Where Market and Health Collide: The Limits of Policy Experimentation in EU Prevention of Non-Communicable Diseases and Tobacco Control

Vincent Delhomme*
Leiden Law School, Leiden, The Netherlands
v.n.delhomme@law.leidenuniv.nl

Abstract

European Union (EU) policy on non-communicable diseases (NCDs) is primarily conducted through Article 114 Treaty on the Functioning of the European Union (TFEU). This contribution submits that the use of this provision to regulate unhealthy consumptions – tobacco, food, and alcoholic beverages – gives rise to a number of constitutional tensions and malfunctions, regarding in particular the principles of subsidiarity, conferral and the use of minimum harmonisation. This is due both to the economic nature of the EU's internal market powers and the characteristics of lifestyle-related health risks as a regulatory object. This affects, as a result, the clarity and legitimacy of EU action in the field, as well as undermines the quality of the legislation and the level of public health protection. To tackle these problems, a Treaty change would be the best way forward, which could be paired to the broader reforms necessary to the building of a strong and balanced EU Health Union.

* The author is Assistant Professor of EU Law at Leiden University.

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I. Introduction

Smoking, drinking alcohol, eating salty or sugary foods: these habits constitute major behavioural risk factors for non-communicable diseases (NCDs), such as cancers, cardio-vascular diseases or diabetes. The prevalence of NCDs is rising globally, fuelled by a growing standardisation of consumption habits and a buoyant world market for unhealthy commodities. To address this mounting health burden,[1] the EU has developed a policy aimed at curbing the consumption of these products.[2] Strong measures have been adopted on tobacco, among which are the prohibition of products for oral use and those with a characterising flavour, rules on packaging and labelling,[3] and a ban on cross-border advertising and sponsorship.[4] As regards food, EU intervention is primarily concerned with the regulation of mandatory and voluntary health and nutrition information.[5] EU alcohol policy remains largely underdeveloped.[6] The 2021 Europe's Beating Cancer Plan provided a

1 Organisation for Economic Co-operation and Development (OECD) and European Commission, 'Health at a Glance: Europe 2024: State of Health in the EU Cycle', OECD Publishing, 18 November 2024.

2 For an overview, see Alberto Alemanno and Amandine Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets', CML Rev. 50 (2013), 1745-1786; Alberto Alemanno and Amandine Garde, *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (Cambridge University Press 2015); Vincent Delhomme, 'Regulating Lifestyle Risks in EU Law: Promoting Health in a Diverse Market', PhD dissertation UCLouvain (2023), available at: <http://hdl.handle.net/2078.1/275547>, last access 14 November 2025.

3 Directive 2014/40/EU 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), OJ 2014 L 127/1.

4 Directive 2003/33/EC 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 2003 L 152/16.

5 See in particular Regulation 1169/2011/EU of 25 October 2011 on the provision of food information to consumers, OJ 2011 L 304/18; Regulation 1924/2006/EC of 20 December 2006 on nutrition and health claims made on foods OJ 2006 L 404/9.

6 See the specific rules contained in Regulation 1169/2011/EU and Regulation 1924/2006/EC. For an introduction to EU alcohol policy and its shortcomings, 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: Tamara K. Hervey, Calum Alasdair Young and Louise E. Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017), 369-397.

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new impetus for EU action, with the objective of achieving a 'tobacco-free' generation by 2040.[7] Possible reforms of the EU legal framework include the introduction of plain tobacco packaging and front-of-pack nutrition labelling, changes to the excise duties regime and stricter regulation of commercial communications for food and alcohol. Despite good intentions, the Plan remains yet to be implemented.[8]

EU intervention in the field of NCDs comes in spite of a limited legal competence in public health matters. Health falls predominantly within the category of supporting competences,[9] which implies that Union action in that field is limited to measures that 'support, coordinate or supplement' those adopted by national governments, excluding any harmonisation of Member States' laws or regulations.[10] Article 114 TFEU, however, the internal market legal basis, offers a strong support for EU prevention and control of NCDs. Tobacco, food, and alcohol are, after all, consumer products traded across borders. Building a market for unhealthy commodities requires regulation at the EU level, to eliminate the barriers to trade resulting from Member State action and limit, to a certain extent, the harmfulness of the products put on the market.

While acknowledging the positive contribution that internal market powers have made to EU health policy, this article investigates the conceptual problems and regulatory malfunctions that arise from pursuing a health policy through the market, especially where that policy aims at reducing the consumption of a given product or eliminating it outright, like it is the case for tobacco. The contribution does so by looking at two specific policies: the prohibition of tobacco for oral use and the use of plain packaging for tobacco products. These two cases studies highlight the contradictions existing between the demands of the internal market – the removal of barriers to trade and a certain degree of regulatory uniformity – and the needs for flexibility and experimentation in NCDs prevention and control, a field characterised by behavioural diversity and a degree of scientific uncertainty. These contradictions can be expressed through the EU law vocabulary of conferral and

7 Communication from the Commission, 'Europe's Beating Cancer Plan', COM/2021/44 final, 8-11.

8 Amandine Garde et al., 'Lobbying, Transparency and Trust: Power Imbalances and the Failure to Implement Europe's Beating Cancer Plan', The Lancet Regional Health – Europe 51 (2025).

9 Health has a mixed competence structure under the TFEU. Art. 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 Art. 4(2)(k), the Union also shares competence with the Member States in the area of 'common safety concerns in public health matters'.

10 Art. 2(5) TFEU.

subsidiarity. These, ultimately, affect the clarity and legitimacy of EU action, the quality of the legislation and the level of public health protection. The article is divided as follows. Section II introduces the reader to some basic features of NCDs prevention and control and clarifies the power attributed to the EU in that regard. Sections III and IV contain the two case studies. Section V offers conclusive remarks on EU prevention and control of NCDs, and EU health law and policy more generally. The need is not for the EU to gain more formal powers, but for a Treaty change that better reflects current legislative developments. Such a change would allow the Union to pursue public health policies openly and legitimately, rather than framing them as internal market measures.

II. Prevention and Control of NCDs in the EU: Between Unity and Diversity

The EU has made positive contributions to the global fight against NCDs. Action at the supranational level nonetheless gives rise to challenges, linked to scientific uncertainty and the diversity of lifestyle practices (1). These challenges are further compounded by the limited nature of the EU's powers in the field of health, which has led to the adoption of control measures through the EU's internal market competence (2).

1. EU and the Diversity of Lifestyles

In high-income countries, 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, progressively replaced by NCDs. Fuelled by this 'epidemiologic transition',[11] a 'new' public health has come of age, less preoccupied with hygiene, filth, and contagion, but focusing on health and the self, how people live and what they eat, drink, or smoke.[12] Lifestyles are an essential determinant of health and a key priority for the

11 Abdel R. Omran, 'The Epidemiologic Transition: A Theory of the Epidemiology of Population Change', The Milbank Quarterly 83 (2005), 731-757; Robert E. McKeown, 'The Epidemiologic Transition: Changing Patterns of Mortality and Population Dynamics', American Journal of Lifestyle Medicine 3 (2009), 19S-26S.

12 Alan Petersen and Deborah Lupton, *The New Public Health: Health and Self in the Age of Risk* (SAGE Publications Ltd 2000).

prevention of NCDs.[13] Tobacco consumption is the largest avoidable behavioural risk factor to health and the most significant cause of premature death in the EU.[14] In 2021, almost 210 000 deaths and 6.8 million disability-adjusted life years were attributable to alcohol consumption in the EU.[15] The rate of people who are overweight or obese has recently increased to over 60 % of the adult population.[16]

The paradox is that, unlike many dangerous or potentially deadly objects, tobacco, alcohol, and unhealthy foods are ubiquitous in our societies. They are lawfully accessible to consumers and may be purchased with limited constraints. Regulators tend to follow what William Bogart describes as a 'permit but discourage' logic,[17] adopting taxes, labels, and warnings to discourage consumption, but refraining from banning unhealthy practices altogether. Part of the explanation for such an approach is that unhealthy products represent a big segment of our economy, with billions in profits and millions of jobs dependent on it. Their consumption, while it is frowned upon by some, is considered acceptable and experienced as pleasurable by many. Eating, drinking, and smoking are entangled in a complex set of moral values, ethical norms, and cultural practices. Lifestyles are not 'the uncoordinated behaviours of disconnected individuals, but are personal routines that merge into an aggregate form representative of specific groups and classes'.[18] They are profoundly influenced by structural factors, such as age, wealth, gender, and ethnicity,[19] and are therefore marked by diversity. These differences between groups highlight the power of social norms, i. e. social attitudes of approval and disapproval.[20] While laws that are buttressed by social norms are more likely to be

13 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>, last access 15 April 2025. For the EU, see most recently Regulation 2021/522/EU of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, OJ 2021 L 107/1, Art. 3(a).

14 OECD and European Commission (n. 1).

15 Michael Brauer et al., 'Global Burden and Strength of Evidence for 88 Risk Factors in 204 Countries and 811 Subnational Locations, 1990-2021: A Systematic Analysis for the Global Burden of Disease Study 2021', The Lancet 403 (2024), 2162-2203.

16 WHO Regional Office for Europe, 'WHO European Regional Obesity Report 2022' (2022), <https://apps.who.int/iris/handle/10665/353747>, last access 01 August 2023.

17 William A. Bogart, *Permit But Discourage: Regulating Excessive Consumption* (Oxford University Press 2010).

18 William C. Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure', Journal of Health and Social Behavior 46 (2005), 51-67 (56).

19 Cockerham (n. 18).

20 Cass R. Sunstein, 'Social Norms and Social Roles', Colum. L. Rev. 96 (1996), 903-968 (914); Shaon Lahiri et al., 'Understanding the Mechanisms of Change in Social Norms Around Tobacco Use: A Systematic Review and Meta-Analysis of Interventions', Addiction 120 (2025), 215-235.

respected, a law that goes against an entrenched social norm, something widely held to be an acceptable behaviour, is likely to fail.[21]

The prevention and control of NCDs is an area where scientific uncertainty persists regarding certain risks and where the effects of regulatory instruments are not always well-known. There is, for instance, still a considerable debate on the risks associated with the electronic cigarettes and the role that this product may play in tobacco control.[22] How effective a policy or instrument will be is affected by social norms and the aetiology of behaviour in a given social group. The multifactorial nature of the underlying causes of NCDs renders the measurement of the effectiveness of different regulatory options as well as the identification of the individual contribution of each of them difficult.[23] Uncertainty and diversity plead for a flexible use of EU powers, which, when necessary, would allow to conduct policy experimentation at the national level and/or allow Member States to deviate from the chosen EU standard. Minimum harmonisation represents therefore an appealing regulatory option in this field. It allows Member States to reach different levels of protection, in accordance with the severity of the public health problem faced in each country and the preferences and habits of the population. It is also a cautionary tool, in an area where a degree of uncertainty remains as to the effectiveness of different regulatory instruments 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'.[24] In the same vein, the principle of subsidiarity may warrant to let the upper hand to Member States, in cases where a health problem or the solution to that problem are country-specific.[25]

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21 Benjamin van Rooij and Adam Fine, *The Behavioral Code: The Hidden Ways the Law Makes us Better or Worse* (Beacon Press 2021), 122-135.

22 Susan Feeney, Victoria Rossetti and Jill Terrien, 'E-Cigarettes – a Review of the Evidence – Harm versus Harm Reduction', Tobacco Use Insights 15 (2022), doi: 10.1177/1179173X221087524.

23 See Alberto Alemanno and Amandine Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' in: Hans-W. Micklitz and Takis Tridimas (eds), *Risk and EU Law* (Edward Elgar Publishing 2015).

24 Sacha Garben, 'Article 169 TFEU' in: Manuel Kellerbauer, Marcus Klamert and Jonathan Tomkin (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (Oxford University Press 2019), 1456-1466 (1460). The argument is made regarding consumer protection but equally applies to public health.

25 According to Art. 5(3) TEU: '[u]nder the principle of subsidiarity, 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, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level'.

As we shall see with the two case studies, due to the limits of its competence to address NCDs risks, the EU is ill-equipped to make space for such regulatory diversity.

2. The Push Towards Market Uniformity

To regulate unhealthy lifestyles and fight NCDs, the EU cannot rely on its limited direct legislative competence in the field of health. It is clear from Article 168 TFEU that the prevention of health damages associated with hazardous lifestyles is one of the EU's main health priorities. The importance of NCDs for EU health policy appears most 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*'.[26] As previously mentioned, however, health falls predominantly within the category of supporting 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. According to Article 2(5) TFEU, '[l]egally binding acts of the Union adopted on the basis of [supporting competences] *shall not entail harmonisation* of Member States' laws or regulations',[27] a prohibition reiterated as regards health at Article 168(5) TFEU, which '*exclud[es] any harmonisation* of the laws and regulations of the Member States'.[28] The EU may therefore only adopt incentive measures or recommendations.[29]

Considering the limitations of Article 168 TFEU, the EU has used another route to legislate in the area, this one related to the market aspect of unhealthy products, Article 114 TFEU. It has allowed the EU to adopt a wide range of NCDs control measures. In its landmark *Tobacco Advertising I* ruling, the Court of Justice, while declaring the Directive at issue invalid, also

26 Art. 168(5) TFEU, emphasis added.

27 Emphasis added.

28 Emphasis added. A derogation exists for the 'common safety concerns in public health matters' referred to at Art. 4(2)(k) TFEU, in relation to which the Union may adopt harmonisation measures, see Art. 168(4). On the matter, see the contribution by Christian Calliess, 'The Corona Crisis (Covid-19 Pandemic) and the European Union (EU) – Health Policy as a Topic for the Conference on the Future of Europe –', Berlin e-Working Papers on European Law (No. 131), 7 May 2021. In this special issue: Christian Calliess, 'Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168 (4) d) TFEU – Lessons Learned from the Covid-19 Pandemic', HJIL 85 (2025), 1045-1074.

29 Art. 168(6) TFEU.

permitted the Union legislator to use its internal market powers to adopt measures in the field of health:

> '[P]rovided that the conditions for recourse to Articles [114 53(1) and 62] as a legal basis are fulfilled, the [EU] 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.'[30]

This aspect of the judgment, often overlooked, is arguably the most important one. It paved the way for the adoption of various NCDs control measures, making up for the EU's lack of direct harmonisation powers in the field of health.

Yet, while being broad in scope, Article 114 TFEU does not provide the EU with an unlimited competence. As ruled by the Court in *Tobacco Advertising I* case, Article 114 TFEU does not grant the EU with a 'general power to regulate the internal market'.[31] 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'.[32] For a measure to be considered 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[33] or future divergences likely to give rise to such obstacles or distortions.[34] Second, the adopted measure must remove these obstacles or distortions.[35] 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 distor-

30 ECJ, *Germany v. European Parliament and Council (Tobacco Advertising I)*, case no. C-376/98, ECLI:EU:C:2000:544, para. 88; ECJ, *Philip Morris Brands*, case no. C-547/14, ECLI:EU:C:2016:325, para. 60.

31 ECJ, *Tobacco Advertising I* (n. 30), para. 83.

32 ECJ, *Tobacco Advertising I* (n. 30), para. 84, emphasis added.

33 ECJ, *Vodafone e. a.*, case no. C-58/08, ECLI: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 ECJ, *Philip Morris* (n. 30), paras 58-59; ECJ, *Poland v. European Parliament and Council*, case no. C-358/14, EU:C:2016:323, paras. 32-33. See also ECJ, *Czech Republic v. Parliament and Council*, case no. C-482/17, EU:C:2019:321, Opinion of Advocate General Sharpston, para. 44, referring to the elimination of 'obstacles to free movement' and 'distortions in competition'.

34 ECJ, *Philip Morris* (n. 30), para. 59; ECJ, *Poland v. Parliament and Council* (n. 33), para. 33.

35 ECJ, *Tobacco Advertising I* (n. 30), paras 84, 95.

tions. This essential requirement gives rise to conceptual and practical difficulties illustrated by the two case studies selected.

III. Tobacco for Oral Use and Harm Reduction

Various forms of tobacco are regulated under EU law, beyond cigarettes and other products for smoking. The Tobacco Products Directive (TPD) also applies to smokeless tobacco products (STPs), i. e. tobacco products that do not involve any inhalation. STPs include tobacco for oral use, chewing tobacco, and nasal tobacco.[36] These are only niche products, consumed by a very small fraction of the EU population.[37] The most commonly known STP is a product called *snus*, a 'moist oral tobacco product which is placed behind the upper lip, either loose or in portioned sachets, which resemble miniature tea bags'.[38] Consuming snus is not risk-free – it is especially associated with a risk of oral cancer – but it is substantially less hazardous than smoking and lowers the risk to which smokers are exposed if used as a substitute.[39] The smoke from cigarettes contains over 4000 chemicals and at least 70 known carcinogens and is responsible for most of the harm associated with tobacco.[40] On the other hand, no smoke is emitted an inhaled during the consumption of snus. Nicotine, the highly addictive stimulant contained in all tobacco products, including snus, is of limited harm per se.[41]

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36 Under the Art. 2(8) 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'.

37 See European Commission, 'Attitudes of Europeans Towards Tobacco and Electronic Cigarettes', Special Eurobarometer 506 (2021).

38 Elizabeth Clarke et al., 'Snus: A Compelling Harm Reduction Alternative to Cigarettes', Harm Reduction Journal 16 (2019), 1-17 (1).

39 Clarke et al. (n. 38); Konstantinos Farsalinos, 'Snus: Swedish Snus Is Different', British Dental Journal 226 (2019), 85; Lars M. Ramström, 'Much Safer with Snus', British Dental Journal 226 (2019), 85; Ellen Meier et al., 'A Randomized Clinical Trial of Snus Examining the Effect of Complete Versus Partial Cigarette Substitution on Smoking-Related Behaviors, and Biomarkers of Exposure', Nicotine & Tobacco Research 22 (2020), 473-481 (478).

40 Shannon Gravely et al., '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', European Journal of Public Health 30 (2020), iii38-iii45 (iii38).

41 Jacques Le Houezec, Ann McNeill and John Britton, 'Tobacco, Nicotine and Harm Reduction', Drug and Alcohol Review 30 (2011), 119-123 (120).

The EU prohibits the placing on the market of tobacco for oral use since 1992,[42] on grounds of the specific health risks associated with it and of its potential role as a gateway to the consumption of other, riskier forms of tobacco products.[43] Consumption of tobacco for oral use was negligible in the EU at that time, to the exception of Sweden, which secured an opt-out from the ban upon its accession to the EU in 1995.[44] The opt-out is still currently in force.[45] The wide consumption of snus in Sweden, as a substitute for cigarettes,[46] is one of the factors behind the lower tobacco-related mortality registered in the country if compared to the rest of the EU Member States.[47] Norway, a country outside the EU, has also seen a gradual shift towards the consumption of snus in recent years.[48]

A number of public health experts call for a removal of the ban on snus, arguing that the product could be used and recommended as a cessation aid, taking the Swedish case as an example.[49] These advocates of '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

42 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, OJ 1992 L 158/30, Art. 1.

43 Council Directive 92/41/EEC, recitals.

44 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, OJ 1994 C 241/09, Art. 151.

45 Pursuant to Art. 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'.

46 Kirsimarja Raitasalo et al., 'Single, Dual, and Triple Use of Cigarettes, E-Cigarettes, and Snus Among Adolescents in the Nordic Countries', International Journal of Environmental Research and Public Health 19 (2022), 683-694.

47 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', Tobacco Induced Diseases 12 (2014), 1-4 (3); Lars Ramström, Ron Borland and Tom Wikmans, 'Patterns of Smoking and Snus Use in Sweden: Implications for Public Health', International Journal of Environmental Research and Public Health 13 (2016), 1110-1124 (1110); Clarke et al. (n. 38); Farsalinos (n. 39); Lars M. Ramström, 'If There Had Been No Snus in Sweden: The Impact of Snus on Mortality Attributable to Smoking', Harm Reduction Journal 21 (2024), 1-5 (4).

48 Tord Finne Vedøy and Karl Erik Lund, 'How Do Smokers in a Snus-Prevalent Society Consider E-Cigarettes, Snus, and Nicotine Replacement Therapy Products as Relevant Replacements for Cigarettes in the Event They Should Stop Smoking?', Nicotine & Tobacco Research 25 (2023), 1753-1761 (1754).

49 Clarke et al. (n. 38), 13; Farsalinos (n. 39); Ramström, 'Much Safer with Snus' (n. 39); Ramström, 'Mortality Attributable to Tobacco among Men in Sweden and Other European Countries' (n. 47), 3.

nicotine'[50] – point to the difficulty that smokers have to quit nicotine altogether, suggesting an approach based on the transition from cigarettes to other lower-risk products, such as tobacco for oral use. Hence, from this perspective, snus should not be banned but regulated in a more nuanced way than cigarettes, so that it remains as little attractive as possible to non-users of tobacco while constituting a suitable alternative to smokers. There is however no consensus on this question in the public health community. If snus were to be reintroduced and led to dual use with cigarettes for current smokers, a documented phenomenon,[51] or, indeed, served as a gateway for non-smokers towards the consumption of cigarettes, the effect on public health would be negative. As observed by the Court in its *Swedish Match II* judgment,[52] uncertainty thus remains about the effectiveness of this form of tobacco, when used as a cessation aid, and its role in reducing exposure in the population to health risks, following a harm reduction strategy.

The prohibition of snus raises two important questions from the perspective of competence and the balance between health, diversity, and market uniformity. If taking a rigorous approach to the use of the EU's internal market powers under Article 114 TFEU, the very existence of the ban is questionable. Its legality was first contested in the *Swedish Match* and *Arnold André* judgments, for breach of the principle of conferral.[53] The Court upheld the ban in both cases, laying down the general principle according to which, under Article 114 TFEU, a measure 'may consist in […] provisionally or definitively prohibiting the marketing of a product or products'.[54] Thus doing, the Court failed to explain, however, how such a ban fulfils the necessary conditions for the use of that legal basis. The Court rightfully observed that prohibitions affecting tobacco for oral use enacted at the national level constitute obstacles to the free movement of goods,[55] 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.[56]

50 Sharon Cox and Lynne Dawkins, 'Global and Local Perspectives on Tobacco Harm Reduction: What Are the Issues and Where Do We Go from Here?', Harm Reduction Journal 15 (2018), 1-2 (1).

51 Raitasalo et al. (n. 46).

52 ECJ, *Swedish Match AB v. Secretary of State for Health (Swedish Match II)*, case no. C-151/17, ECLI:EU:C:2018:938, paras 41-45.

53 ECJ, *Arnold André*, case no. 434/02, ECLI:EU:C:2004:800, para. 35; ECJ, *Swedish Match*, case no. C-210/03, ECLI:EU:C:2004:802, para. 34.

54 ECJ, *Arnold André* (n. 53), para. 35; ECJ, *Swedish Match* (n. 52), para. 34.

55 ECJ, *Arnold André* (n. 53), paras 38-40; ECJ, *Swedish Match* (n. 52), paras 37-39.

56 ECJ, *Swedish Match II* (n. 52), paras 55-58.

In *Swedish Match* and *Arnold André*, Advocate General Geelhoed offered 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' –[57] he nonetheless considered 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.[58] '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.'[59] This may very well be the case. Yet, Advocate General Geelhoed does not 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 be justified on grounds of public health, but does not fulfil the criteria set for the use of the Union internal market competence. The EU legislator may very well consider that uniformity alone, rather than the removal of barriers to trade, is a desirable goal for the internal market, but such are not the criteria set in *Tobacco Advertising I* and confirmed ever since, which the Court decided to disregard.

The push towards market uniformity raises a second problem, this time linked to compliance with the principle of subsidiarity in a harm reduction context. In *Swedish Match II*, the plaintiff argued for a breach of subsidiarity, sustaining 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'.[60] Although that plea was not further substantiated, it could be argued that the effect of the ban on snus on public health is dependent on local circumstances, and that the decision would be better left to the national level. The report of the scientific committee that had informed the adoption of the ban invites to this conclusion, where it states 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

57 Cases C-434/02 *Arnold André* and C-210/03 *Swedish Match*, ECLI:EU:C:2004:487, Joined Opinion of Advocate General Geelhoed, 7 September 2004, para. 78.

58 ECJ, *Swedish Match*, Opinion of the Advocate General (n. 57), para. 79.

59 ECJ, *Swedish Match*, Opinion of the Advocate General (n. 57), para. 79.

60 ECJ, *Swedish Match II* (n. 52), para. 64, emphasis added.

EU country where it is now unavailable'.[61] The decision to use snus or not as a cessation aid recommended by public health authorities should depend on whether we can expect the harm resulting from people taking up snus – in single or dual use with cigarette – not to offset the reduction in harm coming from people who substitute snus for cigarette.[62] This is likely to be influenced by social norms. In countries neighbouring Sweden, such as Finland, where consumers are familiar with the product and use it to an extent,[63] the effect of authorising snus and publicly endorsing it are likely to be different than in countries where the product is virtually unknown. In sum, uncertainty pleads for regulatory diversity and, at the very least, a discussion on the legality of the ban under the principle of subsidiarity.

This discussion, unfortunately, did not take place in *Swedish Match II*. In its judgment, at no point did the Court address the question of subsidiarity from a health and harm reduction perspective,[64] and 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 for oral use, 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 for oral use and that, because of that interdependence, *those two objectives could best be achieved at EU level*.'[65]

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61 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 'Health Effects of Smokeless Tobacco Products' 12 (2008), <https://ec.europa.eu/health/other-pages/health-sc-basic-page/scientific-committee-emerging-and-newly-identified-health-risks-0_en>, last access 5 November 2025.

62 Karl Erik Lund and Tord Finne Vedøy, 'A Conceptual Framework for Assessing the Public Health Effects from Snus and Novel Non-Combustible Nicotine Products', Nordic Studies on Alcohol and Drugs 38 (2021), 586-604.

63 Marjut Salokannel and Eeva Ollila, 'Snus and Snus-Like Nicotine Products Moving Across Nordic Borders: Can Laws Protect Young People?', Nordic Studies on Alcohol and Drugs 38 (2021), 540-554; Raitasalo et al. (n. 46).

64 ECJ, *Swedish Match II* (n. 52), paras 68 f. The Advocate General did not address subsidiarity in his opinion.

65 ECJ, *Swedish Match II* (n. 52), paras 68 f.

The Court, by analysing both objectives together, severely limits the possibility for Member States or other claimants to contest the validity of an EU measure based on the arguments developed above. The EU will always be comparatively better placed than Member States to act for internal market purposes. Indeed, '[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'.[66] Member States alone cannot, by definition, take action to remove obstacles to trade or distortions of competition trough harmonisation.[67] Hence, the internal market nature of legislative acts in the field of NCDs prevents health-based subsidiarity claims from being made. Useful policy experimentation is therefore barred. The absence of any discussion on this point is even more ironic since, as already established, the prohibition of tobacco for oral use does not serve to remove any obstacles to trade in the internal market.

This problem may have repercussions in other areas of EU tobacco control. E-cigarettes are another category of 'tobacco' products with harm reduction potential, because they emit vapour rather than combustion smoke. Evidence is mounting that for some long-term users of traditional cigarettes, e-cigarettes may be helpful for smoking cessation.[68] In England, the use of e-cigarettes has been officially endorsed as a cessation aid.[69] The controversy in this area is similar to the one present for tobacco for oral use, with opponents of harm reduction pointing at the risk of gateway effect and dual use. While the EU does not ban e-cigarettes, it has subjected these products to a drastic advertising and sponsorship ban, similar to the one applicable to other tobacco products. All cross-border advertising and sponsorship for e-cigarettes, on television, radio, or printed media is prohibited.[70] The EU legislator's decision is grounded in the fact that 'electronic cigarettes can develop into a gateway to nicotine addiction and ultimately

66 ECJ, *Poland v. Parliament and Council*, opinion of the Advocate General of 23 December 2015, case no. C-358/14, ECLI:EU:C:2015:848, para. 154, emphasis added.

67 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': Gareth T. Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time', CML Rev. 43 (2006), 63-84 (75).

68 Feeney, Rossetti and Terrien (n. 22).

69 Virginia Berridge et al., 'E-Cigarettes: A Framework for Comparative History and Policy', Addiction 119 (2024), 1864-1870.

70 Art. 9(1)(d) Directive 2010/13/EU 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 Directive), OJ 2010 L 95/1; Art. 20(5) TPD.

traditional tobacco consumption, as they mimic and *normalise* the action of smoking'.[71] 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 less harmful than traditional tobacco.[72] Here as well, that equilibrium is likely to be influenced by social norms,[73] and it is not impossible that some countries might benefit differently from calibrated advertising. Any subsidiarity claim made in that regard is, however, for the reasons outlined above, unlikely to succeed.

IV. Tobacco Plain Packaging and Minimum Harmonisation

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, such as branding, colours, or logos. These elements contribute to the attractiveness of tobacco products, affecting perceptions of harm, and influencing the experience of the taste and strength of tobacco.[74] The packaging area that is not covered by health warnings and other mandated elements must be in plain, standardised colour, usually brown or grey, with the brand name displayed in small font. A number of countries, mostly in Europe, have now adopted plain packaging, with evidence showing that it is an effective means to increase intentions to quit, induce negative attitudes towards smoking, as well as to reduce brand awareness and appeal of tobacco products.[75]

The TPD lays down a number of obligations regarding the packaging and labelling of tobacco products, including the obligation to carry textual and

71 Recital 43 TPD, emphasis added.

72 See Kristin Voigt, 'Smoking Norms and the Regulation of E-Cigarettes', American Journal of Public Health 105 (2015), 1967-1972.

73 Voigt (n. 72); Máirtín S. McDermott et al., 'Social Norms for E-Cigarettes and Smoking: Associations with Initiation of E-Cigarette Use, Intentions to Quit Smoking and Quit Attempts: Findings from the EUREST-PLUS ITC Europe Surveys', European Journal of Public Health 30 (2020), 46-54.

74 David Hammond and Carla Parkinson, 'The Impact of Cigarette Package Design on Perceptions of Risk', Journal of Public Health 31 (2009), 345-353; Lauren K. Lempert and Stanton Glantz, 'Packaging Colour Research by Tobacco Companies: The Pack as a Product Characteristic', Tobacco Control 26 (2017), 307-315.

75 Crawford Moodie et al., 'Plain Tobacco Packaging: Progress, Challenges, Learning and Opportunities', Tobacco Control 31 (2022), 263-271.

pictorial health warnings.[76] The introduction of an EU plain packaging requirement was contemplated upon revision of Directive 2001/37,[77] the previous directive on tobacco products, but was finally not included in the proposal for the current TPD. Plain packaging was still a new measure when the TPD was adopted in 2014, and the impact assessment had observed in this regard that it was 'appropriate to wait for real life experience'.[78] A specific provision in the form of Article 24(2), was inserted in the TPD to formally permit Member States to introduce plain packaging rules at the national level. The idea was that local experimentation would help in building an evidence-base that would inform a potential future adoption by the EU.[79] Eight EU countries have introduced plain packaging to date.[80] Evidence from France, Ireland, and the United Kingdom, which have had the measure in place for a number of years, shows 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.[81] As part of its new Beating Cancer Plan, presented in 2021, the Commission announced that it would be working towards a generalisation of plain packaging at the EU level.[82]

76 Arts 8-12 TPD in particular.

77 Directive 2001/37/EC 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, OJ 2001 L 194/26.

78 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, 118.

79 See European Commission, 'Impact Assessment' (n. 78).

80 In the order in which the measure was adopted: France, Ireland, Belgium, Slovenia, the Netherlands, Denmark, Hungary, and Finland. See European Commission, 'Support Study to the Report on the Application of Directive 2014/40/EU', Final Report, Publications Office (2021), 157-158.

81 European Commission, 'Support Study' (n. 80). Regarding France, see Fabienne El-Khoury, Camille Bolze and Maria Melchior, 'Perceptions of Plain Tobacco Packaging: DePICT, a French National Survey', European Journal of Public Health 27 (2017), 420-421; Fabienne El-Khoury Lesueur, Camille Bolze, Ramchandar Gomajee, Vicki White and Maria Melchior, 'Plain Tobacco Packaging, Increased Graphic Health Warnings and Adolescents' Perceptions and Initiation of Smoking: DePICT, a French Nationwide Study', Tobacco Control 28 (2019), 31-36; Anne Pasquereau, Raphael Andler, Romain Guignard, Richard Jean-Baptiste and Viêt Nguyen Tanh, 'Smokers' Perception of Cigarette Packaging in France Before and After the Plain Packaging', European Journal of Public Health 30 (2020), v636-v637; Anne Pasquereau, Romain Guignard, Raphaël Andler, Karine Gallopel-Morvan and Viêt Nguyen-Thanh, 'Plain Packaging on Tobacco Products in France: Effectiveness on Smokers' Attitudes One Year after Implementation', Tobacco Induced Diseases 20 (2022), 1-11.

82 European Commission, 'Europe's Beating Cancer Plan' (n. 7), 9.

Plain packaging seems to be a pertinent and successful use of minimum harmonisation. The EU could adopt other measures on 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. Local experimentation allowed the EU to gain more certainty over the effectiveness of this regulatory solution and to present a more solid evidence-base for its adoption. Yet, as much as minimum harmonisation may be politically desirable, it still raises thorny legal questions regarding its contribution to market uniformity. An EU act allowing for future divergences in national law seems to make a rather tenuous contribution to the removal of barriers to trade, as required under Article 114 TFEU. As rightly put by Nina Boeger, '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'.[83]

To answer this question, it is useful to look in greater details at Article 24 TPD and its interpretation by the Court of Justice. Before doing so, 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,[84] dimensions which are sometimes conflated by the Court itself.[85] 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.[86] Matters found to lie outside the legislative field of a harmonisation measure remain within the residual powers of the Member States.[87] The Union is not required to fully harmonise every product or service that it

83 Nina Boeger, 'Minimum Harmonisation, Free Movement and Proportionality' in: Philip Syrpis (ed.), *The Judiciary, the Legislature and the EU Internal Market* (Cambridge University Press 2012), 62-91.

84 Piet Jan Slot, 'Harmonisation', ELRev 21 (1996), 378-397 (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), 41-74 (52-63); Robert Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (Oxford University Press 2009), 194-196.

85 See Slot (n. 84), 389.

86 For some elements on partial harmonisation and its different meanings: see Schütze (n. 84), 195. See also ECJ, *Mikrokasa v. XO*, opinion of the Advocate General of 19 December 2019, case no. C-779/18, ECLI:EU:C:2019:1146, paras 48-50.

87 Schütze (n. 84), 194 f.

regulates, even less every policy area in which a measure is adopted. The *intensity* of an EU act, on the other hand, concerns the possibility 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.[88] 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 to adopt a standard stricter than the one set at EU level. A number of TFEU provisions contain a 'constitutional' minimum harmonisation clause, such as Article 168(4)(a) on the safety of organs and substances of human origin, Article 169(4) on consumer protection, and Article 193 on the environment – these routinely provide that EU measures adopted pursuant to these provisions 'shall not prevent any Member State from maintaining or introducing more stringent protective measures'. Article 114 TFEU does not contain such constitutional minimum harmonisation clause,[89] which means that the choice is left to the EU legislature and may vary from one instrument to the other.

With this distinction in mind, it is possible to make a careful reading and interpretation of Article 24 TPD. This provision states the following:

> '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. […]'

Judging from Article 24(1), the TPD appears to be a measure of *partial* and *maximum* harmonisation. Member States are prevented from enacting further measures that would restrict or prohibit the marketing of products complying with the TPD, *but only* for considerations relating to aspects

88 Leaving aside optional harmonisation: see Schütze (n. 84), 197 f.

89 See ECJ, *Commission v. France*, judgment of 25 April 2002, case no. C-52/00, ECLI:EU:C:2002:252, para. 15; ECJ, *Octapharma v. ANSM*, judgment of 13 March 2014, case no. C-512/12, ECLI:EU:C:2014:149, para. 43 f. One could make the argument that recourse to minimum harmonisation is required by the various health mainstreaming clauses contained in the TFEU and the Charter, which all refer to a 'high level of protection'. 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), 175-200 (186 f. and 199).

regulated by the Directive, which implies that some of these aspects are not covered by it. Article 24(2) seems to bring a derogation to the principle contained in the first paragraph, allowing a Member State to maintain or introduce further requirements in relation specifically to the standardisation of the packaging of tobacco products, bringing an element of *minimum* harmonisation to the TPD. How should such a clause be interpreted under Article 114 TFEU?

The Court of Justice provided the answer in the *Philip Morris* judgment. Regarding Article 24(2), a provision that it deemed 'not devoid of ambiguity',[90] the Court considered that two interpretations could be made. That provision 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'.[91] 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'.[92] 'Such an interpretation', the Court adds, '*would render Article 24(2) of Directive 2014/40 incompatible with Article 114 TFEU*'.[93] In a striking statement, the Court seemed to reject the use of minimum harmonisation under Article 114 TFEU.[94]

The other possible interpretation, the one favoured by the Court, was to make of Article 24(2) 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'.[95] Understood in this way, Article 24(2) still fails to guarantee the free circulation of products that comply with the Directive.[96] Yet, such 'partial harmonisation', whilst not eliminating 'all obstacles to trade, […] does eliminate some', which, for the Court, renders it

90 See ECJ, *Philip Morris* (n. 30), para. 69.

91 ECJ, *Philip Morris* (n. 30), para. 71, emphasis added.

92 ECJ, *Philip Morris* (n. 30), para. 71, emphasis added.

93 ECJ, *Philip Morris* (n. 30), para. 72, emphasis added.

94 The Court of Justice had already expressed its hostility towards the use of minimum harmonisation in internal market legislation in previous judgments, although never as clearly: see ECJ, *Tobacco Advertising I* (n. 30); ECJ, *Germany v. European Parliament and Council (Tobacco Advertising II)*, judgment of 12 December 2006, case no. C-380/03, ECLI:EU:C:2006:772.

95 ECJ, *Philip Morris I* (n. 30), para. 73, emphasis added.

96 ECJ, *Philip Morris I* (n. 30), para. 79.

compatible with Article 114 TFEU.[97] Indeed, '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'.[98]

The Court's interpretation of Article 24(2) appears formally correct from a free movement point of view, although one may doubt that this was truly what the legislator had in mind, considering that it renders Article 24(2) redundant with Article 24(1).[99] By ensuring that standards do not diverge in relation to at least some aspects of the product concerned, partial harmonisation, unlike minimum harmonisation, does contribute to removing obstacles to free movement. With partial harmonisation, Member States do not *replace* the EU requirement with a national requirement, they act *alongside* the EU requirement. In practice though, such a 'piecemeal' approach may still raise questions.[100] If the harmonisation of a product was so limited in scope that marketing it in several member States required separate production lines for the manufacturer, the removal of obstacles to trade or appreciable distortions of competition would be quite hypothetical.[101] *Philip Morris* provides a textbook example of the difficulty to reconcile provisions that have primarily, if not only, a public health purpose – ensuring that Member States retain the capacity to adopt more stringent tobacco control measures – with their stated and required objective to contribute to the smooth functioning of the internal market by removing obstacles to free movement or distortions of competition. In order to uphold provisions such as Article 24(2) TPD, without openly renouncing its case law regarding the conditions for the use of Article 114 TFEU, the Court is led to an interpretation that fails to fully convince. Similar difficulties regarding the space for national action under EU internal market

97 ECJ, *Philip Morris I* (n. 30), para. 81.

98 *ECJ, Philip Morris Brands SARL and Others v. Secretary of State for Health*, opinion of Advocate General Kokott of 23 December 2015, case no. C-547/14, ECLI:EU:C:2015:853, para. 119.

99 Indeed, if Art. 24(2) covers aspects of the standardisation of the packaging of tobacco products which have not been harmonised by the directive, then Art. 24(1) alone is sufficient for allowing Member States to act.

100 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), 74-89 (79).

101 Contrary to what was argued by the Court in ECJ, *Philip Morris* (n. 30), para. 103. See also ECJ, *Philip Morris*, Opinion of the Advocate General (n. 98), para. 98.

measures can also be seen in the field of food and nutrition, front-of-pack nutritional labelling more specifically.[102]

If taken at face value, the *Philip Morris* ruling has far-reaching application for the legislative acquis adopted under Article 114 TFEU which pursues health, environmental or consumer protection objectives. The finding that letting a Member State derogate from a standard set in the TPD would undermine the internal market objective of the Directive amounts to a general rejection of minimum harmonisation under Article 114 TFEU. Nothing from the judgment indicates that the solution found was particularly contextual. Yet, that pronunciation has not been repeated to date and recent case law does not indicate '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'.[103] Uncertainty on the issue is thus likely to persist.

V. Concluding Remarks

These two case studies illustrate the limits to the EU practice of pursuing a health policy with internal market means. The reason is twofold. First, because many public health interventions cannot reasonably be considered as contributing to the removal of obstacles to trade. The prohibition of tobacco for oral use is a clear example thereof. Second, because the push for market uniformity – an expression of the same requirement to remove obstacles to trade – is at odds with the needs for flexibility and experimentation, particularly present in the field of NCDs and lifestyle-related risks. The radical approach to minimum harmonisation and the internal market that *Philip Morris* invites us to take may not be satisfactory if viewing the internal market in an embedded way, where non-market values and interests have to be taken into account, and Member State autonomy somewhat accommodated. Full homogeneity is probably not an ideal perspective, if only a

102 Nikhil Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle Between EU Food Law and National Measures' ELRev 47 (2022), 153-174 (154); Vincent Delhomme, 'Minimum Harmonization, Experimentation and the Internal Market' in: Ton Van Den Brink and Virginia Passalacqua (eds), *Balancing Unity and Diversity in EU Legislation* (Edward Elgar Publishing 2024), 194-210.

103 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), 261-284 (275-276). See e. g. ECJ, *Buhagiar v. Minister for Justice*, case no. C-267/16, ECLI:EU:C:2018:26, para. 49.

feasible one, for the Union internal market.[104] It belongs nonetheless to the Court to properly discharge its duty and to clearly explain under which circumstances a measure that does not ensure the free movement of goods can be validly adopted under Article 114 TFEU, or to change its interpretation of the criteria for the use of that provision, going beyond the mere removal of obstacles to trade.

Ideally, the EU legislature should be able to adopt the measures that appear politically desirable to prevent the spread of NCDs, without the legal constraints originating from the internal market and its commitment to free movement. Promoting health, whether in the form of an outright prohibition of a given product on the entire EU market, or, on the opposite of the regulatory spectrum, in the form of a minimum harmonisation measure, should remain the core concern. Such policies should not falsely be based on internal market considerations, where it is clear they do not seek to create greater trading opportunities, but, rather, to diminish those. To tackle these problems, a Treaty change would be the best way forward,[105] which could be paired to the broader reforms necessary to the building of a strong and balanced EU Health Union.[106] This would not only strengthen the EU's NCDs policy but would also provide a solid foundation to any further expansion of EU action in the field of health. The protection of human health should become an area of shared competence, with direct harmonisation powers granted to the EU. A Treaty minimum harmonisation clause, of the kind used in Article 193 TFEU for the environment, should be added, to ensure that Member States can always go beyond the level of protection prescribed by EU law. 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) TFEU 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

104 See 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), 29-60 (47-49); Michael Dougan, 'Minimum Harmonisation after *Tobacco Advertising* and *Laval Un Partneri*' in: Mielle Bulterman, Leigh Hancher, Alison McDonnell and Hanna G. Sevenster (eds), *Views of European Law from the Mountain: Liber Amicorum for Piet Jan Slot* (Kluwer Law International 2009), 3-18 (17 f.).

105 See in this special issue, the contributions by Christian Calliess, 'Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168(4)(d) TFEU – Lessons Learned from the Covid-19 Pandemic', HJIL 85 (2025), 1045-1074 and Markus Frischhut, 'The Missing Keystone of the "European Health Union": Historic Development, *status quo* and Ideas *de lege ferenda*', HJIL 85 (2025), 1011-1043.

106 See Martin McKee and Anniek de Ruijter, 'The Path to a European Health Union', The Lancet Regional Health – Europe 36 (2024), 100794.

and to provide the Union with general harmonisation powers in the field, excluding healthcare.[107]

Finally, a general remark regarding the status of health in the EU framework of competence is in order. In general, Union health powers are underestimated.[108] Such an observation suggests caution, rather than the usual response to call for more Union powers and a Treaty change to respond to every crisis, like it has often been the case with the Covid-19 pandemic and the EU Health Union. One needs to ask *why* more powers for the Union might be needed in the field. Should the Union directly order public health measures or take care of healthcare planning? There are good reasons for a division of tasks whereby the Union takes a leading role in public health and product regulation, while Member States retain primary responsibility for the organisation and delivery of healthcare, as well as the management of health crises.[109] Healthcare systems are at the core of modern welfare states and express sensitive socio-fiscal choices. National or sub-national governments are better placed than the Union to respond to their population's needs and to build a crisis response that panders to different ethos and relationships to risk. In any case, in health as in other matters, action from the EU and the Member States is increasingly intertwined.[110] Hence, what is needed is perhaps not a Treaty change allowing the EU to do more than it already does, but one that would better align what the EU does with the formal division of competence. As this article has hopefully shown, this would lead to better and more legitimate regulation.

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107 For an example of how Art. 168 TFEU could be redrafted, see Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health', European Journal of Risk Regulation 11 (2020), 747-756.

108 See Oliver Bartlett, 'COVID-19, the European Health Union and the CJEU: Lessons from the Case Law on the Banking Union', European Journal of Risk Regulation 11 (2020), 781-789; Tamara Hervey and Anniek De Ruijter, 'The Dynamic Potential of European Union Health Law', European Journal of Risk Regulation 11 (2020), 726-735; Kai P. Purnhagen, Anniek De Ruijter, Mark L. Flear, Tamara K. Hervey and Alexia Herwig, 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306.

109 Vincent Delhomme and Carina van Os, 'Building the European Health Union (2019-2024): Successes, Limits and Future Perspectives', European Journal of Risk Regulation 16 (2025), 942-960.

110 See, in relation to the Covid-19 pandemic: Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', YBEL 41 (2022), 48-82.