broad range of public health interventions, public power is imposed on the individual to protect a broader population-wide health objective,[2711] with the necessity to balance the collective good and individual rights.[2712] This is for instance the case of mandatory lockdowns or vaccination in times of pandemic. While not being devoid of collective aspects, a particular feature of health promotion policies targeting lifestyles is that they pit the *individual* good against individual rights.

The absence of any discussion on autonomy and individual rights can be seen in the TPD Proposal, which observes that:

[2708] European Commission, 'Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods' (n 2094) 34-39, 44, 51, 59.
[2709] Van Aaken, 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' (n 381) 111.
[2710] *Swedish Match II*, Opinion of Advocate General Saugmansgaard Øe (n 1553), para 84, emphasis added.
[2711] de Ruijter (n 47) 46-50; see also Hartlev (n 388) 368.
[2712] de Ruijter (n 47) 48.

> The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property (Article 17). The obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union.[2713]

No reference to rights that may be affected due to a loss in freedom or autonomy is made. Autonomy is far from being a straightforward concept. The extent to which a lifestyle measure constitutes, on balance, a restriction on someone's autonomy, rather than a way of enhancing it, as discussed in greater lengths in Chapter 1 (Section 5.2), is debatable. No general right to freedom or autonomy exists under the Charter or the ECHR, perhaps because these concepts are too vague and broad in character.[2714] As previously discussed in Chapter 4 (Section 3.1.5), the 'right to liberty' contained at Article 6 CFR concerns the physical liberty of the person and possible restrictions thereof by the State and not a general right not to have one's freedom curtailed by the State.[2715]

Respect for private autonomy may nonetheless find an expression in some other provisions of the Charter, such as Articles 1, 3 and 7, protecting respectively human dignity, the integrity of the person and its private and family life.[2716] Article 7 CFR appears in this regard most promising, as it can be construed as imposing to public authority to 'abstain from any unjustified interference in people's private sphere of autonomy'[2717] or as safeguarding a 'right to be left alone'.[2718] Article 8 ECHR, to which Article 7 CFR corresponds almost word for word, encapsulates 'the ability to conduct one's life in a manner of one's own choosing' which 'may also include the opportunity to pursue activities perceived to be of a physically or morally harmful or dangerous nature for the individual concerned'.[2719] In this regard, the European Court of Human Rights observed, in a judgement relating to the right to die with assistance, that:

> *The extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and*

[2713] European Commission, TPD proposal (n 1430) Explanatory Memorandum 11.

[2714] Van Aaken raises the question of the existence of a general right of freedom of action contained in the common constitutional traditions of the Member States, hence part of the general principles of EU law, which could be read for instance in *Rau v BALM*, which referred to a 'general freedom to pursue any lawful activity': Van Aaken 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' (n 381) 104. The reference was however only made 'in passing' and did not at all relate to lifestyle or paternalistic measures. See Joined Cases 133 to 136/85 *Rau v BALM* [1987] EU:C:1987:244, para 19.

[2715] See Tobias Lock, 'Article 6 CFR – Right to liberty and security' in Kellerbauer, Klamert and Tomkin (n 524) 2111-2114.

[2716] On the right to privacy and nudging, see Alemanno and Spina (n 457) 447. On Article 1 and paternalism, see Van Aaken, 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' (n 381) 103.

[2717] In the original text : 's'abstenir de toute ingérence injustifiée dans la sphère d'intimité et d'autonomie des personnes : Nicolas Cariat, 'Article 7. Respect de la vie privée et familiale', in Picod, Rizcallah and Van Drooghenbroeck (n 532). See also Tobias Lock 'Article 7 CFR - Respect for private and family life' in Kellerbauer, Klamert and Tomkin (n 524) 2115-2117.

[2718] Burbergs (n 1226) 324.

[2719] *Pretty v The United Kingdom* App no 2346/02 (ECtHR, 29 April 2002), para 62, emphasis added.

> *jurisprudential discussion* the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate.
>
> However, *even where the conduct poses a danger to health or, arguably, where it is of a life-threatening nature*, the case-law of the Convention institutions has regarded the State's imposition of compulsory or criminal measures as *impinging on the private life* of the applicant within the meaning of Article 8 § 1 and requiring justification in terms of the second paragraph.[2720]

Article 8 ECHR, and Article 7 CFR by way of consequence, may hence reasonably be interpreted as covering the enactment of paternalistic lifestyle interventions by public authorities.[2721] *Alliance for Natural Health* is the only instance where a potential breach of the right to private and family life was discussed in relation to one of the EU's lifestyle interventions. The claimants argued that the provisions of Directive 2002/46 on food supplements, restricting the use of certain supplements in food, breached Article 8 ECHR and constituted 'an infringement of consumer's rights, because the Directive restricts their choice'.[2722] The Court briefly swept aside the argument and replied that:

> The fact that Articles 3, 4(1) and 15(b) of Directive 2002/46 may deprive people of the right to consume food supplements which do not comply with the directive cannot be regarded as amounting to a breach of respect for private and family life.[2723]

Although one may agree with the solution reached, the swiftness of the argumentation may be regretted, especially since breaches of the rights of private individuals are so rarely put forward when challenges to EU lifestyle measures are brought up. It is unclear whether the absence of breach results from the somewhat negligible nature of the restriction in question, which was arguably the case here, or from the fact that such restrictions affecting access to certain food products simply do not come within the scope of the right to private and family life. A general ban on all tobacco products, such as that briefly addressed in the TPD impact assessment, provided it falls within the scope of Article 7 CFR, would probably constitute a breach thereof, whose legality would have to be established by weighing up the limitation on individual autonomy resulting from the ban with its protective effect on human health.[2724]

A closely related issue to that of autonomy is information, insofar as sufficient information is a prerequisite for deliberation and choice. As discussed above, various EU measures restricting the freedom of expression and information have been challenged in that regard, always however from the point of view of companies marketing the products in question. Here again, the right for consumers to receive information, covered by Article 11 CFR, [2725] and, arguably,

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[2720] ibid, emphasis added.
[2721] Van Aaken, 'Constitutional Limits to Regulation-by-Nudging' (n 1229) 310; Van Aaken, 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' (n 381) 102-103.
[2722] *Alliance for Natural Health and Others*, Opinion of Advocate General Geelhoed (n 2362), para 101.
[2723] *Alliance for Natural Health and Others* (n 2359), para 124.
[2724] For Van Aaken, such a ban would be a disproportionate interference with the autonomy of the individual: Van Aaken 'Judge the Nudge: In Search of the Legal Limits of Paternalistic Nudging in the EU' (n 381).
[2725] Under Article 11 CFR, the right to freedom of expression includes 'freedom to hold opinions and to *receive* and impart information and ideas', emphasis added. Regarding Article 10 ECHR, see Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' (n 1319) 119.

by Article 38 CFR on consumer protection,[2726] is absent, although these measures undeniably limit consumers' access to information regarding products they wish to purchase. This is especially true when restrictions are adopted regarding the provision of inherently truthful information, such as claims on HFFS food that currently comply with the Claims Regulation or TNCO information for tobacco products. Unlike for advertising or other promotional tools, where a range of techniques may be relied on to amplify the message conveyed to consumers and strengthen its appeal, in the former cases, the misleading character of the message does not arise from the nature of the information given but from the characteristics of the product itself. Consumers have a right to know the content of a product, a right which may be limited in specific circumstances, such as when dealing with harmful products.

Yet, when grappling with those measures, the Court has failed to acknowledge their restrictive aspect as regards the right for consumers to receive information. The Court thus considered in *Philip Morris* that the elements and features whose use on the packaging and labelling of tobacco products is prohibited under Article 13(1) TPD, could not be construed as 'giving consumers *clear and precise information*, inasmuch as they are intended more to *exploit the vulnerability of consumers* of tobacco products who, because of their nicotine dependence, are particularly receptive to any element suggesting there may be some kind of benefit linked to tobacco consumption, in order to vindicate or reduce the risks associated with their habits'.[2727]

Regarding the same provision, Advocate General Saugmandsgaard Øe argued the following in *Planta Tabak*:

> Nor, in my view, is there any doubt as to whether Article 13(1)(c) of Directive 2014/40 is proportionate in terms of a purported requirement to *keep consumers properly informed*. In certain fields, including that of *food*, *consumers must indeed be given information about the ingredients in the products they consume*, so that they can identify and make appropriate use of a food and make choices that suit their individual needs.
>
> However, *tobacco products are not ordinary commodities*. The aim is not to enable consumers to choose more easily between different products. Here, *giving consumers appropriate information amounts essentially to highlighting the particularly harmful effects of tobacco on their health*.[2728]

Here again, what is striking and objectionable is not that the proportionality of this provision is upheld – it was indeed the legislator's prerogative to consider that the harmful nature of tobacco products justifies restricting the provisions of information that would risk to reinforce their appeal – but that the interest that some consumers may have in knowing the content and characteristics of tobacco products, in order to 'make choices that suit their individual needs', is fully ignored.[2729]

[2726] According to the Explanations relating to the Charter of Fundamental Rights [2007] OJ C303/17, the principles set out in Article 39 is based on Article 169 TFEU, the latter provision making an explicit reference to consumers' right to information.

[2727] *Philip Morris* (n 28), para 160, emphasis added.

[2728] *Planta Tabak*, Opinion of Advocate General Saugmansgaard Øe (n 1928), paras 76-77, emphasis added.

[2729] This appears even more clearly from the French version of the opinion, which mentions 'un prétendu impératif de bonne information des consommateurs', which can be translated as an 'alleged need to properly inform consumers': ibid, para 76.

Advocate General Saugmandsgaard Øe's approach is similar to that adopted by the Court in *Deutsches Weintor* regarding the prohibition on the use of food claims for alcoholic beverages. Relying on Article 35 CFR, the Court upheld the measure, on the ground of the 'ambiguous or even misleading' character of claims relating to alcoholic beverages, which is 'likely to encourage […] consumption and, ultimately, to increase the risks for consumers' health inherent in the immoderate consumption of any alcoholic beverage'.[2730] The question referred to the Court of Justice by the national court – the compatibility of the ban on claims for alcoholic beverages with Articles 15 and 16 of the Charter, 'even if that claim is correct' –[2731] was an invitation to discuss this particular aspect of the deprivation of 'inherently correct' information.[2732] As it did for Article 35 CFR, the Court could have referred to Article 11 or Article 38 CFR on its own motion and integrate the right to information in the discussion, acknowledging that consumers may have an interest in accessing health information about alcoholic beverages, even when that information is not about the health risks associated with alcohol consumption.

This general hostile stance towards the provision of information for unhealthy products takes an avowedly paternalistic and moralistic turn with the following remark made by Advocate General Kokott in *Philip Morris*, referring to the impossibility under Article 13(1) TPD to use the term 'organic' for tobacco products:

> An 'organic cigarette' is still a product that is extremely harmful to health. Information on the product packaging should not suggest *even to consumers who are aware of the health risks of smoking* — even merely subconsciously — that it is desirable for them or beneficial to the environment to smoke 'organic cigarettes'. In addition, *any poor conscience* on the part of smokers on account of the health risks associated with the consumption of tobacco products *should not be appeased* by the fact they are doing something good for themselves or for the planet by turning to 'organic cigarettes' rather than conventional cigarettes.'[2733]

The Advocate General's tone is not without echoing that adopted by Advocate General Bot in *Josemans* regarding cannabis consumption. Health is not the only value at stake here. Advocate General Kokott expresses her opposition to smoking and seems to suggest a form of stigmatisation of smokers, condemned to be perpetually reminded of the harmful aspect of their habit. This, in itself, is problematic from a human rights perspective.[2734]

Moreover, accessing relevant information is not only matter of right to information, but also a matter of right to health. By restricting the provision of information on grounds of its misleading character, EU measures prevent some consumers to make health-based choices and to favour products which, notwithstanding their overall harmfulness, are still less harmful than others. The prohibition on the use of misleading messages for tobacco products, contained in Article 13(1) TPD, applies to information which is not only factually correct, but which may also be used in a way favourable to health. Indeed, some cigarettes are 'better' than others, even if their overall effect is largely negative, because their smoke contains fewer TNCO

[2730] *Deutsches Weintor* (n 2049), para 42.
[2731] ibid, para 26.
[2732] ibid, para 42.
[2733] *Philip Morris*, Opinion of Advocate General Kokott (n 2349), para 222.
[2734] Hartlev (n 388).

emissions for instance. Prohibiting favourable descriptors from being used on tobacco products is congruent with the right to health insofar as it limits their appeal for non-smokers, but it constitutes a limitation thereof for, say, committed smokers which would have smoked anyway but are deprived of a mean to arbitrate between different versions of these products.

Another example is the regulation of e-cigarettes. In *Pillbox 38*, the applicant argued that the maximum nicotine yield for e-cigarettes liquids, set at 20 mg/ml in Article 20(3)(b) of the TPD, was insufficient and 'significantly reduced the efficacy of electronic cigarettes as a substitute for tobacco products, contrary to the objective of protecting human health at a high level'.[2735] While benefiting certain consumers, non-smokers that should not be exposed to e-cigarettes with a higher addictive potential, the limit on nicotine yield may be detrimental to those smokers who would like to use e-cigarettes as a cessation aid but find the limit set in the TPD too low for this device to constitute an attractive alternative to traditional cigarettes. The Court denied that the limit was too low, observing that a regular smoker needs a yield of 18 to 24 mg/ml of nicotine for his electronic cigarette to constitute a suitable cessation aid.[2736] More interestingly, the Court highlighted the fact that e-cigarettes whose liquid contains more than 20 mg/ml of nicotine could still be marketed if regulated as medicinal product or medical device.[2737] The Court concluded that '[i]n providing for such a possibility, the EU legislature took into account the need, for some consumers, on account of their state of dependence or their habits, to use, as an aid to quit smoking, electronic cigarettes containing a nicotine concentration which is higher than that allowed by Article 20(3)(b) of Directive 2014/40',[2738] and balanced the interests of these different consumers.[2739]

The interests of different categories of consumers may not always be balanced, however. In *Deutsches Weintor*, the health claim at issue was a statement that a wine was 'easily digestible' and the Court failed to consider that such a prohibition 'effectively inhibits health-based choices'.[2740] '[W]ithout the possibility to present even scientifically tested health claims in a balanced manner, obtaining easily digestible information for example about the acidity or antioxidant or polyphenol levels in red wines, and their relation to health, is difficult'.[2741] It is not impossible that the absence of such information, for consumers with a particularly low consumption of alcohol but other health problems, has, 'on balance', negative consequences on human health.[2742] In a similar line of argumentation, the prohibition may also constitute a disincentive for manufacturers to develop healthier versions of their alcoholic drinks if they are unable to communicate it to the consumer.[2743]

[2735] *Pillbox 38* (n 1662), para 88.
[2736] ibid, para 93.
[2737] ibid, para 94.
[2738] ibid, para 95.
[2739] ibid, para 96.
[2740] Tuomas Mylly, 'CJEU Approves Ban on Health Claims Related to Alcoholic Beverages' (2013) 4 European Journal of Risk Regulation 271, 274.
[2741] ibid.
[2742] ibid.
[2743] ibid.

The argument that a piece of EU of lifestyle risks regulation may restrict the right to health, was clearly made in *Swedish Match II*. One of the claimants in the main proceedings argued that the ban on tobacco for oral use constituted a 'breach of Articles 1, 7 and 35 of the Charter, since [its effect] is that individuals who want to stop smoking cannot use products that would improve their health'.[2744] What this claim highlights is that even if, on balance, the prohibition can be defended for its overall positive effects on the population, smokers and non-smokers combined, it nonetheless represent for smokers a loss of opportunity to switch to a healthier alternative. The Court could have made an answer similar to that made on proportionality, arguing that uncertainty did not allow to know precisely the overall combined effects of gateway and cessation, and that the ban was still defendable for public health protection. Regrettably, the Court did not engage in this way, simply observing that even if it were the case that the prohibition limited fundamental rights,[2745] it was intended 'not to restrict the right to health but , on the contrary, to give expression to that right and, consequently, to ensure a high level of protection of health with respect to all consumers, by not entirely depriving people who want to stop smoking of a choice of products which would help them to achieve that goal'.[2746] While the outcome is satisfactory, it represents a missed opportunity for the Court to acknowledge that certain EU measures have equivocal impacts on health.

5.3. Interim conclusion

The extent to which an individual may freely decide to engage in harmful behaviour and access information regarding hazardous products are some of the fundamental ethical questions raised by public intervention on lifestyle risks. This makes their near absence in the regulatory conversation all the more remarkable, and regrettable. The current picture does not do justice to the complexity of lifestyle choices.

There may be different explanations to this situation. As regards fundamental rights, the fact that the Court rarely scrutinises EU measures from the perspective of consumer autonomy probably results from the nature of the legal challenges brought against these measures, mostly originating from companies, which naturally argue for a breach of their own rights.[2747] Since companies are those directly affected by EU regulation – impossibility to market a product or to run an advert on television or radio, obligation to change the packaging or composition of a product – restrictions appear more tangible from their perspective. Limitations on freedom and autonomy are more difficult to grasp. More generally, it seems, as it has been observed in relation to EU consumer law and policy, that 'paternalism is not a hot issue' in the EU.[2748] It 'goes back such a long way in the national traditions of some of the founding Member States that it is hardly questioned'.[2749] Finally, the fact that this body of law is made almost entirely

[2744] *Swedish Match II* (n 1620), para 86.
[2745] ibid, para 88.
[2746] ibid, para 89.
[2747] Alemanno and Garde, 'The Emergence of EU Lifestyle Risk Regulation' (n 31) 1784.
[2748] Anne-Lise Sibony and Geneviève Helleringer, 'EU Consumer Protection and Behavioural Sciences: Revolution or Reform?' (n 470) 211.
[2749] ibid. See also Alberto Alemanno and Anne-Lise Sibony, 'Epilogue: The Legitimacy and Practicability of EU Behavioural Policy-Making', in Alemanno and Sibony, *Nudge and the Law* (n 53) 335.

of internal market instruments lead to a framing of the discussion where economic operators are seen as the stakeholders primarily impacted by regulation, overshadowing the effect that it has on individual choices.

For many, fully engaging with these thorny ethical issues is seen as pandering to the industry, in whose interest it is to present the issue of lifestyle risks as a matter of individual freedom. The two following excerpts perfectly illustrate this position:

> Cigarette smoking itself, though, is less an expression of freedom than the robbery of it. And so long as we allow the companies to cast themselves as defenders of liberty, the table is unfairly tilted. We have to recognise that smoking compromises freedom, and that retiring cigarettes would enlarge human liberties.[2750]

> The promulgation of the idea that there is a 'right' to buy cigarettes, and the characterisation of the industry as a simple conduit of those products, an inevitability of a naturally occurring market, are arguably the most potent, deceptive and dangerous aspects of tobacco industry power. The 'right to smoke' framing obscures the generally accepted ethical obligation of reputable companies to sell only products that do not cause great harm when used as intended.[2751]

That the industry has relied on such argumentation to oppose stronger control measures is undeniable, and it is likely that manufacturers of unhealthy commodities care first and foremost about their foregone profits than the loss of individual freedom. This, however, does not mean that the reality of the limitations on individual freedom should be ignored. Recognising that individuals are constrained in their lifestyle choices, sometimes drastically, does not mean that the measures in question are illegitimate and should not be adopted. In their discussion of the ethical implications of a cigarette ban, Grill and Voigt conclude for instance, after careful consideration of all the consumer's interests involved, including that of smokers who do not wish to quit, that such a ban would be justified on balance.[2752] Greater engagement with questions of individual autonomy could even, paradoxically, reinforce the EU's health promotion agenda and bolster its legitimacy, by showing that this important factor to be taken into account in the risk management process has not been entirely neglected.

6. Conclusion

[2750] Robert N Proctor, 'Why Ban the Sale of Cigarettes? The Case for Abolition' (2013) 22 Tobacco Control i27, i28.

[2751] Elizabeth A Smith and Ruth E Malone, 'An Argument for Phasing out Sales of Cigarettes' (2020) 29 Tobacco Control 703, 704.

[2752] Grill and Voigt (n 380) 300: 'Our argument has sought to stake out a more nuanced position, which acknowledges and gives substantial weight to the potential of a ban to disrespect individual autonomy and restrict freedom but emphasises the well-being losses such a ban could avert.' See also Proctor (n 2750); Marita Hefler and Coral E Gartner, 'The Tobacco Industry in the Time of COVID-19: Time to Shut It Down?' (2020) 29 Tobacco Control 245; Smith and Malone (n 2751); John PA Ioannidis and Prabhat Jha, 'Does the COVID-19 Pandemic Provide an Opportunity to Eliminate the Tobacco Industry?' (2021) 9 The Lancet Global Health 12. The idea of ultimately phasing out the sales of cigarettes, or tobacco more generally, is no longer taboo, for instance by preventing those born after a certain year to ever purchase those products. Such a plan is currently under discussion in New Zealand. See Ministry of Health of New Zealand, 'Proposals for a Smokefree Aotearoa 2025 Action Plan' (2021) Discussion document,<https://consult.health.govt.nz/tobacco-control/smokefree2025actionplan/supporting_documents/Proposals%20for%20a%20Smokefree%20Aotearoa%202025%20Action%20Planfinal.pdf> accessed 11/05/2023.

Although this final chapter is most closely linked to Chapters 5 and 6, it also serves as an overall reflection on EU lifestyle risks regulation, weaving together the different threads of the present thesis and providing answers to the main questions that this work sought to address. Arguably, these go well beyond the field of lifestyles. By reaching far and exploring the boundaries of Union action, the field offers lessons which are of broader interest for EU law in general, whose impact on the daily lives of EU citizens may continue to grow in the coming future, as risks to health and the environment gain in intensity and visibility.

As its lifestyle interventions gain in strength and in breadth the EU must confront itself to fundamental questions regarding the boundaries of its actions: what is politically desirable and legally feasible to do, and how much it is ready to promote healthier lifestyles at the expense of other interests and objectives, that of Member States, of companies or individuals. Unfortunately, these questions are largely left unaddressed. The regulatory conversation is lopsided, incomplete, and excludes a breadth of societal concerns. This is particularly visible as regards consumer autonomy, a value which, despite its central role in a field of law which pursues behavioural change, is almost never discussed.

EU law and policy on lifestyle risks is based on a fiction: that it is possible to conduct a health policy whose objectives are inherently at odds with business interests under an internal market competence primarily concerned with facilitating free movement. Measures 'are adopted but under a false label, as if they are all about promoting trade, making more of it and removing obstacles in a concrete, narrow, sense'.[2753] This affects the legitimacy of EU action. Interestingly enough, this discrepancy between health and market objectives affects both the possibility for the EU to do more, to adopt measures which are too restrictive of trade, and to do less, where subsidiarity would justify for the Union to take a step back or where the Union decides to use flexible modes of harmonisation. The tension between market and health is plainly visible as regards proportionality and fundamental rights, for it is clear there that the promotion of healthier lifestyles is in no way beneficial to market actors.

Our plea is therefore for a more honest and inclusive law, one that openly acknowledges the fact that some products are too dangerous to be marketed or advertised, if that is what is politically desired, and openly discusses the hard issues faced. One where no regulatory option should be excluded a priori but could be evaluated on its merits, in function of how well it contributes to the objective of improving the health of Europeans and of how much it affects other legitimate interests. For this to happen, the Court has a role to play, ensuring that all voices are heard in the regulatory and the judicial process. Crucially, however, a Treaty change is unavoidable if one is to treat the fundamental constitutional problems identified and grant the EU legislator with a direct harmonisation competence in public health matters.

It should be stressed, once again, that these developments were not meant to show that the EU was intervening too much or that we should contain its expansion. That public health greatly overshadows economic interests is the legislator's contention and is a balance of values which

[2753] Davies, 'The Competence to Create an Internal Market: Conceptual Poverty and Unbalanced Interests' (n 523) 85. See also Sébastien Guigner, 'Le Marché Commun, un Ecran de Fumée pour la Législation Communautaire contre le Tabagisme' (2009) 527 Revue du Marché commun et de l'Union européenne 257.

probably fits with prevailing societal views, as is the case that a degree of paternalism is necessary and that public intervention in people's lifestyles is not objectionable per se. Precisely, as the EU wants to do more, the tensions and problems highlighted are likely to become more acute.

General Conclusion

The EU is increasingly present in the daily lives of Europeans. Going well beyond its original programme of economic integration, it strives to protect and promote a 'European way of life', a concept that remains as blurry as it is contested.[2754] In doing so, the EU faces sensitive normative questions that it is not fully equipped to answer: what space should be left to risk, harm and pleasure in everyday activities and whether the plurality of lifestyle practices, including unhealthy ones, is something worth preserving. How to effectively control lifestyle-related health risks in a supranational and diverse polity such as the EU, through the use of regulatory powers primarily geared towards economic integration ? The answer to this question holds lessons for the EU and EU law at large.

Lifestyle risks are complex social phenomena. As cultural practices embedded in a consumer and market relationship, as 'industrially engineered' epidemics, they are located at the crossroads of economic regulation and health promotion. Regulating lifestyles raises significant moral and ethical questions. Chapter 1 addressed these various dimensions. Lifestyle risks have been defined as (i) consumption behaviours (ii) chosen by individuals within the constraints of their social position, (iii) expressing belonging to certain social groups and (iv) giving rise to specific and measurable health risks. These health risks mostly materialise as long-term NCDs, among which cancer, diabetes or cardio-vascular diseases, but can also lead to sudden and acute harm. On the basis of these characteristics, a range of control interventions may be selected, going from awareness raising measures to stricter product regulations, including, in certain cases, bans. These measures reflect different degrees of risk perception as well as judgements about social and cultural acceptability of the risk.

EU law and policy on lifestyle risks is plainly situated at the juncture of economic regulation and health promotion. Chapter 2 showed that the EU constitutes at the same time a commitment to the establishment of a market where hazardous goods and services, as well as people, circulate freely, and an ambition to control the risks created and amplified by that market. This is reflected in the EU's constitutional mandate: its core objectives and the specific powers attributed to it to attain these objectives. Under these powers, national control measures may be disapplied, insofar as they constitute restrictions to free movement. The EU legislature may also adopt internal market harmonisation measures, which remove obstacles to trade between Member States while at the same time setting common health standards. This is the role of Article 114 TFEU, the central legislative provision analysed in this thesis. The EU, however, has few powers to protect and promote health in its own name. The regulation of lifestyle risks therefore remains constitutionally tied to the EU's internal market objective, with profound consequences for the regulatory regime that it has adopted.

The bulk of the thesis is devoted to identifying and analysing these consequences. Thus doing, it answers this work's central research questions, laid down as follows: (i) how does the EU

[2754] On the EU 'European way of life' narrative, see Francois Foret and Noemi Trino, 'The "European Way of Life", a New Narrative for the EU? Institutions' vs Citizens' View' [2022] European Politics and Society.

meets its two constitutional objectives of removing obstacles to free movement and promoting health and preventing disease? (ii) how does this dual character of EU lifestyle risks regulation affect the application of the EU's fundamental constitutional principles of conferral, subsidiarity, proportionality and respect for fundamental rights?

Chapters 3 and 4 addressed these questions from the perspective of the internal market fundamental freedoms and their effect on national regulatory choices. These two chapters essentially function as a case study of the application of the TFEU free movement provisions in the specific field of lifestyle risks. Chapter 3 shows that most national lifestyle interventions qualify as restrictions to free movement, meaning that they are in principle prohibited unless justified by a legitimate public interest, and proportionate. Some uncertainties remain, such as the status of price measures under article 34 TFEU after the judgements in *Scotch Whisky* and *Colruyt*. A notable exception to the broad scope of the internal market provisions concerns unlawful economic activities, such as trade in illicit drugs, to which free movement does not apply. For the rest, the Court's appraisal of national measures is category-based and formalistic, meaning that it is not based on the actual effect of the measure in question. Measures that are most restrictive of individual autonomy, as per the 'intervention ladder' introduced in Chapter 1, are not necessarily those which straightforwardly qualify as restrictions to free movement, free movement of goods in particular. Price and tax measures, on the one hand, which are located at the top of the intervention ladder, are recognised as powerful incentives to guide individual choice. Where no discriminatory effect is present, however, they are likely not to constitute unlawful restrictions under Articles 34 or 110 TFEU. Labelling requirements, on the other hand, although they have a limited impact on consumer autonomy, always constitute measures having equivalent effect to quantitative restrictions under Article 34 TFEU.

Chapter 4 focused on Member States' justifications of lifestyle risks measures. First, it analysed the balance that the Court strikes between free movement and health protection. The Court recognises that unhealthy lifestyles pose health risks and is willing to accept Member State's justifications in that regard. Successfully upholding national restrictions, however, appears highly circumstantial, depending on the way the principle of proportionality is applied. Member States do generally decide of the level of protection to be attained on their territory. Yet, contrary to the Court's contention, it does not appear that Member States benefit from a more generous margin of appreciation for public health, if compared to other areas affected by free movement. Nothing in the case law suggests a specific relaxation of the justificatory requirements or of the proportionality test in health matters. This is particularly true of the necessity test, whose application sometimes leads to the elimination of useful national measures. *Rosengren* is for instance a case in point.

Chapter 5 and 6 looked at the EU's lifestyle risks policy and provided a detailed analysis of the measures adopted to date to promote healthier lifestyles, which complement action undertaken at the national level. These interventions may be sorted in four broad categories: (i) measures that restrict choice, such as bans and composition requirements, (ii) measures disincentivising choice, taxation in particular, (iii) measures enabling choice, through the regulation or restriction of commercial communications, and, finally, (iv) measures that inform choice, regulating the information that must or may accompany the marketing of a product or the

provision of a service. These two chapters showed that the use and trade in harmful products or services in the EU is increasingly framed as a public health issue and regulated accordingly. Rules regulating the provision of information had originally been adopted for internal market purposes, facilitating the free movement of products through the EU and ensuring a minimum level of consumer protection. They have taken over the years a more affirmed public health aspect. Yet, the fundamental internal market nature of the EU's policy on lifestyle risks is still particularly visible. For instance, internal market concerns strongly underpin EU rules on the taxation of unhealthy commodities, failing to support Member States in their fiscal policies and even undermining them at times.

Chapter 7 analysed the application of the EU's core constitutional principles of conferral, subsidiarity, proportionality and respect for fundamental rights to the EU lifestyle risks *acquis*. These principles are meant to strike the balance between the functional demands of a safe internal market and the other interests involved in the regulation of lifestyle risks: that of economic operators trading hazardous products or services, that of Member States wishing to retain a certain degree of autonomy in an area of cultural and ethical relevance and that of individuals which resist behaviour change and oppose the EU-promoted lifestyle. The main contention of this chapter is that these fundamental principles of Union law do not perform well. Conferral is too often disregarded. Subsidiarity is reduced to the fulfilment by the EU of free movement objectives, and therefore largely rendered toothless. The judgements in *Poland v Parliament* and *Council and Philip Morris*, which contain developments on all four constitutional principles identified above, offers prime examples of these malfunctions. The reason for such malfunction is mainly structural and pertains to the centrality of the internal market as a constitutional objective. It also reflects a somewhat narrow vision of what managing lifestyle risks entail. This affects the clarity, the sincerity and, ultimately, the legitimacy of Union action in that field.

Promoting health through the market: a case study of the EU's constitutional conundrums

As mentioned in the introduction, it was hoped that this thesis would prove useful for three specific categories of readers. The first of this reader is the 'classic' EU lawyer. The regulation of lifestyle risks is here envisaged as a 'privileged forum for thinking about Union law'[2755] and reflecting on some of its perennial questions: the *raison-d'être* of EU action, the boundaries of its competences and the importance given to free movement over competing non-market interests.

Lifestyle risks invite us to see the internal market not as an area of unregulated free movement but as a place where the health and safety of consumers can adequately be protected, provided there is a political will to do so. Judging from policy developments at both national and Union levels, EU law has so far provided a fertile ground for the adoption of lifestyle risks control measures. It can accommodate national rules that restrict trading opportunities for manufacturers and importers of harmful products, and providers of harmful services. It also

[2755] Saydé (n 2320) 370.

provides the EU legislator with a range of regulatory options to reduce the consumption of these products and services. This use of legislation echoes what Azoulai describes as an evolution of the *scope* and *quality* of EU internal market harmonisation.[2756] As regards the scope, lifestyle risks are a clear example of an internal market law that goes far beyond the removal of obstacles to trade but shapes the institutional, the social, and the moral infrastructure of the market, 'protecting the non-market interests that are deemed to be essential to the pursuit of European integration'.[2757] As regards quality, that Azoulai defines as the integration of fundamental rights and values in internal market law, this work also shows that harmonisation 'does not simply influence the lifestyle of European populations through the regulation of environmental and public health risks' but 'directly affects the basic ethical and social conditions of human life'.[2758] EU lifestyle risks regulation contributes to an understanding of the market that is more embedded in social life, providing more texture to internal market law.

Lifestyle risks also invite us to re-think the 'market v social' asymmetry traditionally identified in EU (legal) scholarship.[2759] The alleged deregulatory effect of free movement provisions, as interpreted by the Court, is a classic scholarly critique. The usual suspect is here proportionality, whose application is often seen as giving precedence to 'fundamental' freedoms of movement over non-market interests. In that regard, the present work is not conclusive. In the field of alcohol for instance, strictly decided cases like *Rosengren* should be read against those that are more respectful of Member States's prerogatives, such as *Aragonesa* or *Bacardi France*. In any case, the deregulatory effect of free movement provisions, to be convincingly studied, should be approached from an empirical perspective. The ultimate outcome of a case is conditional upon the way national courts receive it and economic operators use it.[2760] While, at times, the internal market limits the attainment of certain health objectives at the national or EU level, the reverse may also be seen. As regards tobacco, it is hard to argue that current EU regulation serves primarily to further free movement. Hence, once one takes a broader view of the internal market, combining negative and positive integration, a more complex and nuanced picture emerges. The EU is not as constitutionally hard-wired in favour of free movement as it is often claimed.

That being said, pursuing a health policy with internal market means only takes the EU so far. In the case of lifestyle risks, these two objectives are fundamentally at odds. Through free movement, consumers are exposed to new products and services. They may adopt new (unhealthy) lifestyles. The Court of Justice envisions the internal market as a dynamic place, were consumer habits evolve in the course of time and should not be 'crystallised' for the benefit of domestic operators.[2761] Opening up markets to a more diverse offer, however, not

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[2756] Azoulai, 'The Complex Weave of Harmonisation' (n 488), emphasis added.
[2757] ibid 593.
[2758] ibid 594.
[2759] Fritz W Scharpf, 'The Asymmetry of European Integration, or Why the EU Cannot Be a "Social Market Economy"' (2010) 8 Socio-Economic Review 211; Sacha Garben, 'The Constitutional (Im)Balance between "the Market" and "the Social" in the European Union' (2017) 13 European Constitutional Law Review 23.
[2760] Gareth Davies, 'Activism Relocated. The Self-Restraint of the European Court of Justice in Its National Context' (2012) 19 Journal of European Public Policy 76.
[2761] *Commission v United Kingdom (beer and wine I)* (n 748), para 14; see also *Commission v Germany (Beer purity)* (n 612), para 32.

only carries risks for traditional ways of life – the consumption of Italian pasta or German beer – it also does for the health of the population. More alcoholic drinks or ultra-processed food products to choose from increase the chances that unhealthy behaviours develop. Greater choice, lower prices and increased market concentration in the lifestyle risks industry is rarely conducive to healthier patterns of consumption in the population. A the end of our enquiry, this tension evolves thus into a more radical questioning. Is an internal market for products and services hazardous to human health desirable? Is the free movement of, say, tobacco products a pertinent objective for the EU? Do we really want to preserve, as the excise duties regime does, 'the imperative needs of competition' in the tobacco sector, implying 'a system of freely formed prices' ?[2762] Lifestyle risks question the 'soul of the internal market',[2763] and by the same token, that of the EU in general.

In some ways, these questions have already been answered. The Court of Justice has so far prevented a genuine internal market for gambling services from emerging, on grounds of the risk to public order and public health, and of the legitimacy of Member States to regulate these services according to their own cultural and moral standards. In defending a smoke-free Europe, the European Commission essentially proposes to eliminate the market for tobacco products, that of cigarettes to the very least. The irony, of course, is that this policy is being conducted with recourse to market-building instruments. When prohibiting the placing on the market of certain categories of tobacco products, such as tobacco for oral use or tobacco with a characterising flavour, the EU legislator builds a devitalised market, one that is more uniform but where opportunities for cross-border trade are reduced.

To alleviate the concrete legal problems identified in Chapter 7, resulting from the conceptual mismatch between internal market competence and health promotion, one could argue for a change of approach as regards the scope of the Union internal market competence. Leaving *Tobacco Advertising* behind, Article 114 TFEU could be construed as empowering the EU with a general competence to regulate the internal market, disconnected from the facilitation of cross-border trade. This would have the advantage of avoiding the judicial circumvolutions contained in cases such as *Swedish Match* and *Arnold André*, *Philip Morris* or *Poland v Parliament and Council*. How this would be in line with Article 26 TFEU, which defines the internal market as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured', remains however an open question. Moreover, broadening the Union internal market competence would only lead to further contradictions between a carefully defined catalogue of competence and sweeping general harmonisation powers.

The best way forward, even if not the most feasible, would be a Treaty change. To address the various legal malfunctions outlined above and provide a solid foundation to any further expansion of EU action in the field of lifestyle risks, and health in general, amendments could be brought to the TFEU along the following lines. The protection of human health would become an area of shared competence, with direct harmonisation powers granted to the EU. A

[2762] Tobacco Excise Duties Directive, recital 10.
[2763] Weatherill, 'Maximum versus Minimum Harmonization: Choosing between Unity and Diversity in the Search for the Soul of the Internal Market' (n 2531).

constitutional minimum harmonisation clause should be included, ensuring that Member States can always strive for better protection at the national level. In concrete terms, the area of 'protection and improvement of human health' would be moved from Article 6 to Article 4 TFEU. Article 4(2)(k) would hence no longer be needed and the prohibition of harmonisation contained in Article 2(5) TFEU would cease to apply to health. Article 168 TFEU would be amended to reflect these changes and to provide the Union with general harmonisation powers in the field, excluding healthcare.[2764] Article 114 TFEU would remain pertinent to adopt internal market measure, understood as a measure *genuinely* concerned with the removal of barriers to trade, with an incidental and indirect effect on health. It would however cease to be used for measures having health as their primary purpose.

Regulating risks in the EU: the complex interplay of law, science and politics

For the second reader, the (EU) risk scholar, this work addressed some important aspects of risk studies and illustrated some of the specific challenges with the regulation of risk at the EU level. Risk regulation requires to integrate complex scientifically established facts into law-making and judicial reasoning, and to answer highly salient normative questions. In the EU, this must be done on the basis of a limited mandate and in the face of a great political and cultural diversity in the Member States, especially relevant in the case of lifestyle risks. The lessons learned appear particularly pertinent for neighbouring fields of EU law where risks to health, safety or the environment are regulated, and where Union action remains primarily market-based, such as consumer protection.[2765]

Maria Weimer concludes her book *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology*, a study on EU GMO regulation, with the following remarks:

> In fact, certain features of the EU's current legal and regulatory framework tend to exacerbate the […] paradox of risk regulation, creating EU-specific pathologies that contribute to ongoing tensions and malfunctioning in regulatory law and practice. These features, as identified in this

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[2764] For an example of how Article 168 TFEU could be redrafted, see Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health' (2020) 11 European Journal of Risk Regulation 747.

[2765] The following concluding remarks by Helberger and others regarding consumer vulnerability in the digital economy appear strikingly close to those made here: 'Consumer law, with its current *focus on economic decision-making*, is *little prepared to deal with the broader societal implications* of consumer vulnerability in other aspects of social life. Broadly, the same is true for data protection law, which very much focuses on concrete acts of data processing in individual cases, and the rights and concerns of individual users vis-à-vis digital market practices. *Partly this is a result of the way the competencies between the EU and Member States are distributed*. The EU is granted powers to regulate the market and adopt consumer policies. The EU, however, has no power to regulate the society. This, if at all, is left to the Member States. *Consumer policy is being understood first and foremost as a tool to complete the internal market*. This is reflected in the rather narrow definition of the consumer in EU law. The failure to address the more societal implications of consumer vulnerability is the result of a gap in the European legal framework—a gap that needs addressing. *Put to the extreme it means to question whether the EU has the competence and therewith the legitimacy to shape a digital European society through the backdoor of the internal market competence in Art. 114 TFEU*.' See Natali Helberger and others, 'Choice Architectures in the Digital Economy: Towards a New Understanding of Digital Vulnerability' (2022) 45 Journal of Consumer Policy 175, 23–24, emphasis added.

> book, are the functional nature of EU risk regulation as legislative harmonization based on the internal market competence of Article 114 TFEU.[2766]
>
> [G]iven the derived and functionally limited nature of the EU as a polity expressed in the principle of conferred powers, the EU's response to risk is framed in economic terms—as necessary for the smooth operation of the EU internal market. This significantly limits the EU's capacity to respond to the political, cultural, and value dimensions of risk and technology, which go beyond economic (ie internal market-related) and scientific (ie safety-related) concerns.[2767]

These remarks apply, word for word, to the regulation of lifestyle risks. EU legislation remains primarily framed in economic terms, as necessary to lift obstacles to trade, and the regulatory conversation remains largely limited to a dialectic between internal market and scientific, health-related concerns. This is also true of the Court of Justice's application of free movement provisions to national lifestyle risks measures, which stays away from moral and ethical discussions. In gambling, the reference to national views over morality stops rather than starts the discussion. The political, cultural and value dimensions of risk regulation are largely ignored, in a field where these are however particularly salient. Sooner, rather than later, the EU will have to openly discuss these aspects. Heavier regulation will lead to a greater uniformity of lifestyles throughout Europe, between individuals and between peoples. A Europe free of unhealthy behaviours may be a desirable future to some, but it is unlikely to gather support if it is justified by scientific concerns, or, worse, economic concerns, alone. More comprehensive and inclusive impact assessments would allow citizens and stakeholders to further understand the choices made by the EU legislator, and vice versa. It would lead the Court to a better monitoring of compliance with the principles of conferral, proportionality, subsidiarity and respect for fundamental rights.

The Nutri-Score controversy provides a good illustration of the difficulty for the EU to embed the regulation of lifestyle risks in its broader political and cultural context. For its promoters, and the European Commission, selecting an EU front-of-pack nutrition label is about selecting the scheme that works best according to available evidence, the one that is most likely to guide consumers towards products that are low in energy, fat, sugar or salt. For its opponents, the prospect of a common European label 'telling people what to eat', recommending the consumption of industrial products rather than natural traditional products, represents both an inacceptable intrusion in the lifestyle choices of consumers and a threat to national culinary identity. Dismissing these criticisms, or fears, as purely rear-guard actions of disgruntled industry actors does not do justice to the complexity of the issue. If a European front-of-pack label is to be adopted and to succeed, it will have to acknowledge and accommodate these concerns, in one way or another.

For the Court of Justice, more openness to the social, cultural and ethical dimensions of lifestyle risks would result in a control of proportionality that is less abstract, more respectful of regulatory diversity across Member States and, ultimately, more convincing. This needs not be at the expense of the basic principles on which the internal market is founded, ensuring that Member States do not treat foreign products or services less favourably and base their decisions

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[2766] Weimer (n 2) 227.
[2767] ibid 228.

on a certain objective assessment of risk. More coherence and predictability in the way the Court engages with evidence would help increase the legitimacy of its case law, as regards especially the application of free movement provisions. Historically, the Court has heavily relied on intuitionism when judging the reality of certain risks or the respective effectiveness of different risk regulatory options, in a manner not always aligned with scientific or empirical evidence. Relying on common sense on the part of a court of law is understandable, and to a degree inevitable, but it generates errors. A greater culture of evidence would mean more extensive and transparent flagging of and engagement with the evidence submitted. It could also entail a more frequent recourse to external experts, as well as a reinforcement of the in-house expertise of the Court of Justice.

EU lifestyle risks policy and its future

Finally, for readers which are specifically interested in (EU) health law and policy, this thesis offers a first comprehensive overview of the measures adopted by the EU to promote healthy lifestyles and prevent the development of NCDs. In a number of strategy and guidance documents, the EU has tried to formalise and give an overarching coherence to this policy, both as regards the specific objectives pursued and the measures to be adopted to meet them. There is an understanding on the EU's part that lifestyle behaviours share common characteristics, lead to similar negative health outcomes and can be regulated with recourse to similar instruments.

Cutting across the different risk factors, general orientations may be identified. Overall, the EU follows a 'permit but discourage' approach, as there is no question, for the moment, leaving illicit drugs and minor exceptions aside, to prohibit the placing on the market of unhealthy products or the provision of services harmful to health. The protection of minors appears as the main priority, reflecting both the vulnerability of this category of the population and the necessity to act early in life to prevent the formation of unhealthy habits. To prevent or discourage unhealthy behaviours, the EU has adopted various measures, as part of a regulatory mix. As we have said, these may be regrouped into four main categories: measures that restrict choice by prohibiting the placing on the market of certain products or setting the composition thereof, tax measures which disincentivise the unhealthy choice, rules that restrict or prohibit the use of commercial communications and, finally, rules which regulate the information given to the consumer.

Recourse to the two first categories of measures by the EU, situated at the higher end of the intervention ladder, has been limited. Under EU law, most unhealthy commodities may be marketed freely and at a price freely set by business operators. Bans on products or categories of products are little used by the EU legislator. As regards regulation of the composition of products, the lack of EU engagement appears particularly regrettable, considering that food supply is a major driver of the rise in unhealthy diets and obesity. The analysis of the least restrictive of EU lifestyle interventions, rules on information and commercial communications, reveals enduring divergences between risk factors. As regards tobacco, the regulatory goal is to communicate clearly and vividly the hazardous nature of the products concerned and to

deprive manufacturers of most of the promotional techniques at their disposal. This is not the case for food and alcoholic beverages.

What clearly meets the eye are elements of fragmentation across risk factors, as regards both the ultimate objectives of EU intervention, 'responsible' consumption or no consumption at all, and the breadth and nature of the measures adopted. The EU strives for a 'smoke-free' and 'drug-free' future but is at no point calling into question the presence of alcoholic beverages and unhealthy foods in our lives. These differences in risk management strategies reflect a different perception of the risk and a different evaluation of the importance of these various products in our societies, economically and culturally.

While this has not been its main purpose, for various methodological and epistemic reasons exposed in the introduction, the present thesis contains elements that allow to critically evaluate the adequacy of the EU's response to the NCDs 'epidemic' that affects its population. It is clear, for instance, that the classic disclosures of information provided for in EU legislation, while they may be justified on other grounds, do not have any significant impact on consumer behaviour. It is equally clear that the current reliance on self-regulatory schemes in the area of commercial communications is entirely misguided, if one is to effectively protect children and minors from harmful advertising and other promotional techniques. Some of these shortcomings result from political decisions, such as in the cases just mentioned, some others result from the limited powers attributed the EU, as it is the case, for instance, of smoke-free environments. A number of them also result from the EU's incapacity to ensure that its policies are protected from the commercial interests of the industry and its undue interference. This is particularly true in the field of tobacco control, as shown during the TPD revision process and as repeatedly established by the European Ombudsman (see Chapter 5, Section 2.2). Interactions with the industry should be kept to the minimum necessary for ensuring proper regulation. To quote again the FCTC, there is a 'fundamental and irreconcilable conflict between the […] industry's interests and public health policy interests'.

A particularly weak spot of EU lifestyle risks policy is the regulation of alcoholic beverages. No meaningful control measures have been adopted at the EU level to date, whether it concerns taxation, labelling or commercial communication. It is highly unlikely that the current body of rules contributes to reducing alcohol consumption in Europe in any significant way. Worse, the EU's approach is based on dubious assumptions, the persisting belief that alcohol is risk-free under a certain threshold and that moderate and responsible consumption, whatever these terms mean, are not harmful to health. The problem is thus not only, or mostly, that EU alcohol policy remains so limited, but that it is not evidence-based, in contradiction with the EU's regulatory commitments.

Whatever the future holds, more intervention on the EU's part would ideally be accompanied by reforms to its constitutional framework of competence and greater engagement with the political, moral and cultural dimensions of lifestyles risks. This is the condition for developing a law that is truer to itself, more convincing and legitimate.

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2.1.1. Court of Justice

2.1.1.1. Judgements

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