Emancipating health from the internal market: for a stronger EU (legislative) competence in public health

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I) Introduction

The covid-19 pandemic has given rise to ambivalent feelings among EU health lawyers. To those criticising the lack of EU response, it was necessary to point at the limited powers granted to the Union in this field. At the same time, the often-heard assertion that 'EU has no competence in health' resonated oddly,[1] for it is far from the reality of EU action. The body of EU health law and policy is vast and growing.[2] We find ourselves in a paradoxical situation: there is an apparent need and desire for a common European response to health emergencies and greater involvement of the Union in health matters, but the crisis has also highlighted the fact that EU health law and policy have mostly been developing under the radar, as a 'silent revolution'.[3]

The present piece argues that, prior to any new and significant development in this field, the status of health in the EU constitutional framework should be clarified and enhanced legislative powers should be granted to the EU. The Treaty framework already allows for a lot, and could arguably be further used,[4] but this approach has its limits. Indeed, to compensate for its lack of direct powers, the EU has used legal bases relating to other fields of law, in particular Article 114 TFEU. This method gives rise to three main problems: it undermines the legitimacy of EU health policy, it limits the range of actions that can be adopted and it also prevents Member States from enacting more protective health measures. These three issues will be taken in turn, after which the paper will present a concrete proposal for a Treaty reform.

This piece takes a narrow view and focuses on legislative activity, leaving aside other crucial aspects of EU health law, important also in their relation to the internal market: negative

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[1] See for instance this French governmental website, https://www.europe-en-france.gouv.fr/fr/articles/la-sante-publique-nest-pas-une-competence-de-lunion-europeenne-mais [last accessed 25/08/2020], and this Belgian newspaper, https://www.lecho.be/dossiers/coronavirus/les-europeens-paient-cash-l-absence-d-europe-de-la-sante/10215297.html, [last accessed 25/08/2020].

[2] For a definition of EU health law and policy and a historical perspective on its developments, see Tamara Hervey and Bart Vanhercke, 'Health care and the EU: the law and policy patchwork', in Elias Mossialos, Govin Permanand et al. (eds), *Health Systems Governance in Europe : The Role of EU Law and Policy* (Cambridge University Press 2010), pp. 84-133; Tamara K. Hervey and Jean V. McHale, 'What is European Union health law?' in Tamara K. Hervey and Jean V. McHale (eds), *European Union Health Law: Themes and Implications* (Cambridge University Press 2015), pp. 30-70; Mary Guy and Wolf Sauter, 'The history and scope of EU health law and policy', in Tamara Hervey, Calum Young et al. (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017), pp. 17-35; Anniek De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP, 2019), especially pp. 53-91.

[3] Anniek De Ruijter, supra note 1, p.1 and following.

[4] Kai P. Purnhagen, Anniek De Ruijter et al., 'More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak' (2020) 11 *European Journal of Risk Regulation* 2, pp. 297-306.

integration and freedoms of movement, fundamental rights, and executive power. The examples used here are drawn from EU anti-tobacco legislation, an area which is both rich in Union measures and case law, but the arguments developed can be applied to other fields of EU health law.

II) A limited Union competence in the field of health

The protection of human health can be considered as a fundamental objective of the European Union.[5] According to Article 3(1) TEU, the 'Union's aim is to promote peace, its values and the well-being of its peoples'.[6] Health is also the object of various mainstreaming clauses present in the TFEU and the Charter of Fundamental Rights, demanding that a high level of human health protection be taken into account in the definition and implementation of all Union policies and activities.[7]

The importance of health as a constitutional objective contrasts highly with its position in the Union's competence framework. Pursuant to Article 6 TFEU, public health is an area of complementary competence for which Union action is limited to 'actions to support, coordinate or supplement the actions of the Member States',[8] with the narrow exception of the safety concerns of Article 4(2)(k) TFEU for which the EU is granted a shared competence.[9] The nature of complementary competences remains somewhat unclear,[10] but Article 2(5) TFEU clearly states that 'legally binding acts of the Union adopted on the basis of the provisions of the Treaties relating to these areas shall not entail harmonisation of Member States' laws or regulations'. Whichever view is taken on the precise meanings of this blanket exclusion of harmonisation, it must at least mean that approximation of existing Member States' legislation is prohibited.[11] This prohibition is echoed in Article 168 TFEU, the health legal basis, whose fifth paragraph excludes 'any harmonization of the laws and regulations of the Member States', with the exception again of the safety concerns foreseen by Article 4(2)(k) TFEU.[12] Article 168 TFEU is therefore a rather weak legal basis, mostly enabling the Union to spend 'small sums of money to promote European networks that connect people and organizations, put items on the agenda for the future, and sometimes produce research.'[13]

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[5] Human health, public health and health are used interchangeably as umbrella terms. For the absence of difference between 'human health' and 'public health' in the EU legal framework, see Anniek De Ruijter, supra note 1, p.55-57.

[6] Art. 3(1) TEU.

[7] Art. 9 TFEU, 168(1) TFEU and Article 35 of the Charter.

[8] Art. 6(1) TFEU.

[9] Art. 4 TFEU.

[10] Robert Schütze, 'Co-operative Federalism Constitutionalized: The Emergence of Complementary Competences in the EC Legal Order' (2006) 31 *European Law Review* 167.

[11] Robert Schütze, 'Classifying EU Competences: German Constitutional Lessons?', 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), pp. 50-51.

[12] Article 168(4) TFEU. These are : measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health and measures setting high standards of quality and safety for medicinal products and devices for medical use.

[13] Scott L. Greer, 'The three faces of European Union health policy: Policy, markets, and austerity' (2014) 33 *Policy and Society* 1, p. 15.

Confronted with this severe limitation, the EU legislator has had recourse to the internal market legal basis of Article 114 TFEU to enact legislation in the field of health. It is the case for most of the flagship pieces of EU health policy, such as the Patients' Rights Directive,[14] the General Food Law Regulation,[15] the Directive on the Community code for medicinal products,[16] or the Tobacco Products Directive.[17] Internal market measures often follow a dual objective, in the present case the establishment and functioning of the internal market and the protection of human health. This practice has been approved by the Court of Justice which held in the landmark *Tobacco Advertising* ruling that 'provided that the conditions for recourse to Articles [114, 53(1) and 62 TFEU] as a legal basis are fulfilled, the Community 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'.[18] The Court considered that the exclusion of harmonisation contained in Article 168(5) TFEU did not limit the possibility for other harmonisation measures, adopted under other legal bases, to have an impact on the protection of health, to the condition that such legal bases are not used in order to circumvent the exclusion of Article 168(5) TFEU.[19]

That internal market powers can be used to regulate the field of health should not in itself be controversial. Creating a single market implies lifting barriers that are very often the product of diverging health standards between Member States. Medicinal products or products having an impact on human health, such as foodstuffs or tobacco products, are also tradable products for which a market exists. Article 114 TFEU is functional in nature and, as rightly pointed out by Advocate General Fennelly, 'is not limited in advance by reference to a particular subject-matter defined ratione materiae'.[20] The internal market provides the EU with a powerful and broad competence to enact measures in the field of health. Yet, this indirect competence gives rise to a series of problems.

III) Problems with the recourse to Article 114 TFEU for health purposes

The intensive use of Article 114 TFEU in the field of health creates three main problems.

1. Lack of legitimacy of EU action

The first problem, probably the most obvious, is one of legitimacy. 'In light of the degree and extent of EU action in this field, of all the supporting policy areas public health is probably the

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[14] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65.
[15] 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, OJ L 31, 1.2.2002, p. 1–24.
[16] 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 OJ L 311, 28.11.2001, p. 67–128.
[17] 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, OJ L 127, 29.4.2014, p. 1–38.
[18] Case C-376/98, *Germany v European Parliament and Council*, EU:C:2000:544, para 88.
[19] Ibid. paras 78-79.
[20] Opinion of Advocate General Fennelly, case C-376/98, *Germany v European Parliament and Council*, EU:C:2000:324, para. 62.

one that is the most difficult to distinguish from a shared competence'.[21] There is a clear discrepancy between the letter of the Treaty and the reality of EU health law and policy.[22] The EU acts in the field of health without a clear mandate to do so.

Moreover, the reliance on the internal market powers of Article 114 TFEU means that health 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'.[23] It is for instance clear to everyone that the EU anti-tobacco policy does not actually aim at facilitating the smooth functioning of the tobacco market but rather at curbing the use of tobacco in the European population and, ultimately, eradicating it.[24]

Union action in the field of health is a clear example of competence creep, if understood as 'a process whereby the powers of the EU [is] perceived as expanding in covert or somehow unclear ways, including into areas where Member States [are] supposed to remain fully in charge'.[25] This is even more controversial if one considers that the introduction of the health legal basis in the Treaties system after the Maastricht revision, which already contained an express exclusion of harmonisation at the time, was seen by the most reluctant Member States as a way to stop the expansion of Union legislation in this area.[26] Needless to say that they have failed in this regard. One could object that Member States have agreed to these legislative developments, as co-legislators of the Union. Such an approach would however render meaningless the limits on EU action and the very idea of having constitutional constraints on political power.

2. Limits on EU action

The second issue takes us to the heart of EU action in the field of health. Defending health with the words of the market is not only a conceptual problem, it is also a practical one. Not all necessary health measures can be said to remove obstacles to free movement or distortions to competition, the two alternative conditions needed for a measure to be lawfully adopted under

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[21] Sacha Garben 'Supporting policies', in Pieter J. Kuijper and Fabian Amtenbrink (eds), *The Law of the European Union* (5th Edition Kluwer Law International 2018), p. 1208.

[22] An example out of many: the statement at Art. 168(7) that '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' comes in contradiction with the very existence of the Patients' Rights Directive.

[23] Gareth Davies, 'The Competence to Create an Internal Market: Conceptual Poverty an 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), see also Robert Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (OUP 2009), p. 282.

[24] This appears clearly from the European Commission webpage dedicated to EU anti-tobacco policy: https://ec.europa.eu/health/tobacco/overview_en, [last accessed 25/08/2020].

[25] 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 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), p.7.

[26] 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), pp. 58-60.

Article 114 TFEU.[27] This will be illustrated with two examples taken from tobacco control, the prohibition of advertising and the protection from exposure to tobacco smoke, which are widely recognised as key components of anti-tobacco policies.[28]

In the well-known *Tobacco Advertising* judicial saga, the Tobacco Advertising Directive was finally declared valid by the Court after it had been expunged from the aspects that did not comply with Article 114 TFEU.[29] Contrary to the prohibition of advertising in magazines or radio programmes, which could considered as removing obstacles to trade,[30] the prohibition of more static forms of advertising, on billboards or in cinemas, did not make such a contribution and could hence not be lawfully adopted by the EU.[31]

Regarding smoke-free environments, the only instrument currently in place at the EU level is the non-binding Council Recommendation of 2009,[32] despite the European Commission's strong political will on the issue.[33] This can partly be explained by the lack of legal basis to adopt binding legislation.[34] Recourse to Article 114 TFEU appears impossible, for it is hard to see how a general ban on smoking throughout the Union, say in cafes and restaurants, could help removing obstacles to trade between Member States.[35]

These two examples show that the EU is limited in its public health action by the legal constraints of Article 114 TFEU. This is problematic. The developments of EU health policy should be the outcome of a political process, where market concerns may very well be taken into account, but not be primarily decided in function of their merits for economic integration.

3. Lack of flexibility for Member States

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[27] *Germany v European Parliament and Council*, supra note 18, paras. 84 and 95, see more recently Opinion of Advocate General Sharpston, Case C-482/17, *Czech Republic v Parliament and Council*, EU:C:2019:321, para 44. On the non-cumulative aspect of these two conditions, see Case C-380/03, *Germany v European Parliament and Council*, ECLI:EU:C:2006:772, para 67.

[28] See Articles 8 and 13 of the WHO Framework Convention on Tobacco Control, to which the European Union is a signatory

[29] 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, OJ L 152, 20.6.2003, p. 16–19; see *Germany v European Parliament and Council*, supra note 27.

[30] *Germany v European Parliament and Council*, supra note 18, para 98.

[31] Ibid., para 99, 108-104.

[32] Council Recommendation of 30 November 2009 on smoke-free environments, OJ C 296, 5.12.2009, p. 4–14.

[33] European Commission, 'Green Paper. Towards a Europe free from tobacco smoke: policy options at EU level', COM (2007) 27 final.

[34] Karen Banks, 'The Lisbon Treaty's Competence Arrangement Viewed from European Commission Practice', in Garben S. and Govaere I. (eds.), *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future*, Oxford, Hart Publishing, pp. 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.'

[35] Vincent Delhomme, 'Smoke-free environments: the missing link in EU anti-tobacco policy' (2018) 8/18 *College of Europe Policy Brief*.

The last problem with the use of Article 114 TFEU to pursue public health objectives reside in the limited capacity for Member States to conduct an autonomous policy adapted to local circumstances. This appears if looking at the issues of minimum harmonisation and subsidiarity.

There is an inherent tension between the protection of health and the deepening of market integration. Ideally, health would be better served if EU measures offered a common minimal level of protection from which Member States were allowed to deviate to adopt more stringent measures. This need appears clearly from Article 168(4) TFEU that grants power to the EU to enact 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives' without preventing 'any Member State from maintaining or introducing more stringent protective measures'. This constitutionalisation of minimum harmonisation can also be seen in other non-market areas such as environmental protection[36] or social policy.[37]

However, such an approach would be problematic under Article 114 TFEU. The elimination of obstacles to trade would be hypothetical if Member States were always able to derogate from an EU internal market measure. This question was already at stake in the first *Tobacco Advertising* judgement, where the Court partially based its decision to annul the directive at issue on its failure to ensure the free movement of the products that were in conformity with its provisions.[38] The Court seemed to consider that the possibility left to Member States to apply stricter standards would jeopardise the actual removal of obstacles to trade. This concern appears even more clearly from the recent *Philip Morris* judgement.[39] Called to interpret Article 24(2) of the Tobacco Products Directive, the Court considered that if this article 'were 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*, that would amount, in essence, *to undermining the harmonisation effected by the directive* with regard to the packaging of those products. [..]. *Such an interpretation would render Article 24(2) of Directive 2014/40 incompatible with Article 114 TFEU*'.[40]

This tension can be further illustrated by the current debates over nutritional labelling at the EU level. The current Regulation on food information to consumers (FIC Regulation)[41] contains important provisions for public health but still mostly operates as an internal market instrument, aimed at facilitating the free movement of foodstuffs across the EU. The nutrition declaration provided for in the Regulation is widely seen as insufficient from a public health point of view, which has prompted Member States to experiment with new, more effective front-of-pack labelling schemes.[42] However, these additional schemes can at the moment only be used on a

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[36] Article 193 TFEU.
[37] Articles 153(2)(b) and 153(4) TFEU.
[38] *Germany v European Parliament and Council*, supra note 18, para 101.
[39] Case C-547/14, *Philip Morris Brands SARL e.a. v Secretary of State for Health*, EU:C:2016:325.
[40] Ibid., paras 71-72, emphasis added.
[41] 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, OJ L 304, 22.11.2011, p. 18–63.
[42] Vincent Delhomme, Improving Food Choices Through Nutrition Labelling: Towards a Common 'Nutri-Score' Scheme Across the EU' (2020) 3/20 *College of Europe Policy Brief*.

voluntary basis. The FIC Regulation does not allow Member States to impose different labels[43] for it would run contrary to its free movement objective.

The impossibility to pursue public health objectives independently from internal market objectives also affects subsidiarity control. It is indeed inherent to the internal market objective that it cannot be achieved by Member States alone, since it requires harmonisation that only the EU can provide.[44] This means, as expressed by the Court in several judgements, that although Member States might be better placed to achieve the health objective underlying a measure, the EU will always be better positioned to fulfil the two objectives combined.[45] When Article 114 TFEU is used, the subsidiarity principle offers no help to challenge a measure where the EU appears to be less well suited than Member State to protect human health.

The EU prohibition of tobacco for oral use, contained in Articles 1(c) and 17 of the Tobacco Products Directive, provides a concrete example. In the second *Swedish Match* judgement, claims that such a prohibition breached subsidiarity were swiftly brushed off by the Court for the reason outlined above,[46] even though it seemed that a *health* argument could be made to let Member State decide whether or not to authorise the marketing of tobacco for oral use. Indeed, regarding the use of this form of tobacco as an aid to stop smoking, the report of the scientific committee on which the Directive is based indicated that '[the] data imply 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.'[47] This point was unfortunately not addressed by the Court.

These two examples, minimum harmonisation and subsidiarity, show that the internal market nature of EU public health instruments limits the capacity for Member States to reach a stronger level of protection or to enact divergent measures that are better suited to local circumstances.

IV) Health as a shared competence with direct harmonisation powers

To address these three issues and provide a solid foundation to any further expansion of EU action in the field of health, amendments must be brought to the Treaty. Public health should become an area of shared competence, with direct harmonisation powers granted to the EU and the inclusion of a constitutional minimum harmonisation clause. This would improve the clarity and legitimacy of EU action and ensure that autonomous public health policy objectives can be pursued, without the limitations inherent to the use of Article 114 TFEU. This provision would remain pertinent, whenever an internal market measure has an incidental and indirect effect on health, but would cease to be used for measures having health as their primary purpose.

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[43] Articles 35 and 36 of Regulation (EU) No 1169/2011.
[44] See Gareth Davies, 'Subsidiarity: The wrong idea, in the wrong place, at the wrong time' (2006) 43 *Common Market Law Review* 1, pp. 63-84.
[45] See cases C-151/17, *Swedish Match AB v Secretary of State for Health*, ECLI:EU:C:2018:938, paras 64-69; case C-547/14, *Philip Morris Brands SARL e.a. v Secretary of State for Health*, EU:C:2016:325, paras 221-222; case C-358/14, *Poland v European Parliament and Council*, EU:C:2016:323, paras 117-118.
[46] *Swedish Match*, supra note 45, paras 64-69.
[47] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 'Health Effects of Smokeless Tobacco Products' (2008) European Commission, p. 12.

In more concrete terms, the 'protection and improvement of human health' would be taken out from Article 6 TFEU and inserted in Article 4 TFEU listing the areas of shared competence. This means that Article 4(2)(k) would no longer be needed and that the prohibition on harmonisation contained in Article 2(5) TFEU would cease to apply to public health. Article 168 TFEU would be amended to reflect these changes and provide the Union with general harmonisation powers in the field, to the exclusion of healthcare.[48] Paragraph 1, 4 and 5 would be modified and a new paragraph 6 would be inserted. The new Article 168 TFEU could read as follows:[49]

> 1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
>
> 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. […]
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> […]
>
> 4. ~~By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k)~~ the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall adopt in order to meet common safety concerns:
>
> (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; ~~these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;~~
>
> (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
>
> (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.
>
> 5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt ~~incentive~~ measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, ~~excluding any harmonisation of the laws and regulations of the Member States.~~
>
> *6. The protective measures adopted pursuant to this Article shall not prevent any Member State from maintaining or introducing more stringent protective measures.*

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[48] Healthcare touches upon fundamental components and values of national welfare States and therefore deserves to be treated separately from public health. For the difference between the public health and healthcare, see Anniek De Ruijter, supra note 1, pp. 62-63.

[49] Only the part that have been altered have been reproduced. The deleted text appears struck-through and the added text appears in italic.

Such measures must be compatible with the Treaties. They shall be notified to the Commission.

[…][50]

V) Conclusion

This short piece argues that only a Treaty change can provide the Union with the adequate competence that it needs to tackle the various health challenges that Europe does and will face. Considering the unlikeliness of any Treaty revision in the short-term, this should of course not prevent the EU to continue using the legal tools currently available, including Article 114 TFEU, while being mindful of its limitations. Conversely, one should bear in mind that such a targeted constitutional change would not alleviate the broader shortcomings of the EU competence framework,[51] a question that goes far beyond the scope of the present piece.

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[50] Former paragraphs 6 and 7 would be renumbered 7 and 8.

[51] In a vast literature, see e.g. Takis Tridimas, 'Competence after Lisbon: The Elusive Search for Bright Lines', in Diamond Ashiagbor (ed.), *The European Union after the Treaty of Lisbon* (Cambridge University Press, 2012), pp. 47-76; Sacha Garben, 'Confronting the Competence Conundrum: Democratising the European Union through an Expansion of its Legislative Powers' (2015) 35 *Oxford Journal of Legal Studies* 1, pp. 75-76.