Articles

"Breaking through the Foul and Ugly Mists of Vapours"—Regulation of Alternative Tobacco and Related Products by the New TPD and Exercise of EU Competence

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Abstract

Directive 2014/40—the new Tobacco Products Directive—was unsuccessfully challenged in three cases, *Philip Morris*, *Poland v. European Parliament and Council*, and *Pillbox 38*. This Article examines provisions of the Directive relating to some alternative tobacco and related products, both in terms of exercise of EU competence and substantive regulation of these products. The main flavored tobacco products can no longer be placed on the market. Electronic cigarettes are regulated by the Directive, as the initial provisions of the Commission proposal were substantially amended. The new Tobacco Products Directive reproduced the prohibition of tobacco for oral use, already at issue in the *Swedish Match* and *Arnold André* cases, and again subject of another preliminary ruling reference by Swedish Match, the Advocate General's Opinion having concluded in its validity. The Directive also provides the possibility for Member States to prohibit categories of tobacco or related products. Parallel to its analysis of their substance in terms of health regulation, this Article considers European Union competence issues relating to these provisions and examines the adequacy of the Article 114 TFEU internal market legal basis as well as compliance with the principles of proportionality and subsidiarity.

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A. Introduction

Regulation of tobacco and related products has been an important element of the EU's public health policy since Directive 89/622.[1] Despite the nature of internal market legislation and its relationship with other policy areas,[2] it has also been at the center of debates on EU competence, in light of the limited health legal bases and express exclusion of harmonization now included in Article 168 TFEU,[3] with significant cases in the previous decade on the validity of both Tobacco Advertising Directives and the previous Tobacco Products Directive.[4] Excluding the annulled Directive 98/43, the Court of Justice has been rather lenient in its review of recourse by the Union legislature to the Article 114 TFEU general internal market legal basis for the adoption of tobacco control measures, as it has in other recent cases relating to this legal basis.[5] The three rulings of the Second Chamber of May 2016 on Directive 2014/40, the new Tobacco Products Directive—Case C-547/14 *Philip Morris*, Case C-358/14 *Poland v European Parliament and Council* and Case C-477/14 *Pillbox 38*—are no exception to this trend in case law.[6] The Court relies on Article 114(3)

[1] *See* Council Directive 89/622, on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the labelling of tobacco products, 1989 O.J. (L 359) 1 (EEC).

[2] *See* B. de Witte, *Non-Market Values in Internal Market Legislation, in* REGULATING THE INTERNAL MARKET (N. Nic Shuibhne ed., 2006).

[3] Legal bases: Consolidated Version of the Treaty on the Functioning of the European Union, 2016 O.J. (C 202) 1, art. 168(4)(a)-(c) and (5) [hereinafter TFEU]. Express exclusion of harmonization: now in art. 168(5) TFEU, after the added reference to tobacco and alcohol abuse in this paragraph: Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C 306) 1, art. 2(127)(d)(iv).

[4] *See* Directive 98/43 of the European Parliament and the Council, on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, 1998 O.J. (L 213) 9 (EC); Case C-376/98, *Germany v. European Parliament and Council,* 2000 E.C.R. I-8419; Directive 2003/33 of the European Parliament and of the Council, 2003 O.J. (L 152) 16 (EC); Case C-380/03, *Germany v. European Parliament & Council,* 2006 E.C.R. I-11573; Directive 2001/37 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 products, 2001 O.J. (L 194) 26 (EC); Case C-491/01, R (*British American Tobacco (UK) Ltd) v. Sec'y of State for Health*, 2002 E.C.R. I-11453; Case C-434/02, *Arnold André GmbH & Co. KG v. Landrat des Kreises Herford*, 2004 E.C.R. I-11825; Case C-210/03, *R (Swedish Match AB and Swedish Match UK Ltd) v. Secr'y of State for Health*, 2004 E.C.R. I-11893.

[5] *See* Case C-66/04, *United Kingdom of Great Britain v. European Parliament & Council,* 2005 E.C.R. I-10553; Case C-217/04, *United Kingdom v. European Parliament & Council,* 2006 E.C.R. I-3771; Joined Cases C-154 and 155/04, *R (Alliance for Natural Health) v. Sec'y of State for Health* 2005 E.C.R. I-6451; Case C-58/08, *R (Vodafone Ltd) v. Sec'y of State for Business* 2010 E.C.R. I-4999; Case T-526/10, *Inuit Tapiriit Kanatami v. Comm'n* ECLI:EU:T:2013:215; Case C-398/13P, *Inuit Tapiriit Kanatami v. Comm'n,* ECLI:EU:C:2015:535; Case C-270/12, *United Kingdom v. European Parliament & Council* ECLI:EU:C:2014:18.

[6] *See* Directive 2014/40 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 and repealing Directive 2001/37/EC, 2014 O.J. (L 127) 1 (EU); Case C-547/14, *R (Philip Morris Brands Sarl) v. Sec'y of State for Health*, ECLI:EU:C:2016:325 (Judgment), ECLI:EU:C:2015:853

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and other health "mainstreaming provisions,"[7] its "decisive factor" formula, in other words the fact that the Union legislature "cannot be prevented from relying on [Article 114 TFEU] on the ground that public health protection is a decisive factor in the choices to be made,"[8] types of measures available under this legal basis,[9] and the discretion of the Union legislature as regards the most appropriate method of harmonization, to justify the adequacy of the Article 114 legal basis.[10] The Court also relies on the EU legislature's broad discretion in areas "entail[ing] political, economic and social choices" in support of the measure's proportionality.[11]

Directive 2014/40 was adopted in April 2014 under Articles 53(1), 62, and 114 TFEU, providing for the ordinary legislative procedure, and had to be implemented by the Member States by May 20, 2016. This new Tobacco Products Directive repealed and replaced Directive 2001/37, which had already recast former tobacco control directives,[12] and was challenged in the *British American Tobacco*, *Swedish Match,* and *Arnold André* cases.[13] Directive 2014/40 had a significant impact on the packaging of tobacco products, with provisions on the minimum weight of tobacco and number of cigarettes per packet, as well as on labelling, with further provisions on misleading descriptors and health warnings,

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(Opinion of Advocate General Kokott); Case C-358/14, *Poland v. European Parliament & Council*, ECLI:EU:C:2016:323 (Judgment), ECLI:EU:C:2015:848 (Opinion); Case C-477/14, *R (Pillbox 38 (UK) Ltd.) v. Sec'y of State for Health*, ECLI:EU:C:2016:324 (Judgment), ECLI:EU:C:2015:854 (Opinion).

[7] TFEU art. 168(1); TFEU art. 9; Charter of Fundamental Rights of the European Union, art. 35, Dec. 7, 2000, 2016 O.J. (C 202) 389. S*ee* T. Hervey, *Community and National Competence in Health after Tobacco Advertising*, 38 COMMON MKT. L. REV. 1421 (2001).

[8] *See* Case C-491/01, *supra* note 4, at para. 62; *Arnold André*, Case C-434/02, *supra* note 4, at paras. 32-33; *Swedish Match*, Case C-210/03, *supra* note 4, at paras. 31–32; *Germany*, Case C-380/03, *supra* note 4, at paras. 39–40; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 60–61; *Poland*, Case C-358/14, *supra* note 6*,* at paras. 34–35.

[9] *See Arnold André*, Case C-434/02, *supra* note 4, at para. 35; *Swedish Match*, C-210/03, *supra* note 4, at para. 34; *Germany*, Case C-380/03, *supra* note 4, at para. 43; *Philip Morris*, C-547/14, *supra* note 6, at para. 64; *Poland*, Case C-358/14, *supra* note 6*,* at para. 38.

[10] *See Germany*, Case C-380/03, *supra* note 4, at para. 42; *Philip Morris*, Case C-547/14, *supra* note 6, at para. 63; *Poland*, Case C-358/14, *supra* note 6*,* at paras. 37, 68–69.

[11] *See* Case C-491/01, *supra* note 4, at para. 123; *Arnold André,* Case C-434/02, *supra* note 4, at para. 46; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 48; *Germany*, Case C-380/03, *supra* note 4, at para. 145; *Philip Morris*, Case C-547/14, *supra* note 6, at para. 166; *Poland*, Case C-358/14, *supra* note 6*,* at para. 79; *Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 49, 61, 96.

[12] *See* Council Directive 89/622, *supra* note 1, amended by Council Directive 92/41, 1992 O.J. (L 158) 30 (EEC); Council Directive 90/239 on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the maximum tar yield of cigarettes, 1990 O.J. (L 137) 36 (EEC).

[13] *See* Case C-491/01, *supra* note 4; *Arnold André*, Case C-434/02, *supra* note 4; *Swedish Match*, Case C-210/03, *supra* note 4.

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including larger combined health warnings, thus adapting provisions of the previous Tobacco Products Directive in light of FCTC provisions and Guidelines.[14] The new Tobacco Products Directive also bans characterizing flavors from cigarettes and roll-your-own tobacco, as they enhance their palatability. Furthermore, the Directive regulates new products, electronic cigarettes, and refill containers, with substantial amendments since the Commission proposal article on nicotine-containing products. Finally, the new Tobacco Products Directive reproduced the prohibition of tobacco for oral use, and moreover provides the possibility for Member States to ban certain categories of tobacco or related products.

The regulation of alternative tobacco and related products under the new Tobacco Products Directive will be examined—flavored tobacco, electronic cigarettes, tobacco for oral use, and the possibility to prohibit categories of products. This Article will consider both the substantive content and competence justifications of these provisions. Regulatory choices will be assessed by analyzing health concerns at issue and by evaluating the Directive's requirements, their evolution and different perspectives envisaged—Commission proposal, Council general approach, opinions of European Parliament Committees, amendments adopted. Questions of Union competence relating to provisions on these products will also be addressed, with reference to the Court's three rulings on their validity, in terms of adequacy of the Article 114 TFEU internal market legal basis for health matters, as well as compliance with the proportionality and subsidiarity principles. The extent of competence issues' impact on regulatory content should moreover be noted. The internal market objective may in some instances influence the scope of provisions, as in the past for tobacco advertising, and now similar requirements for electronic cigarettes. However, this is not necessarily the case, with justifications based on the discretion as to the most appropriate method of approximation, types of harmonization measures, health mainstreaming provisions and the "decisive factor" formula, as for prohibitions of characterizing flavors and oral tobacco. Similarly, the proportionality principle's incidence on provisions adopted may also be limited by arguments based on the broad discretion in areas involving complex assessments and mainstreaming provisions, as can be seen for the prohibition of flavors, regulation of electronic cigarettes, or the ban of tobacco for oral use.

This Article will begin by considering flavored tobacco products, appraising the necessity of the prohibition of characterizing flavors in Article 7 of Directive 2014/40, and the argument in favor of distinct regulation of mentholated tobacco products. It will address competence issues in both *Philip Morris* and *Poland v. EP and Council*, on the Article 114 TFEU legal basis, in terms of existing and future national disparities and obstacles to trade, FCTC Partial Guidelines, and types of approximation measures, on conformity with the proportionality principle, in particular arguments based on the EU legislature's broad

[14] *See* World Health Organization Framework Convention on Tobacco Control (May. 2003), art. 11; Framework Convention on Tobacco Control Guidelines for Implementation of Article 11, Decision FCTC/COP3(10) (Nov. 2008).

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discretion and mainstreaming provisions, as well as on both substantive and procedural compatibility with the principle of subsidiarity. Regarding electronic cigarettes, Article 20 of the Directive will be considered, with detailed assessment of health concerns and scientific uncertainties, highlighting the difficulty of regulating novel products, yet arguably lower risk alternatives to tobacco. In this respect, the significant evolution from the Commission proposal to the Directive's provisions will be analyzed. Concerning competence matters, at issue in *Pillbox 38*, the proportionality of Article 20 and its specific provisions will be examined. More specifically, provisions on cross-border distance sales will be appraised in terms of legal basis and proportionality. As will those on advertising and sponsorship of electronic cigarettes, with reference to the first *Tobacco Advertising* ruling and parallel provisions in the second Tobacco Advertising Directive, along with the legal bases of this measure and of the Audiovisual Media Services Directive,[15] justifying the supplementary legal bases added to the new Tobacco Products Directive. The reproduction of the ban on tobacco for oral use will then be considered, questions of competence relating to the Article 114 legal basis for the ban of a product, as well as the proportionality of the prohibition, having already been appraised by the Court in *Swedish Match* and *Arnold André*. National differences in terms of other smokeless tobacco products moreover raise issues as to the legal basis of the snus ban. The prohibition of tobacco for oral use is once again the subject of another preliminary ruling reference in Case C-151/17 *Swedish Match*, the Advocate General having recently concluded in the provisions' compliance with the principles of proportionality and non-discrimination.[16] Again, in addition to Union competence concerns, the issue of the prohibition of an arguably lower risk alternative to tobacco for smoking will be examined, echoing the debate on regulation of electronic cigarettes. Finally, this Article will consider the possibility for Member States to prohibit categories of tobacco or related products under Article 24(3) of the new Tobacco Products Directive, the adequacy of its Article 114 TFEU legal basis being at issue in *Philip Morris*.

B. Regulation of Flavored Tobacco Products and Union Competence

I. The Prohibition of Characterizing Flavors

Article 7 of Directive 2014/40 provides that "Member States shall prohibit the placing on the market of tobacco products with a characterizing flavor,"[17] with implementing acts

[15] *See* Directive 2010/13 of the European Parliament and of the Council, on the coordination of certain provisions concerning the provision of audiovisual media services, 2010 O.J (L 95) 1 (EU).

[16] *See* Case C-151/17, *Swedish Match AB v. Secretary of State for Health* ECLI:EU:C:2018:241, Opinion of Advocate General Saugmandsgaard Øe.

[17] *See* Directive 2014/40, *supra* note 6, at art. 7(1) subpara. 1. Article 2(25) defines characterizing flavor as "a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives . . ."*Id.*

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facilitating the determination of such characterizing flavors in tobacco products.[18] It also bans flavorings in components of tobacco products, including filters, papers, packages, and capsules, as well as "any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity," and prohibits tobacco and nicotine from filters, papers, and capsules.[19] A number of additives are prohibited, such as vitamins, suggesting that the product is healthy or less harmful, consistently with the provisions in Article 13, or additives facilitating inhalation and nicotine uptake,[20] but not those additives necessary for the manufacture of tobacco products, unless they result in a characterizing flavor,[21] or increase substantially addictiveness, toxicity, carcinogenic, mutagenic, or reprotoxic properties.[22] These last elements are moreover monitored, for additives included in a priority list, subject to enhanced reporting obligations for manufacturers and importers under Article 6.[23] The above provisions on flavors and

[18] *See* Directive 2014/40, *supra* note 6, at art. 7. Article 7(2) provides for the adoption of implementing acts by the Commission on whether a tobacco product falls within the prohibition. *Id.* Article 7(3) concerns implementing acts to establish uniform rules on procedures to determine whether a tobacco product has a characterizing flavor, adopted as Commission Implementing Regulation 2016/779, 2016 O.J. (L 131) 48 (EU). *Id.* Article 7(4) provides for implementing acts as to procedures for the independent advisory panel, adopted as Commission Implementing Decision 2016/786, 2016 O.J. (L 131) 79 (EU). *Id.*

[19] *See* Directive 2014/40, *supra* note 6, at art. 7(7); s*ee however* Committee on Agriculture and Rural Development Opinion (EP) PE507.956 of 27 Jun. 2013, Amendment 39 ("regulate").

[20] *See* Directive 2014/40, *supra* note 6, at art. 7(6)(a), (d), added by the *Council of the European Union General Approach,* 11483/13 (June 24, 2013), annex, at art. 6(4)(d). Also prohibited are additives or stimulants "associated with energy and vitality" such as caffeine and taurine—Article 7(6)(b)—additives with "coloring properties for emissions"—(c)—as well as additives having CMR properties in unburnt form—(e).

[21] *See* Directive 2014/40, *supra* note 6, at art. 7(1) subpara. 2. *See however* Committee on Industry, Research and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendment 5 (refers to consumer choice). Article 7(5) of Directive 2014/40 provides that the Commission may adopt delegated acts to set maximum content levels for additives resulting in a characterizing flavor, if at least three Member States have issued prohibitions.

[22] *See* Directive 2014/40, *supra* note 6, at art. 7(1) subpara. 2. Article 7(9) subpara. 1 provides that Member States are to prohibit additives substantially increasing toxic or addictive effect and CMR properties at consumption stage, based on scientific evidence. *Id.* The Commission can adopt—under article 7(10)—implementing acts concerning the scope of paragraph 9, and under article 7(11) delegated acts setting maximum content levels for such additives where paragraph 9 prohibitions have been adopted in at least three Member States, at the lowest maximum level. *Id. See also* the prohibitions in article 7(6)(b), (d), and (e); *Commission Staff Working Document Impact Assessment*, SWD (2012) 452 final (Dec. 19, 2012), part 1 at 55–56, 97–104, 118, and part 5 at 7 (options envisaged).

[23] *See* Directive 2014/40, *supra* note 6, at art. 6(1) subpara. 1 (a) and (2)(a) to (d) (toxicity/addictiveness (a), flavor (b), inhalation/nicotine uptake (c), and CMR properties (d). Article 6(1) provides for implementing acts to lay down and update the priority list of additives. Such an implementing act was adopted as Commission Implementing Decision 2016/787, 2016 O.J. (L 131) 88 (EU). *See also* Directive 2014/40, *supra* note 6, at art. 5; Directive 2001/37, *supra* note 4, at art. 6; *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: First Report on the Application of the Tobacco Products Directive*, at 6–7, COM (2005) 339 final (July 27, 2005); *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Second Report on the Application of the Tobacco*

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additives apply only to cigarettes and roll-your-own tobacco.[24] A four-year derogation from the provisions of Article 7 applies to products the sales volume of which constitute at least 3% of the product category,[25] and thus menthol cigarettes, at issue in *Poland v. EP and Council* and *Philip Morris*. No such derogation had initially been envisaged in the Commission proposal, but was included in the Council general approach,[26] with a five-years derogation adopted at the European Parliament partial vote,[27] then reduced to four years.[28]

II. The Alleged Specificity of the Menthol Flavor

Despite Article 7(1) prohibiting generically "tobacco products with a characterizing flavor," the first plea in *Poland v. EP and Council*, alleging infringement of Article 114 TFEU, concerned specifically the prohibition of "tobacco products containing menthol as a characterising flavour." Similarly, the question in *Philip Morris* on the adequacy of Article 114 as legal basis for this article referred to the prohibition of menthol cigarettes before that of tobacco products with a characterizing flavor generally.[29] The JURI Committee of the European Parliament had also considered the prohibition of menthol cigarettes separately, on the basis of the absence of a genuine internal market object, as no Member State had or intended to prohibit such products,[30] which distinguished this ban from that

Products Directive, at 7–8, COM (2007) 754 final (Nov. 27, 2007); *Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 3–4.

[24] *See* Directive 2014/40, *supra* note 6, at art. 7(12). The Commission may remove exemption of other tobacco product categories by delegated acts. *See below* on proportionality.

[25] *See* Directive 2014/40, *supra* note 6, at art. 7(14) and art. 29(1) subpara. 2.

[26] *See Council of the European Union General Approach*, *supra* note 20, annex, at recital 15 ("to give consumers the adequate time to switch to other products and thus to limit the risks associated with illicit trade"); Directive 2014/40, *supra* note 6, at recital 16 ("to allow consumers adequate time to switch to other products").

[27] Amendments adopted by the European Parliament on the 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, EUR. PARL. DOC. P7_TA(2013)0398 (Oct. 8, 2013), Amendments 50, 87 and 95 (art. 6(10b)) (five years from date of transposition and specific reference to menthol).

[28] Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932, at art. 6(12) (six years from entry into force, four years from transposition).

[29] *See Poland*, *supra* note 6, at paras. 23–25; *Philip Morris*, Case C-547/14, *supra* note 6, at question 1(c)(ii).

[30] *See however below on "capsules embedded in the filter": Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 34, part 4 at 4, 6, 39, and 41; *Poland,* Case C-358/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 59 and 62; *Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 67 and 70.

of snus at issue in *Arnold André/Swedish Match*.[31] The Committee deemed the true aim of the provision to be the high level of health protection, and concern for young people, recital 15 of the Commission proposal referring expressly to the effect of mentholated tobacco product on the latter.[32] On the other hand, the AGRI, INTA, and IMCO Committees would also have excluded menthol from the prohibition, but precisely as menthol did not encourage taking up smoking, and was "consumed by adults of an advanced age," in line with the argument of the parties as to the lesser attractiveness of menthol to young people.[33] As regards the claim that provisions on menthol could be based on Article 114 TFEU only in the presence of national divergences relating specifically to menthol cigarettes, Advocate General Kokott warned against such "'salami slicing' . . . of each market segment regulated in an internal market harmonization measure and indeed even individual product components."[34] The Advocate General noted that the capacity of removing obstacles to free movement resulting from divergences in national legislation should be assessed for "provisions in their entirety" rather than for "each detailed provision."[35] The case law in this respect provides that reliance on Article 114 TFEU as legal basis "does not presuppose the existence of an actual link with free movement between the Member States in every situation covered by the measure founded on that basis,"[36]

[31] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, at 3 and Amendment 20; *Arnold André*, Case C-434/02, *supra* note 4; *Swedish Match*, Case C-210/03, *supra* note 4.

[32] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, at 3 and Amendment 20; *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*, *supra* note 27, at recital 15 (providing that "a number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people"). This recital was removed from the Directive).

[33] *See* Committee on Agriculture and Rural Development Opinion (EP) PE507.956 of 27 June 2017, Amendment 6 (noting that mentholated cigarettes consumption was high in only three Member States); Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendment 19; Committee on the Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments, 7, 8, 25 (on insufficient evidence of their "bad influence on the smoking behavior among youngsters," and time on the market, as used "in traditional tobacco products since the 1920s"), 33 (art. 2(1)(35a)) and 39.

[34] *See Poland*, Case C-358/14, *supra* note *6,* Opinion of Advocate General Kokott at paras. 45–47; *Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 62–64.

[35] The Advocate General added that excluding menthols would have limited the impact of the ban in achieving the high level of health protection. *See Poland*, Case C-358/14, *supra* note *6,* Opinion of Advocate General Kokott at paras. 60–61; *Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 68–69.

[36] *See* Joined Cases C-465/00, C-138, and 139/01, *Rechnungshof v. Österreichischer Rundfunk* 2003 E.C.R. I-4989, para. 41; Case C-101/01, *Bodil Lindqvist* 2003 E.C.R. I-12971, para. 40; *Germany*, Case C-380/03, *supra* note 4, at para. 80.

provided "the measure . . . [is] actually . . . intended to improve the conditions for the establishment and functioning of the internal market."[37]

The Court of Justice, with reference to the preamble and FCTC Partial Guidelines[38]—which made no distinction between different flavors and referred expressly to menthol flavor masking the harshness of tobacco and its impact on tobacco consumption—dismissed arguments for a separate treatment of menthol from the general prohibition of all characterizing flavors. The Union Legislature's decision to adopt uniform rules for all flavors was justified, as these had "certain similar objective characteristics and similar effects" on initiation and consumption patterns.[39] It should be noted in this respect that all European Parliament committees for opinion were in favor of the exclusion of menthol from the ban on flavors.[40] In *Poland v. EP and Council*, the Court of Justice conceded differences in terms of degrees in which flavors alter the taste and smell of tobacco, but again discarded this argument on the basis that all flavorings reduced harshness and encouraged consumption. As to the absence of special status of menthol cigarettes, the Advocate General noted similar characteristics in terms of physical nature, manner of consumption, role in reducing bitterness of tobacco, and risk in facilitating initiation. It was added that the presence of "products long established on the market" did not justify the application of "more relaxed rules,"[41] even though the novelty of some products can on the other hand warrant special or stricter rules,[42] as it is clear from *Pillbox* in relation to

[37] *See Österreichischer Rundfunk*, Joined Cases C-465/00, C-138 and 139/01, *supra* note 36, at para. 41; Case C-491/01, *supra* note 4, at para. 60; *Germany*, Case C-380/03, *supra* note 4, at para. 80.

[38] *See* World Health Organization Framework Convention on Tobacco Control Partial Guidelines for Implementation of Articles 9 and 10, Decision FCTC/COP4(10), (Nov. 2010), Decision FCTC/COP5(6), (Nov. 2012), at sec. 3.1.2.2; Directive 2014/40, *supra* note 6, at recitals 15–16.

[39] *Poland*, Case C-358/14, *supra* note 6, at paras. 40–49, Opinion of Advocate General Kokott at para. 78; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 106–15, Opinion of Advocate General Kokott at para. 75.

[40] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendments 4 and 20 ("characterizing flavors/aroma/taste other than tobacco and traditional flavors such as menthol"); Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013, Amendments 6, 8, 21, 33 ("additives that create or release a flavor which is not predominantly that of tobacco or menthol"), and 40 (art. 6(7) subpara. 1a); Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendments 4 and 23; Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendments 2, 16 ("distinctive fruity or confectionary-like taste . . . tobacco and menthol . . . not [being] considered a fruity or confectionary-like taste"), 19, and 24; Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 7, 8, 25 ("traditional tobacco products flavors such as menthol are not considered to be characterizing flavors"), and 39.

[41] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendments 4 and 20; Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 8, 25 and 39 ("traditional"). The four years derogation based on sales volume was stressed by the Court in relation to proportionality.

[42] *See Arnold André*, Case C-434/02, *supra* note 4, at para. 69; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 71.

electronic cigarettes. Moreover, while acknowledging the possible lesser attractiveness of menthol to young consumers in comparison with other flavors, the Court dismissed an assessment based "solely [on] the tastes and habits of a single group of consumers disregarding the others"—a point also made in relation to proportionality. The Advocate General stressed in this respect that "the objective of a high level of health protection . . . does not cease with the protection of adolescents and young adults, even if the Directive does focus on that group of people."[43]

III. The Prohibition and its Article 114 TFEU Legal Basis

1. Existing and Future Obstacles to Trade and the FCTC Partial Guidelines

In *Poland v. EP and Council* and *Philip Morris*, Advocate General Kokott noted the presence of existing provisions on flavors in some Member States resulting in "appreciable substantive differences," including on distinct flavors, and thus in considerable obstacles to free movement, with national legislation in Belgium, France, Germany, and Lithuania. Although an irrelevant distinction, this also included national differences as to menthol "capsules embedded in the filter," with prohibitions in Belgium and Germany, but not in other Member States—as apparent from the impact assessment.[44] The Advocate General added in *Poland v. EP and Council* that the number of Member States having or intending to legislate at the time of the adoption of the Commission proposal was not decisive—provided conditions for recourse to the Article 114 TFEU legal basis were present at the time of the adoption of the measure, and that these were "not quantitative but qualitative." The Court in both cases referred more generally to some Member States having adopted different lists of prohibited or permitted flavors, and to the absence of specific rules on flavors in other Member States.[45]

Regarding prevention of future obstacles to trade, the case-law requires that the emergence of future obstacles be likely and the harmonization measure designed to prevent them.[46] In addition to existing differences in national regimes, the Court

[43] *See Poland*, Case C-358/14, *supra* note 6, at paras. 50–55, Opinion of Advocate General Kokott at paras. 48–57; *Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at para. 65.

[44] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 34, part 4 at 6 ("Member States are also taking different legal approaches as regards additives integrated in the filter of cigarettes . . . Germany does not allow cigarettes with flavored capsules embedded in the filter to be placed on the market . . . in Belgium 3 ingredients . . . needed to include the "menthol capsules" in cigarettes were recently banned."), and 39–45.

[45] *See Poland*, Case C-358/14, *supra* note 6, at para. 57, Opinion of Advocate General Kokott at paras. 59, 62–65; *Philip Morris*, Case C-547/14, *supra* note 6, at para. 117, Opinion of Advocate General Kokott at paras. 67 and 70.

[46] *See* Case C-376/98, *Germany*, *supra* note 4, at para. 86; Case C-377/98, *Netherlands v. European Parliament & Council* 2001 E.C.R. I-7079, para. 15; *British American Tobacco*, Case C-491/01, *supra* note 4, at para. 61; *Arnold André,* Case C-434/02, *supra* note 4, at para. 31; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 30;

considered that the adoption of further disparate national legislation was likely, given that the FCTC Partial Guidelines recommended the prohibition or restriction of "ingredients . . . increas[ing] palatability in tobacco products," including menthol as an example,[47] leaving a broad discretion as to the choice of measures—in particular in that between restrictions or prohibitions—rather than providing for specific measures, as noted by the Advocate General. She also stressed that the limited national legislation on the subject resulted from the fact that the Commission was preparing for the adoption of its proposal at that time. The Court concluded that the prohibition at EU level was designed to prevent such likely future obstacles.[48]

2. Diversity of Article 114 Measures and Discretion as to the Most Appropriate Method of Approximation

Concerning the improvement of conditions for the functioning of the internal market, the Court in *Philip Morris* and *Poland v. EP and Council* referred to the importance of intra-Union trade in tobacco products,[49] and to the possibility for an Article 114 TFEU measure "to consist . . . in prohibiting, provisionally or definitively the marketing of a product or products,"[50] consistently with the case law on the diversity of harmonization measures available.[51] Advocate General Kokott considered that the prohibition—although not improving those for flavored tobacco products—"improve[d] trade conditions for a class of other products", that is "normal" tobacco products complying with the Directive, in

Germany, Case C-380/03, *supra* note 4, at para. 38; Case C-301/06, *Ireland v. EP & Council*, 2009 E.C.R. I-593, para. 64; *Vodafone*, Case C-58/08, *supra* note 5, at para. 33; *Inuit Tapiriit Kanatami*, Case C-398/13P, *supra* note 5, at para. 27; *Alliance for Natural Health*, Joined Cases C-154 and 155/04, *supra* note *5,* at para. 29; *Poland,* Case C-358/14, *supra* note 6*,* at para. 33; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 59 and 122.

[47] *See* World Health Organization Framework Convention on Tobacco Control Partial Guidelines for Implementation of Articles 9 and 10, Decision FCTC/COP4(10), (Nov. 2010), Decision FCTC/COP5(6), (Nov. 2012), at sec. 3.1.2.2(i).

[48] *See Poland*, Case C-358/14, *supra* note 6*,* at paras. 58–61, Opinion of Advocate General Kokott at paras. 73–82; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 118–22, Opinion of Advocate General Kokott at paras. 71–80.

[49] The Advocate General Kokott had noted the "lively cross-border trade" when considering existing obstacles.

[50] *See Poland*, Case C-358/14, *supra* note 6*,* at paras. 63 and 38; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 124 and 64.

[51] *See* Case C-359/92, *Germany v. Council of the European Union*, 1994 E.C.R. I-3681, paras. 4 and 33; *Arnold André,* Case C-434/02, *supra* note 4, at para. 35; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 34; *Germany*, Case C-380/03, *supra* note 4, at para. 43; *Alliance for Natural Health* Joined Cases C-154 and 155/04, *supra* note 5, at para. 33.

accordance with the Article 24(1) free movement clause, regarding the prohibition as that of a product facilitating free movement of other compliant products.[52]

The ban of a product or component of a product—such as additives—may contribute to the better functioning of the internal market, if removing national differences that prevent market access in some Member States.[53] However, despite the free movement clause for compliant products, the prohibition can be considered as a "destructive" rather than a "constructive" ban, in that it is "part of a strategy to put the product . . . off the market in the immediate or long term . . . seek[ing] not genuinely to improve internal market conditions, but rather to worsen them."[54] Moreover, reasoning based on the free movement of compliant products again highlights the paradox of relying on Article 114 TFEU for such a measure, allegedly aimed at facilitating free movement of unhealthy tobacco products, despite its detrimental provisions and Article 114(3) requiring a high level of health protection.

In *Poland v. EP and Council*, the applicant Member State argued that the prohibition of flavors created new obstacles to free movement, as a result of its imprecision and the absence of lists of prohibited or permitted flavorings.[55] The Court noted the presence in the Directive of a definition of characterizing flavors,[56] and provisions for the adoption of Commission implementing and delegated acts.[57] In comparison with such "dynamic mechanisms," lists of permitted or prohibited products were considered inadequate as an alternative, in light of the need for constant updating resulting from developments in

[52] *See Poland*, Case C-358/14, *supra* note 6, at paras. 62–64, Opinion of Advocate General Kokott at paras. 39–41 and 59; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 123–25, Opinion of Advocate General Kokott at paras. 67 and 81–85. Advocate General Kokott dismissed the argument on smuggling and black-market trade.

[53] *See* D. Wyatt, *Community Competence to Regulate the Internal Market*, OXFORD LEGAL STUD. RES. PAPER, No. 9/2007, 6–7 (referring to Council Directive 88/146, 1988 O.J. (L 70) 16 (EEC) prohibiting the use in livestock farming of certain substances having a hormonal action, based on Article 43 EEC (now art. 43 TFEU)–component of a product–and Council Directive 88/378, 1988 O.J. (L 187) 1 (EEC) concerning the safety of toys, based on Article 100a EEC (now art. 114 TFEU)–"product in its own right". *See below* on the snus ban as a "prohibition outright of a product".

[54] *See* S. Crosby, *The New Tobacco Control Directive: An Illiberal and Illegal Disdain for the Law*, 27 EUR. L. REV. 177, 186–87 (2002).

[55] "Negative" and "positive" lists.

[56] *See* Directive 2014/40, *supra* note 6, at art. 2(25).

[57] *See* Directive 2014/40, *supra* note 6, at art. 7(2) on implementing acts determining whether a tobacco product falls within the scope of the prohibition, art. 7(3) on implementing acts providing uniform rules for procedures to determine whether a tobacco product falls within that scope, adopted as Commission Implementing Regulation 2016/779, 2016 O.J. (L 131) 48 (EU), and art. 7(5) on delegated acts setting maximum content levels, where such levels led to the adoption of national prohibitions in at least three Member States.

commercial strategies, as well as the facility of circumvention.[58] As often, the Court also relied on the Union legislature's discretion as to the choice of method of approximation.[59] The Advocate General further noted that imprecision resulted from the very nature of directives, requiring national implementation, yet the limited scope of national discretion when implementing a ban of all characterizing flavors.[60]

IV. Proportionality of the Prohibition of Characterizing Flavors

1. Appropriateness—Broad Discretion, Twofold Objective, and the Precautionary Principle

The proportionality of the prohibition of flavors was at issue in *Philip Morris* and *Poland v. EP and Council*, again with specific reference to menthol flavor and mentholated tobacco products.[61] The Court in both cases reiterated its traditional argument as to the EU legislature's broad discretion in "area[s] . . . entail[ing] political, economic and social choices on its part, and in which it is called upon to undertake complex assessments," in order to limit its proportionality review only to "manifestly inappropriate" measures, in accordance with its case law.[62] In regards to the appropriateness of the ban to achieve the health protection objective, arguments against the prohibition of menthol were based on its lack of attractiveness to young people and impact on initiation. The Court, stressing as usual the twofold objective of ensuring the good functioning of the internal market while taking as base a high level of health protection, in accordance with Article 114(3) TFEU, considered that the provision fulfilled both aims, noting the possibility for a prohibition to contribute to the functioning of the internal market,[63] and that certain flavorings were

[58] A point made in *Philip Morris* on proportionality: *see Philip Morris*, Case C-547/14, *supra* note 6, at para. 183, Opinion of Advocate General Kokott at para. 175.

[59] *See Germany*, Case C-380/03, *supra* note 4, at para. 42; *United Kingdom*, Case C-66/04, *supra* note 5, at para. 45; *United Kingdom*, Case C-217/04, *supra* note 5, at para. 43; *Vodafone*, Case C-58/08, *supra* note 5, at para. 35; *United Kingdom*, Case C-270/12, *supra* note 5, at para. 102.

[60] *See Poland*, Case C-358/14, *supra* note 6, at paras. 65–69, Opinion of Advocate General Kokott at paras. 66–71.

[61] *See Philip Morris*, Case C-547/14, *supra* note 6, at question 3(a) (on Article 7(1) and (7)); *Poland*, Case C-358/14, *supra* note 6, 2nd plea, at paras. 71–73.

[62] *See Poland*, Case C-358/14, *supra* note 6, at para. 79; *Philip Morris*, Case C-547/14, *supra* note 6, at para. 166; Case C-491/01, *supra* note 4, at para. 123; *Arnold André*, Case C-434/02, *supra* note 4, at para. 46; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 48; *Germany*, Case C-380/03, *supra* note 4, at para. 145; *Alliance for Natural Health*, Joined Cases C-154 and 155/04, *supra* note 5, at para. 52; *Vodafone*, Case C-58/08, *supra* note 5, at para. 52.

[63] *See Germany*, Case C-359/92, *supra* note 51, at paras. 4 and 33; *Arnold André*, Case C-434/02, *supra* note 4, at para. 35; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 34; *Germany*, Case C-380/03, *supra* note 4, at para. 43; *Alliance for Natural Health*, Joined Cases C-154 and 155/04, *supra* note 5, at para. 33. The Court referred to its ruling on the legal basis. *See above* on prohibition of flavors and methods of approximation, *below* on oral tobacco.

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liable to attract and facilitate initiation of young people. In relation to the absence of attractiveness of menthol to young people, it reiterated its points as to the lack of specificity of menthol and the application of the same legal rules to all characterizing flavors,[64] the appropriateness of the provision not being assessed in relation to a specific flavor. The FCTC Partial Guidelines, moreover, refer to menthol among flavors encouraging consumption as a result of its palatability.[65] Similarly, the fulfilment of a high level of health protection was not to be assessed for a specific category of consumers, despite the Court's constant association of this high level of health protection with young people. The prohibition was thus not manifestly inappropriate to attain the twofold objective.[66]

In *Poland v. EP and Council*, the argument as to the lack of contribution of the prohibition to the reduction in the number of smokers was dismissed by the Court, considering the preventive nature of the provision, intended at limiting tobacco initiation. The Advocate General had further noted the difficulty of proving with accuracy, objectively and scientifically, the impact of the prohibition on consumer behavior and forthcoming market developments, focusing instead on the plausibility of the ban's effects.[67] Another argument focusing on illicit trade was rejected by the Court, with provisions on traceability and the unique identifier in Article 15, as well as the tamper proof security feature in Article 16 of the Directive. The Advocate General—while conceding the limited ability of such provisions to reliably prevent smuggling and black market—nonetheless considered that these safeguards rendered such activities more difficult and more readily detectable.[68] She elaborated—in both opinions—on the argument based on the insufficiency of scientific evidence and the application of the precautionary principle,[69] with reference to the four mainstreaming provisions and Union legislature's broad discretion.[70]

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[64] *See above* on the absence of specificity of the menthol flavor.

[65] *See* World Health Organization Framework Convention on Tobacco Control Partial Guidelines for Implementation of Articles 9 and 10, Decision FCTC/COP4(10), (Nov. 2010), Decision FCTC/COP5(6), (Nov. 2012), at sec. 3.1.2.2(i); *Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 35.

[66] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 170–77, 64, and 124–25; *Poland*, Case C-358/14, *supra* note 6, at paras. 80–86, 89, 38 and 63–64; Opinion of Advocate General Kokott at para. 100.

[67] *See Poland*, Case C-358/14, *supra* note 6, at paras. 71, 83 and 87; Opinion of Advocate General Kokott at paras. 101-103.

[68] *See Poland*, Case C-358/14, *supra* note 6, at para. 88; Opinion of Advocate General Kokott at paras. 105-108.

[69] The AG noted the immateriality of proving scientifically with sufficient accuracy health effects of the prohibition of mentholated cigarettes, in light of the precautionary principle, and the possibility of adopting restrictive measures in the presence of insufficient studies, but of a "likelihood of real harm to public health," as apparent in the Partial Guidelines for Implementation of Articles 9 and 10, at sec. 3.1.2.2(i).

[70] *See Poland*, Case C-358/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 92–98 and 78 ; *Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 155–60 and 75. As in *Pillbox 38*, a sub-section was devoted to the precautionary principle in the *Poland v EP and Council* Opinion.

2. Necessity—Knowledge of Health Risks, Broad Discretion, and Exempted Products

Regarding the prohibition's necessity, in both cases, the Court noted the recommendation in the Partial Guidelines to prohibit or restrict ingredients increasing the palatability of tobacco products, and encouragement to adopt stricter measures than those recommended,[71] considered by the Union legislature, once again with reference to its broad discretion. Advocate General Kokott had moreover stressed that menthol was included in examples provided in the Partial Guidelines. The Advocate General also dismissed the argument as to the well-known nature of health risks of smoking—in particular for young people—on the basis that the knowledge of many of the risks involved did not warrant the removal of or failure to adopt safeguards, with analogy to helmets and seatbelts. Common knowledge of risks associated to tobacco constitutes, however, an important factor to consider when intervening in lifestyle choices, through combined health warnings pictures or prohibition of flavors. The Advocate General reiterated the lack of special status of menthol cigarettes and lesser contribution to the high level of health protection if these were excluded. She also noted that exclusion of menthol would have subjected the EU to WTO proceedings, on the basis of the WTO Appellate Body decision on clove and menthol-flavored cigarettes[72]—referred to in the Commission proposal.[73] The JURI Committee of the European Parliament, however, had a different perspective on this decision.[74] Advocate General Kokott also dismissed the argument based on the exemption from the prohibition of tobacco products other than cigarettes and roll-your-own tobacco,[75] especially cigars that are not "particularly attractive to young people," unlike cigarettes and roll-up tobacco—also noted by the ITRE and ENVI Committees—[76] again

[71] *See* World Health Organization Framework Convention on Tobacco Control Partial Guidelines for Implementation of Articles 9 and 10, Decision FCTC/COP4(10), (Nov. 2010), Decision FCTC/COP5(6), (Nov. 2012), at sec. 3.1.2.2(i) and 1.1.

[72] *See* Appellate Body, WTO Doc. AB-2012-1, WT/DS406/AB/R ("United States — Measures affecting the production and sale of clove cigarettes."); *see also* C. Pitschas, *The New EU Tobacco Products Directive and the Regulation of Tobacco Products with a Characterizing Flavor*, 20 INT'L TRADE L. & REG. 60 (2014) (on the compatibility of Directive 2014/40, *supra* note 6, art. 7(1) with the TBT Agreement, menthol flavor and lists of additives); Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendments 19 and 32.

[73] *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*, *supra* note 27, at recital 15.

[74] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 3.

[75] *See* Directive 2014/40, *supra* note 6, at art. 7(12). The Commission may by delegated act withdraw the exemption for a product category, in the presence of a "substantial change of circumstances as established in a Commission report".

[76] *See* Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, at 3 and Amendment 6; Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, Amendment 78.

with reference to the Union legislature's broad discretion under Article 114 TFEU and the possibility to rely on gradual harmonization.[77] The IMCO Committee, however, considered in its opinion that no tobacco product should be exempt from the ingredients provisions, in order to "ensure uniform treatment of all tobacco products and avoid fragmentation of the market."[78] The exemption of certain products from the prohibition therefore tends to indicate that health considerations prevail over internal market concerns, despite comments as to the Union legislature's broad discretion and gradual harmonization.

3. Necessity—Alternative Less Restrictive Measures

A number of alternative, less-restrictive measures were considered and dismissed by the Court, whether the adoption of higher age limits for flavored tobacco products, information campaigns on these products, "positive" and "negative" lists of permitted and prohibited flavors respectively, prohibition of cross-border sales, and health warnings stating that such products are as harmful as other tobacco products. Regarding specific age limits for flavored tobacco products, in both cases, the Court considered the lack of effect on the attractiveness of the product and the facility of circumventing such measures. The Advocate General had further noted the difficulty of monitoring compliance, and, in *Poland v. EP and Council*, the vulnerability of consumers in the 18 to 25 age group.[79] Concerning information campaigns, at issue in *Philip Morris*, the Court held that those were unlikely to eliminate national divergences. The Court thus oscillates between health and internal market concerns in support of the proportionality and adequacy of the Directive's provisions. Regarding lists of prohibited or permitted flavorings, also at issue in *Philip Morris*, while a positive or negative list of additives or combination thereof would have provided legal certainty,[80] the Court noted that such lists would create unwarranted differences in treatment of flavored tobacco products, along with the likelihood of circumvention, and the need for constant updating due to commercial developments. The Advocate General also considered that such lists would restrict remaining national freedom of action. However, the scope for national discretion is limited with a prohibition

[77] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 178–79, Opinion of Advocate General Kokott at paras. 163–70; *Poland*, Case C-358/14, *supra* note 6, at paras. 90–91, Opinion of Advocate General Kokott at paras. 112–17; M. Elsmore & V. Obolevich, *Thank You for Not Smoking: The Commission's Proposal for a New Tobacco Products Directive*, 38 EUR. L. REV. 552, 562 (2013).

[78] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 3 and 9.

[79] In *Poland*, Case C-358/14, *supra* note 6, Advocate General Kokott referred to the help of family, friends and acquaintances. The Advocate General referred to age limits for the purchase/sale of such products, while the Court referred to both age limits for consumption and purchase/sale of such products.

[80] *See* Pitschas, *supra* note 72. Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013, Amendment 32 (possibility for the Commission to adopt a negative list of additives resulting in a characterizing flavor excluding the "traditional use of menthol").

of all flavors, and provisions for further implementing and delegated acts.[81] Concerning the prohibition of cross-border sales as an alternative measure—as argued in *Poland v. EP and Council*—the Court noted that Article 18 already provided this possibility, and that—while seeking to prevent circumvention of the Directive's provisions—this was inadequate in achieving the high level of health protection, as consumers would still be attracted to flavored products in the absence of a ban. Finally, on the possibility of adopting health warnings stating that flavored tobacco products are as harmful as other tobacco products, also at issue in *Poland v. EP and Council*, the Court held that this would not be as adequate as a full-scale prohibition of flavors in terms of health protection, again resulting from the availability of flavorings' impact on consumption. The Advocate General further referred to the argument as to the counterproductive nature of such warnings, potentially acting as an advertisement, "direct[ing] the consumer's attention . . . to the existence of characterizing flavors."[82]

4. Disproportionate Effects—Negative Economic/Social Consequences and Mainstreaming Provisions

With regard to proportionality in the strict sense and arguments based on "negative economic and social consequences" of the prohibition, the Court in *Philip Morris* and *Poland v. EP and Council*, acknowledging the requirement in the Protocol on the Application of the Principles of Subsidiarity and Proportionality for draft legislative acts to take into account "the need for any burden . . . falling upon . . . economic operators . . . to be minimized and commensurate with the objective to be achieved,"[83] considered that this had been the case. It noted the extended deadline of May 20, 2020—instead of 2016—provided by Article 7(14) of the Directive, for "tobacco products with a characterizing flavor whose Union-wide sales volumes represent 3% or more in a particular product category," and thus applicable to mentholated cigarettes. Reference was also made to the expected decrease of 0.5% to 0.8% in cigarette consumption predicted over five years in the impact assessment.[84] However, regarding allegations of insufficient consultation prior to the drafting of the Commission proposal, Advocate General Kokott in *Philip Morris*

[81] *See* Directive 2014/40, *supra* note 6, at art. 7(3), on implementing acts as to procedural rules for determining whether a tobacco product falls within the scope of the prohibition, adopted as Commission Implementing Regulation 2016/779. *See also* the possibility, or obligation at the request of a Member State, to adopt implementing acts on whether a tobacco product falls within the scope of the prohibition, under Article 7(2), and delegated acts on maximum contents levels for additives resulting in a characterizing flavor, if three or more Member States adopt prohibitions, under Article 7(5)).

[82] *See Poland*, Case C-358/14, *supra* note 6, at paras. 92–96, Opinion of Advocate General Kokott at paras. 118–23; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 180–84, Opinion of Advocate General Kokott at paras. 171–75.

[83] Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality, art. 5., Dec. 13, 2007.

[84] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 114, part 6 at 2.

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stressed the non-binding nature of such impact assessments, the inconclusiveness of errors in the consultation in terms of the measure's lawfulness, the irrelevance of a failure to influence the consultation process,[85] and in *Poland v. EP and Council* the lack of special status and need to specifically examine mentholated cigarettes in the impact assessment. The Court in *Philip Morris* and *Poland v. EP and Council* relied upon the four mainstreaming provisions and Article 114(3) respectively, using the requirement of a high level of health protection to balance these economic consequences. The Advocate General went further by noting the "greater importance [of health protection] in the value system under EU law than such essentially economic interests," and that it was justified "to give precedence to the desired high level of health protection over economic and social considerations," which again may be considered problematic for an internal market measure, in spite of mainstreaming provisions and the "decisive factor" formula. In *Poland v. EP and Council,* an argument was also made that the measure affected certain Member States particularly in light of the importance of manufacture and consumption of such products. The Court, however, dismissed a proportionality assessment based on the impact of a Union measure in a specific rather than all Member States.[86] In this respect, Advocate General Kokott rightly noted in both opinions that, by their very nature, internal market approximation measures harmonize national provisions entailing different conditions for Member States and undertakings.[87]

V. Subsidiarity of the Prohibition of Characterizing Flavors

1. Interdependence of Objectives—Exclusion of a Subsidiarity Assessment Based Exclusively on Public Health

[85] The undertaking having made these allegations had moreover been consulted during the process.

[86] *See* Case C-508/13, *Estonia v. European Parliament & Council*, ECLI:EU:C:2015:403, at para. 39.

[87] *See Poland*, Case C-358/14, *supra* note 6*,* at paras. 97–103, 73, Opinion of Advocate General Kokott at paras. 125–35; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 185–90, Opinion of Advocate General Kokott at paras. 176–83. Having acknowledged temporary effects on farmers, manufacturers, suppliers, and marketing undertakings, the Advocate General noted in both opinions the possibility of support to farmers from the common agricultural policy, and, in *Poland*, Case C-358/14, *supra* note 6, assessed losses to the Polish agriculture and tobacco trade as "relatively moderate and manageable," considering these were limited to declines in sales, not including net profit losses. On socio-economic concerns as to the tobacco growing, production and distribution sectors: Committee on Agricultural and Rural Development Opinion Amendments, (EP) PE507.956 of 27 June 2013, at 3, and Amendments 2 (recital 6a), 7 (recital 15a), 18 (recital 40a), 20 (recital 43a), 74-76 (article 23(2) subpara. 1 (ca)-(cb)); Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, at 3; Committee on International Trade Opinion (EP) PE510.734 of 27 May 2013, Amendment 12; *Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 11, 97–98, 100, 102, 115, 120–23, part 2 at 4, part 3 at 8, part 6 at 8–11 and 36.

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The question on compliance with the principle of subsidiarity referred in *Philip Morris*, although citing a number of provisions of Directive 2014/40,[88] was held admissible only in relation to Article 7.[89] In *Poland v. EP and Council*, the applicant Member State's argument on subsidiarity focused again on mentholated tobacco products. It concerned exclusively the health protection objective, alleging an absence of national divergences for such products.[90] As to whether the objective could be better achieved at Union level, the Court—in both cases—dismissed arguments based exclusively on the health objective of the measure, considering the "interdependence" of the two objectives,[91] and the primary objective of improving the functioning of the internal market, with the risk of entrenching or creating national divergences. The mainstreaming provision offers the best of both worlds, providing support for health-related measures based on the general internal market legal basis, while preventing a subsidiarity assessment based solely on the health objective of the measure. Regarding specific consideration of the menthol flavor, the Court in *Philip Morris* referred back to the adequacy of the legal basis and the possibility to subject all flavors to the same legal rules.[92] As for proportionality, a further argument in *Poland v. EP and Council* concerned differences in consumption patterns between Member States. In a similar manner, the Court rejected a subsidiarity assessment based on "the situation of any particular Member State taken individually,"[93] and on consumption of mentholated products being limited to a few Member States.[94] It noted, moreover, that their national market share was higher than that of the whole Union in at least eight other Member States. Rather than dismissing the presence of different market conditions as inaccurate—furthermore rarely similar in all Member States—the Advocate General considered the argument irrelevant considering the measure's internal market objective, in presence of a significant cross-border trade, existing and future national divergences, and

[88] *See Philip Morris*, Case C-547/14, *supra* note 6, question 7, on Directive 2014/40, *supra* note 6, art. 7, 8(3), 9(3), 10(l)(g), 13 and 14.

[89] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 47-53, Opinion of Advocate General Kokott at paras. 48–52. The referring court had not provided reasons in its order for reference as to why art. 7, 8(3), 9(3), 10(l)(g), 13 and 14 failed to comply with the principle of subsidiarity.

[90] *See Poland*, Case C-358/14, *supra* note 6, 3rd plea, at para. 105. *See above* on the presence of national divergences on flavors and menthol capsules.

[91] *See Vodafone*, Case C-58/08, *supra* note 5, at paras. 77–78; *Estonia*, Case C-508/13, *supra* note 86, at paras. 46–48.

[92] *See above* on the absence of special of status of the menthol flavor–similar characteristics and effects. The Advocate General Kokott also noted in both opinions the need to assess compliance with subsidiarity of the Directive as a whole: *Estonia*, Case C-508/13, *supra* note 86, at para. 51.

[93] *See Estonia*, Case C-508/13, *supra* note 86, at paras. 53–54.

[94] The Member States were Poland, Slovakia, and Finland.

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thus obstacles to trade—again in light of the interdependence of the measure's objectives.[95]

2. Deficiencies in Procedural Compliance with the Subsidiarity Principle

Regarding formal or procedural compliance with the subsidiarity principle and the duty to state reasons, in both *Philip Morris* and *Poland v. EP and Council*, the Court referred to the case law providing that evaluation of this requirement was not limited to the wording of the measure, taking also into consideration the "context and circumstances" of the case at issue.[96] It therefore considered that both the Commission proposal's explanatory memorandum and impact assessment had provided sufficient information on subsidiarity for the Union legislature and national parliaments to assess compliance with the principle, for individuals to ascertain reasons, and for judicial review by the Union judicature. In *Poland v. EP and Council*, the participation of Poland in the legislative process was further noted.[97]

While considering that the measure complied with subsidiarity and the duty to state reasons in Article 296 TFEU paragraph 2, Advocate General Kokott acknowledged the reproduction by the Union legislature of "standard/empty/set formulas," referred to as "boilerplate language" in the order for reference. The wording of Article 5(3) TEU was merely replicated in the recital of the preamble,[98] and the reasoning and extent of the Union legislature's subsidiarity assessment was unclear. The Advocate General described these formulas as "not exactly a shining example of the frequently invoked technique of 'better regulation,'" rightfully recommending for the Union legislature not to rely on set formulas, but rather to substantiate its statements in relation to the specific measure at issue. She nonetheless considered that recitals on the choice of Article 114 TFEU as legal basis—while not referring as such to subsidiarity—could also be applied to this principle, considering the significant overlap in reasoning,[99] duty to state reasons case law,[100] as well

[95] *See Poland*, Case C-358/14, *supra* note 6, at paras. 114–21, Opinion of Advocate General Kokott at paras. 149–60; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 218–24, Opinion of Advocate General Kokott at paras. 277–85.

[96] *See Estonia*, Case C-508/13, *supra* note 86, at para. 61; Case C-185/83, *IIE der Rijksuniversiteit te Groningen v. Inspecteur der Invoerrechten en Accijnzen te Groningen*, 1984 E.C.R. 3623, para. 38, and subsequent case-law.

[97] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 225-227; *Poland*, Case C-358/14, *supra* note 6, at paras. 122–25; *Estonia*, Case C-508/13, *supra* note 86, at para. 62.

[98] *See* Directive 2014/40, *supra* note 6, recital 60.

[99] This is the case considering the very nature of Article 114 TFEU, approximating national provisions. *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 45 (on labelling and ingredients).

[100] The statement of reasons is "not required to go into every relevant point of fact and law" and its assessment not limited to wording but including also the "context and the whole body of legal rules governing the matter in

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as subsidiarity justifications in the Commission preparatory work, impact assessment,[101] and proposal's explanatory memorandum, consistently with Article 5 of Protocol No. 2, which moreover only refers to draft legislative acts.[102]

C. Regulation of Electronic Cigarettes and Proportionality

I. Electronic Cigarettes and Refill Containers: The Difficulty of Regulating Novel Products

1. Evolution of the Provisions—From the Commission Proposal to the Directive

Article 18 of the Commission proposal provided for the authorization—under Directive 2001/83 on medicinal products[103]—of nicotine-containing products the nicotine level, nicotine concentration, and maximum peak plasma concentration of which exceeded respectively 2 mg per unit, 4 mg/ml, and 4 ng/ml.[104] The proposal was therefore regarded as adopting an "abstinence-only" rather than a "risk-reduction policy," considering these products as medicinal products rather than as lower risk alternatives to traditional tobacco

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question": *see* Case C-466/93, *Atlanta Fruchthandelsgesellschaft mbH v. Bundesamt für Ernährung und Forstwirtschaft*, 1995 E.C.R. I-3799, para. 16.

[101] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 45–46.

[102] *See Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 286–301; *Poland*, Case C-358/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 172–88. *See also* S. Weatherill, *The Limits of Legislative Harmonization Ten Years After Tobacco Advertising: How the Court's Case Law Has Become a 'Drafting Guide'*, 12 GERMAN L.J. 827, 845 (2011) (on recitals' "assertion rather than demonstration" and "mechanical recitation"; regarding the Court's subsidiarity and proportionality assessments: "the problem . . . lies in the nature of the principles themselves, not in lenient judicial review").

[103] *See* Directive 2001/83 of the European Parliament and of the Council, 2001 O.J. (L 311) 67 (EC) on the Community code relating to medicinal products for human use. *See also Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 4 at 1–2 (on Directive 2001/83, Council Directive 93/42, 1993 O.J. (L 169) 1 (EEC) concerning medical devices, as well as Regulation 178/2002 of the European Parliament and of the Council, 2002 O.J. (L 31) 1 (EC) 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, Regulation 258/97 of the European Parliament and of the Council, 1997 O.J. (L 43) 1 (EC) concerning novel foods and novel food ingredients, Directive 2001/95 of the European Parliament and of the Council 2002 O.J. (L 11) 4 (EC) on general product safety. *See also* Union legislation listed in Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 74 (annex Ia); Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 73 (annex IIb).

[104] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 18(1)(a)-(c), with the possibility under art. 18(2) for the Commission to update by delegated acts nicotine quantities in light of scientific developments and authorizations granted under Directive 2001/83, *supra* note 103; *Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 52-53, 77-84 and 117-118, part 5 at 4 (on the various policy options and impacts considered in the impact assessment).

products.[105] The JURI and INTA Committees proposed instead to apply Directive 2001/83 to nicotine-containing products making health claims,[106] based on its Article 1(2) subpara 1 definition,[107] while the AGRI and ENVI Committees would have applied the Medicinal Products Directive to all nicotine-containing products "regardless of nicotine quantity,"[108] considering the difficulty of "measuring nicotine delivery . . . as it depends on the products and how they are being used."[109] The IMCO Committee would have removed maximum peak plasma concentration as a criterion for the application of Directive 2001/83, noting also the use of potentially dangerous substances, independent of nicotine concentration, and the perception of such products as a medicinal products to stop smoking.[110] Similarly, the Council's general approach deleted the reference to maximum peak plasma concentration, but would have also reduced the nicotine level and concentration respectively to 1 mg per unit and 2 mg/ml.[111] The article was substantially amended by the European Parliament on two occasions.[112]

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[105] *See* A. Alemanno, *EU Tobacco Control 2.0*, POLITICO.EU (Sept. 1, 2013); C. Bates, *Amending the Tobacco Products Directive—How to Fix the Harm Reduction Agenda*, CLIVEBATES.COM (April 22, 2013). Note the requirement of a high level of health protection in mainstreaming provisions. A similar point was made in relation to the prohibition of snus, this time not by the classification/authorization of the product, but more radically by the ban of the product itself.

[106] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 65 (art. 18(1), (1a)(1b)—"nicotine-containing products that are presented as having properties for treating or preventing disease in human beings"); Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendment 55 ("if nicotine containing products are presented as having properties for treating or preventing disease").

[107] *See* Directive 2001/83, *supra* note 103, art. 1(2) subpara. 1 (defining a medicinal product *inter alia* as "any substance or combination of substances presented for treating or preventing disease in human beings").

[108] *See* Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013, Amendment 69 (referring to the high level of health protection); TFEU art. 168(7).

[109] *See* Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, Amendments 34, 33, and 71; Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendments 13, ("regulated either under the upcoming review of the pharmaceutical package or by virtue of a specific legal instrument . . . may include provisions allowing the placing on the market of lower-risk nicotine containing products . . . provided they feature an appropriate health warning"), 14 and 65.

[110] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, at 4, Amendments 16 and 59.

[111] *See Council of the European Union General Approach*, *supra* note 20, annex, at art. 18(1).

[112] *See* Amendments adopted by the European Parliament, P7_TA(2013)0398, *supra* note 27, Amendments 170, 165, 118 and 137/REV on recitals (EP Partial Vote); Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932, at art. 18a; Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendments 12-14.

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Article 20 of Directive 2014/40 now applies to most electronic cigarettes and refill containers,[113] but not to those subject to authorization under Directive 2001/83 or to Directive 93/42 on medical devices.[114] For such products marketed without authorization, Directive 2014/40 requires most notably that the nicotine concentration does not exceed 20 mg/ml.[115] Other conditions include maximum volume requirements of 10 ml for refill containers and 2 ml for cartridges and tanks, the absence of additives listed in Article 7(6), requirements as to the purity, presence, and health-risks of ingredients, consistency in nicotine delivery levels, as well as leakage and breakage protection.[116] Are also required a leaflet with information including instructions, contra-indications, adverse effects, addictiveness, and toxicity,[117] as well as packaging information including ingredients, nicotine content—considered misleading and no longer provided for tobacco products[118] but important for nicotine substitutes—and delivery per dose,[119] and excluding deceptive elements with the exception of indications as to nicotine content and flavorings.[120] With regard to health warnings, the Directive provides two alternative warnings,[121] the wording of which may be adapted by delegated acts.[122] The Commission proposal had also envisaged a health warning for non-tobacco products below the thresholds listed above.[123]

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[113] *See* Directive 2014/40, *supra* note 6, at art. 30(b) (transitional provision that allowed the placing on the market until 20 May 2017 of "electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016").

[114] *See* Directive 2001/83, *supra* note 103; Directive 93/42, *supra* note 103; Directive 2014/40, *supra* note 6, at art. 20(1) subpara. 2.

[115] *See* Directive 2014/40, *supra* note 6, at art. 20(3)(b).

[116] *See* Directive 2014/40, *supra* note 6, at art. 20(3)(a), 20(3)(c)-(g). Article 20(13) provides for the adoption of an implementing act on technical standards for the refill mechanism preventing leakage, adopted as Commission Implementing Decision 2016/586, 2016 O.J. (L 101) 15 (EU).

[117] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(a)(i)-(iv) (requiring information as to use and storage, reference to young people/non-smokers, contra-indications, specific risk group warnings, adverse effects, addictiveness/ toxicity, and contact details).

[118] *See* Directive 2014/40, *supra* note 6, at art. 13(1)(a) (alongside tar and carbon monoxide).

[119] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(b)(i) (list of ingredients, nicotine content, delivery per dose, batch number, and recommendation to keep out of reach of children).

[120] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(b)(ii) (referring to article 13, except article 13(1)(a) on nicotine and 13(1)(c) on flavorings).

[121] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(b)(iii) ("This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers," or the simplified formula "This product contains nicotine which is a highly addictive substance"); Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932, at art. 18a(4)(b)(iii).

[122] *See* Directive 2014/40, *supra* note 6, at art. 20(12).

[123] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture,*

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Again such warnings have been criticized for treating these products in a similar manner to tobacco products and for not highlighting the lower risk of these alternatives, considering their role in preventing smoking and their relatively less dangerous nature.[124] The difference in size with tobacco products warnings should, however, be noted,[125] as well as the removal of the reference to health originally in the Commission proposal version of the warning.[126]

2. Health Concerns and Scientific Uncertainties Versus Regulation of a Lower Risk Alternative to Tobacco Products

The difficulty in regulating electronic cigarettes lies in balancing, on the one hand, the application of the precautionary principle, considering the uncertainty and limited research on a relatively new product, and, on the other hand, regulating what should arguably be a lower risk alternative to traditional tobacco products and cessation tool. Electronic cigarettes do not produce carbon monoxide, nor tar, in the absence of combustion, thus reducing the risk of lung cancer.[127] While tobacco specific nitrosamines—carcinogens from tobacco—may be present in e-liquids and aerosols, as a result of nicotine extraction from tobacco and nitrosation, levels are much lower than in cigarette smoke.[128] Nicotine may

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Presentation and Sale of Tobacco and Related Products, *supra* note 27, at art. 18(3) ("This product contains nicotine and can damage your health"); Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 59 ("This product contains nicotine and *damages* your health."); *Council of the European Union General Approach*, *supra* note 20*,* annex, at art. 18(3) ("This product contains nicotine *which is an addictive substance* and can damage your health."); Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 65 ("This product contains nicotine *which is addictive and may* damage your health."); Amendments adopted by the European Parliament, P7_TA(2013)0398, *supra* note 27 (EP Partial Vote), Amendment 170 ("This product is *intended for use by existing smokers. It* contains nicotine *which is a highly addictive substance.*").

[124] Bates, *supra* note 105.

[125] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(c) (referring to article 12(2) on smokeless tobacco products), and art. 12(2) subpara. 2(b) (30% of the two largest surfaces of the packet and outside packaging, 32% or 35% if two or more official languages).

[126] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 18(3); Directive 2014/40, *supra* note 6, at art. 20(4)(b)(iii). *See also* the requirement that the health warning be "factual" in Article 20 on adaptation of their wording by delegated acts.

[127] *See* Blasi & Ward, *Electronic Nicotine Delivery Systems (ENDS): The Beginning of the End or the End of the Beginning*, 44 EUR. RESPIRATORY J. 585, 585–86 (2014); Nitzkin, *The Case in Favor of E-Cigarettes for Tobacco Harm Reduction*, 11 INT. J. ENV. RES. AND PUB. HEALTH 6459 (2014); Public Health England, *E-Cigarettes: A Developing Public Health Consensus* (July, 2016), at 1, WWW.GOV.UK.

[128] U.S. DEP'T OF HEALTH AND HUM. SERVICES, E-CIGARETTE USE AMONG YOUTH AND YOUNG PEOPLE—A REPORT OF THE SURGEON GENERAL (CDC 2016), at 116; Oh & Kacker, *Do Electronic Cigarettes Impart a Lower Potential Disease Burden than Conventional Tobacco Cigarettes?*, 124 LARYNGOSCOPE 2702, 2703–04 (2014); Goniewicz et al., *Levels*

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have atherosclerotic effects, yet these are reduced for electronic cigarettes, due to a relatively stable white blood cell count.[129] Nevertheless, nicotine may have other cardiovascular effects, increasing heart rate and blood pressure, linked to plasma nicotine concentration, which, although usually lower for electronic cigarettes, may be as high as or higher than cigarettes with certain devices, increased voltage, and consumption behavior.[130] Moreover, carbonyl compounds have been identified in some electronic cigarettes, including formaldehyde, acetaldehyde, acrolein, glyoxal and methylglyoxal, some of which are specific to e-cigarettes. Glyoxal and methylglyoxal are particular to aerosols of e-cigarettes, and limited in traditional cigarette smoke. Formaldehyde—a carcinogen—is present in cigarette smoke at higher levels, but an increase in voltage of electronic cigarettes may result in similar levels. Acrolein—which has DNA-damaging effects and may cause lung cancer, pulmonary, and cardiovascular diseases—is present in higher levels in cigarette smoke, and limited in e-cigarettes.[131] These chemical compounds result from the contact between the e-liquid in the cartridges, which include propylene glycol or glycerol/vegetable glycerine to transform the e-liquid into an aerosol, and the heated nichrome wire in electronic cigarettes, the oxidation forming carbonyl compounds, with variations based on the type of e-liquid used, the battery voltage—which has an impact on levels of formaldehyde, acetaldehyde, acetone—and the output wattage applied. Voltage can be increased in newer devices, and high voltage results in formaldehyde levels close to those in cigarette smoke. Devices also evolved in terms of e-liquid volumes held.[132] Propylene glycol, which produces higher levels of carbonyl

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of Selected Carcinogens and Toxicants in Vapor from Electronic Cigarettes, 23 TOB CONTROL 133 (2014); Farsalinos et al., *Tobacco-Specific Nitrosamines in Electronic Cigarettes*, 12 INT'L JOURNAL OF ENVL. RESEARCH & PUB. HEALTH 9046 (2015).

[129] Oh and Kacker, *supra* note 128, at 2704 (2014); U.S. DEP'T OF HEALTH, *supra* note 128, at 101; Santanam et al., *Nicotinic Acetylcholine Receptor Signaling in Atherogenesis*, 225 ATHEROSCLEROSIS 264 (2012); Benowitz & Burbank, *Cardiovascular Toxicity of Nicotine*, 26 TRENDS IN CARDIOVASCULAR MED. 515 (2016).

[130] U.S. DEP'T OF HEALTH, *supra* note 128, at 100–03; McNeill et al., *E-Cigarettes: An Evidence Update* (Public Health England, 2015), at 71, 75; Vansickel & Eissenberg, *Effective Nicotine Delivery After Acute Administration*, 15 NICOTINE & TOB. RES. 267 (2013); Yan & D'Ruiz, *Effects of Using Electronic Cigarettes on Nicotine Delivery and Cardiovascular Function,* 71 REG. TOXICOLOGY AND PHARMACOLOGY 24 (2015); Bhatnagar, *E-Cigarettes and Cardiovascular Disease Risk*, 10 CURRENT CARDIOVASCULAR RISK REPS. 24 (2016); St.Helen et al., *Nicotine Delivery, Retention and Pharmacokinetics from Various Electronic Cigarettes*, 111 ADDICTION 535 (2016).

[131] Bekki et al., *Carbonyl Compounds Generated from Electronic Cigarettes*, 11 INT'L J. OF ENVTL. RES. & PUB. HEALTH 11192, 1194–95, 1197 (2014); U.S. DEP'T OF HEALTH, *supra* note 128, at 117–18; IARC, *List of Classifications* (2016); Uchiyama et al., *Determination of Carbonyl Compounds Generated from the E-Cigarette*, 29 ANALYTICAL SCI. 1219 (2013); Goniewicz et al., *supra* note 128; DeJarnett et al., *Acrolein Exposure is Associated with Increased Cardiovascular Disease Risk*, 3 J. AM. HEART ASSOC. (2014).

[132] *See Report from the Commission to the European Parliament and the Council on the Potential Risks to Public Health Associated with the Use of Refillable Electronic Cigarettes* COM (2016) 269 final (May 20, 2016), at 7; Bekki et al., *supra* note 131, at 11195–97; U.S. DEP'T OF HEALTH, *supra* note 128, at 100, 117–18; Kosmider et al., *Carbonyl Compounds in Electronic Cigarette Vapors - Effects of Nicotine Solvent and Battery Output Voltage*, 16 NICOTINE & TOB. RES. 1319 (2014); Jensen et al., *Hidden Formaldehyde in E-Cigarette Aerosols*, 372 NEW ENGLAND J. MED. 392

compounds, and may result in respiratory irritations, is increasingly replaced by another solvent, glycerine, and distilled water.[133] Metals such as lead, aluminum, cadmium, iron, nickel, silicate, silver, or tin—originating from cartomizers and their heating mechanism, and which may cause respiratory diseases—have also been found in some aerosols.[134] E-liquid may, moreover, result in nephrotoxicity—renal toxicity—and may have an impact on the liver.[135] The Commission adopted a report—as required by Article 20(10) of Directive 2014/40—on "potential risks to public health associated with the use of refillable electronic cigarettes," which examined four elements: Ingestion of e-liquid, dermal contact, mixing/customization of e-liquids, and combination of e-liquids and devices/hardware customization.[136] The Commission also has the power to adopt delegated acts to extend to the Union prohibitions of specific, or types of, electronic cigarettes, or refill containers, adopted by at least three Member States and justified as presenting a serious risk to health.[137]

Linked to the issue of regulation as a lower risk cessation tool, or as a novel and possibly unhealthy product, is the question whether electronic cigarettes users—the number of which has increased significantly—are mostly reformed or reforming smokers, or whether these devices also attract non-smokers, in particular young people, potentially leading to traditional tobacco products consumption. This concern is behind a number of provisions of the Directive, and even more so behind the stricter provisions of the Commission proposal. Electronic cigarettes have addictive potential, nicotine plasma concentration having an impact on the neuronal nicotinic acetylcholine receptors. Although they generally display a lower maximum nicotine plasma concentration than traditional

(2015); Talih et al., *Effects of User Puff Topography, Device Voltage, and Liquid Nicotine Concentration on Electronic Cigarette Nicotine Yield*, 17 NICOTINE & TOB. RES. 150 (2015); Geiss et al., *Correlation of Volatile Carbonyl Yields Emitted by E-Cigarettes with the Temperature of the Heating Coil* 219 INT'L J. HYGIENE & ENVTL. HEALTH 268 (2016); Sleiman et al., *Emissions from Electronic Cigarettes: Key Parameters Affecting Release of Harmful Chemicals*, 50 ENVTL. SCI. & TECH. 9644 (2016); Directive 2014/40, *supra* note 6, at art. 20(3)(a) (on volumes limits).

[133] Bekki et al., *supra* note 131, at 11197; Kosmider et al, *supra* note 132; Oh & Kacker, *supra* note 128; U.S. DEP'T OF HEALTH, *supra* note 128, at 115; Offermann, *Chemical Emissions from E-Cigarettes*, 93 BUILDING & ENV. 101 (2015).

[134] U.S. DEP'T OF HEALTH, *supra* note 128, at 119; Williams et al., *Metal and Silicate Particles Including Nanoparticles are Present in Electronic Cigarette Cartomizer Fluid and Aerosol*, 8 PLOS ONE (2013); Mikheev et al., *Real-Time Measurement of Electronic Cigarette Aerosol Size Distribution and Metals Content Analysis*, 18 NICOTINE & TOB. RESEARCH 1895 (2016).

[135] Golli et al., *Impact of E-Cigarette Refill Liquid Exposure on Rat Kidney* 77 REG. TOXICOLOGY & PHARMACOLOGY 109 (2016); Golli et al., *Impact of E-Cigarette Refill Liquid with or Without Nicotine on Liver Function*, 26 TOXICOLOGY MECHANISMS & METHODS 419 (2016).

[136] *See Report from the Commission to the European Parliament and the Council on the Potential Risks to Public Health Associated with the use of Refillable Electronic Cigarettes* COM (2016) 269 final (May 20, 2016).

[137] *See* Directive 2014/40, *supra* note 6, at art. 20(11) and recital 46.

cigarettes, such plasma concentration may sometimes reach the same level as cigarettes or above, with higher nicotine concentrations, voltage, sophisticated devices, and intensive consumption behavior.[138] The question of addictiveness has been an important concern in relation to young people.[139] Newer brands of electronic cigarettes sold online have been "less likely to compare themselves with conventional cigarettes," while older brands claimed that electronic cigarettes were healthier than traditional cigarettes. Newer brands have tended to manufacture larger, refillable, and customizable devices, rather than "models resembling conventional cigarettes in shape and size," being therefore less obvious as alternatives to traditional cigarettes.[140] While the number of electronic cigarette users among former or current smokers increased significantly in earlier years, and continues to increase for ex-smokers, a very limited number of users had never smoked before.[141] Concerns of electronic cigarettes being a "gateway" to smoking for non-smokers should thus be limited, use being mostly by former and current smokers, and the purpose of use being primarily to quit or reduce consumption of tobacco. Moreover, even trial of electronic cigarettes does not usually lead to continued use.[142] Nevertheless, some among dual users of tobacco and electronic cigarettes may have no intention to quit smoking, as opposed to dual users—current smokers and vapers—intending to stop

[138] U.S. DEP'T OF HEALTH, *supra* note 128, at 100, 102–03; Kandel & Kandel, *A Molecular Basis for Nicotine as a Gateway Drug*, 371 NEW ENGLAND J. MED. 932 (2014); Nides et al., *Nicotine Blood Levels and Short-Term Smoking Reduction with an Electronic Nicotine Delivery System*, 38 AM. J. HEALTH BEHAV. 265 (2014); Vansickel and Eissenberg, *supra* note 130; Dawkins and Corcoran, *Acute Electronic Cigarette Use: Nicotine Delivery and Subjective Effects in Regular Users*, 231 PSYCHOPHARMACOLOGY 401 (2014); Talih et al., *supra* note 132; Yan and D'Ruiz, *supra* note 130; Ramôa et al., *Electronic Cigarette Nicotine Delivery Can Exceed That of Combustible Cigarettes*, 25 TOB. Control (2016); St.Helen et al., *supra* note 130; *see Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 18(1)(c) (on maximum peak plasma concentration).

[139] On the developing adolescent brain, synaptic change, myelination, and evolving nicotinic acetylcholine receptors, *see* U.S. DEP'T OF HEALTH, *supra* note 128, at 102 and 104–05; England et al., *Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate* 49 AM. J. PREVENTIVE MED. 286 (2015); O'Loughlin et al., *The Nicotine Dependence in Teens Study* 44 INT'L J. EPIDEMIOLOGY 1537 (2015); Yuan et al., *Nicotine and the Adolescent Brain* 593 J. PHYSIOLOGY 3397 (2015).

[140] Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 BMJ 3, 3–5 (2014).

[141] ACTION ON SMOKING AND HEALTH, *Use of Electronic Cigarettes (Vaporizers) Among Adults in Great Britain*, 2–3 (2016 Factsheet No. 33) (noting that the estimated number of electronic cigarette users tripled in Britain between 2012 and 2014 (700,000 to 2.1 million), and increased from 2.1 to 2.8 million between 2014 and 2016. The percentage of ex-smokers in Britain using electronic cigarettes increased from 4.5% to 8.4% between 2014 and 2016, but the number of current smokers, which had increased from 2.7% to 17.6% between 2010 and 2014, did not increase between 2014 and 2015, and only increased from 17.6% to 19.4% between 2015 and 2016. They note, however, that "use among never smokers remains negligible and [in 2016] has not changed since 2012" in Britain).

[142] McNeill et al., *supra* note 130, at 53–56.

smoking or reduce their consumption.[143] Electronic devices can be used to bypass smoke-free environment measures.[144] Another question is whether vapers—former smokers and dual users intending to quit smoking—also intend to eventually stop using or reduce use of electronic cigarettes. In regards to electronic cigarettes and young people, regular use remains low and limited to ex- and current smokers.[145]

3. Flavors and Electronic Cigarettes

Under the Commission proposal, most nicotine-containing products would have required authorization under Directive 2001/83.[146] Considering the costs and burden involved for approval of numerous combinations of flavors and strengths, it was argued that this "amount[ed] to a *de facto* ban on most flavors."[147] The amendment adopted at the European Parliament partial vote on such products included a paragraph providing that flavorings were to be allowed in these nicotine-containing products.[148] A separate vote was in fact taken on this specific paragraph, at the request of the Greens, and with a narrower margin of votes.[149] Directive 2014/40 does not ban flavors from electronic cigarettes and refill containers—the possibility to adopt such prohibitions remaining with the Member States[150]—and allows reference to flavorings on packaging.[151] Prohibiting flavors for such

[143] Harrell et al., *E-Cigarettes and Expectancies: Why Do Some Users Keep Smoking?*, 110 ADDICTION 1833 (2015).

[144] ASH, *supra* note 141, 4 (noting that 22% of smokers also using e-cigarettes used both products "to help deal with situations where [they] cannot smoke . . . 41% of dual users to reduce but not stop smoking, and 35% to stop completely, while 67% of ex-smokers and current vapers used electronic cigarettes to stop entirely); U.S. DEP'T OF HEALTH, *supra* note 128, 53–55. Electronic cigarettes are, however, often also banned in public places. Directive 2014/40, *supra* note 6, at recital 48 (noting that the Directive "does not harmonize the rules on smoke-free environments").

[145] Action on Smoking and Health, *Use of Electronic Cigarettes Among Children in Great Britain*, 1-2 (2016 Factsheet No. 34) (showing that regular use among children surveyed—ages 11 to 18—amounted to 2%—1% more than once a month and 1% more than once a week—including 5% of current smokers for monthly and 13% for weekly use, 1% of ex-smokers for both monthly and weekly use, but 0% of never smokers for both monthly and weekly use); Britton and Bogdanovica, *Electronic Cigarettes – A Report Commissioned by Public Health England* (2014), 8 PUB. HEALTH ENGLAND, *supra* note 127, at 1; U.S. DEP'T OF HEALTH, *supra* note 128, at 28–30, 43—46; *Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 27.

[146] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Rated Products*, *supra* note 27, at art. 18(1).

[147] C. Bates, *The Case for Regulating E-Cigarettes as Medicines*, CLIVEBATES.COM (July 6, 2013).

[148] *See* Amendments adopted by the European Parliament, P7_TA(2013)0398, *supra* note 27 (EP Partial Vote), Amendment 170, art. 18(3)(h).

[149] *See* C. Bates, *Tobacco Products Directive: After The Insurrection—What Next?*, CLIVEBATES.COM (Aug 31, 2013).

[150] *See* Directive 2014/40, *supra* note 6, at recital 47 (provided such prohibitions are justified and notified).

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products would have limited their appeal to smokers,[152] while a possibility could have been a distinction as to types of flavors allowed, considering the concern not to appeal to non-smokers and young people.[153] A wide range of flavors are available, reference to flavors being, moreover, a major tool for online promotion of electronic cigarettes by new brands,[154] and there has been an evolution to larger refillable devices,[155] comparable to waterpipes. In addition to the attractiveness of the product, health issues may also arise in relation to certain flavors if heated—such as diacetyl and acetyl propionyl—which, although in lower proportions than in traditional cigarettes, may be detrimental for the lungs.[156]

II. Equal Treatment and Proportionality of Electronic Cigarettes Provisions

1. Equal Treatment—Different Product Characteristics and a More Lenient Regime

Pillbox concerned exclusively the validity of Article 20 of Directive 2014/40 on electronic cigarettes, the national judicial review proceedings having been brought by this e-cigarette

[151] *See* Directive 2014/40, *supra* note 6, art. 20(4)(b)(ii), (referring to article 13(1)(c) on flavorings, alongside article 13(1)(a) on nicotine content).

[152] ASH, *supra* note 141, at 12 (noting that in Britain in 2016, a majority of vapers preferred tobacco flavor (33%), yet an important proportion of vapers chose fruit flavors (22%) and menthol or mint flavor (also 22%), while a limited proportion preferred vanilla (3%) or sweet and candy flavors (also 3%)); C. Bates, *Tobacco Products Directive, E-Cigarettes and Snus*, CLIVEBATES.COM (June 27, 2013).

[153] Blasi and Ward, *supra* note 127, at 585 (2014); McNeill et al., *supra* note 130, at 54; Bates, *supra* note 147; U.S. DEP'T OF HEALTH, *supra* note 128, at 115. Fruit flavors were popular among young people—ages 11 to 18—in 2016, both regular users (36%) and those having tried but not currently using electronic cigarettes (49%), while sweet flavors were relatively popular for the latter (13%) but not as much for regular users (7%)): *see* ASH, *supra* note 145, at 4–5. *See also Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 27; Directive 2014/40, *supra* note 6, at recital 47 (referring to young people and non-smokers, although noting benefits of Member States allowing flavored products).

[154] Zhu et al., *supra* note 140, at 3 (referring to 7764 flavors and 242 new flavors each month on English language websites at the beginning of 2014 and noting the large number of brands selling e-cigarettes online).

[155] ASH, *supra* note 141, at 10 (use of devices with refillable tanks increased from 41% to 71% between 2014 and 2016 in Britain, while those with pre-filled cartridges decreased from 47% to 23%, with more ex-smokers than smokers using the former—81% and 63% respectively—and more smokers than ex-smokers using the latter—29% and 16%); Zhu et al., *supra* note 140, at 3–5; ASH, *supra* note 145, at 4 (noting that similarly, for young people—ages 11 to 18—55% used devices with refillable tanks and 13% those with pre-filled cartridges).

[156] *See Report from the Commission to the European Parliament and the Council on the Potential Risks to Public Health Associated with the use of Refillable Electronic Cigarettes*, COM (2016) 269 final (May 20, 2016), at 6; U.S. DEP'T OF HEALTH, *supra* note 128, at 115–16, 184; Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An Unrecognised Respiratory Health Hazard?*, 312 JAMA 2493 (2014); Farsalinos et al., *Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins*, 17 NICOTINE & TOB. RES. 168 (2014).

manufacturer. The Article 114 TFEU legal basis was not at issue for electronic cigarettes.[157] Regarding equal treatment and free competition, the Court considered the argument based on a less favorable treatment of electronic cigarettes than tobacco products, despite their presumably less harmful nature. The principle of equal treatment requires comparable situations to be treated in the same way and different situations differently, in the absence of objective justification for such difference in treatment.[158] The Court identified a number of "different objective characteristics" of electronic cigarettes in comparison to tobacco products—in terms of composition, pattern of consumption, relative novelty of the product, implying uncertainty as to possible health risks—and rightly concluded that such difference in situation justified a separate legal regime, especially as such treatment remained "less strict than [that] applicable to tobacco products."[159]

2. Proportionality—Broad Discretion, Normalization, National Disparities, and the Precautionary Principle

Concerning compliance of Article 20 as a whole with principles of proportionality and legal certainty, the argument of the claimant in the main proceedings was that, as a result of the "less harmful or even beneficial nature for public health" of electronic cigarettes, these products should not be subject to a specific regime with comparable or even stricter rules than those for tobacco products. Having noted the broad discretion of the Union legislature in areas entailing "political, economic, and social choices" and thus "complex assessments," resulting in the invalidity of the measure only if manifestly inappropriate in light of its objective,[160] the Court stressed uncertainties and divergent opinions among parties and experts, apparent in the ENDS report,[161] as to health implications of electronic cigarettes consumption.[162] These could be considered as an adequate substitute to

[157] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 26, part 4 at 2 and 15–22 (on differences in national legislation).

[158] *See* Case C-304/01, *Spain v. Commission of the European Communities*, 2004 E.C.R. I-7655, para. 31; *Arnold André*, Case C-434/02, *supra* note 4, at para. 68; Swedish Match, Case C-210/03, *supra* note 4, at para. 70; Case C-344/04, *R (IATA) v. Department of Transport*, 2006 E.C.R. I-403, para. 95; Case C-558/07, *R (S.P.C.M. SA) v. Secretary of State for the Environment, Food and Rural Affairs*, 2009 E.C.R. I-5783, para. 74; Case C-579/13, *P and S v. Commissie Sociale Zekerheid Breda*, ECLI:EU:C:2015:369, para. 41.

[159] *See Pillbox 38*, Case C-477/14, *supra* note 6, at para. 33–45, Opinion of Advocate General Kokott at para. 36–52.

[160] *See* Case C-491/01, *supra* note 4, at para. 123; *Arnold André*, Case C-434/02, *supra* note 4, at para. 46; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 48; *Germany*, Case C-380/03, *supra* note 4, at para. 145.

[161] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report, FCTC/COP6(10), at para.2 (Nov. 2014).

[162] *See* P. Koutrakos, *Reviewing Harmonization: The Tobacco Products Directive Judgments*, 41 EUR. L. REV. 305, 305 (2016) (noting that, given the division of the scientific community on electronic cigarettes, "interference by the Court with the substantive policy choice of the EU legislature to impose restrictions would have amounted to an extraordinary and unwarranted display of activism").

tobacco and cessation tool, or at least as a "means of reducing tobacco consumption." Alternatively, e-cigarettes could constitute a trigger for nicotine addiction and "point of entry to smoking for non-smokers," arguably "renormalizing" or "undermin[ing] efforts to de-normalize tobacco use,"[163] and "trivializ[ing] the action of smoking," possibly resulting in intensive consumption and maintaining nicotine addiction, especially if combined with tobacco use. The Court also noted the possibility of nicotine poisoning,[164] and presence of "certain health risks related to the inhalation of nicotine and toxicants in aerosol and to nicotine exposure by means other than inhalation." While one may be skeptical as to electronic cigarettes being a "gateway" to smoking for non-smokers and young people,[165] arguments based on uncertainties as to health risks involved, composition, use of toxicants in the aerosol, intensive nicotine consumption, and dual use of electronic cigarettes and tobacco products, are more convincing, despite electronic cigarettes constituting a valuable tool to stop smoking. In light of limited scientific evidence and conclusions—both as to the effectiveness as a cessation method or as an introduction to and "renormalization" of smoking, noted in the ENDS report[166], and the "toxic and carcinogenic components" present in both e-liquid and vapor, acknowledged by *Pillbox*[167]—the Union legislature had to take into account the precautionary principle.[168]

A first issue related to whether e-cigarettes should be subject to specific rules despite their less harmful or beneficial nature. This was held justified in light, first, of the presence of significant differences in national legislation—with prohibitions in some Member States, an absence of regulation in others, or regulation as medicines in yet other Member States, identified in the impact assessment and preamble[169]—as well as differences in national

[163] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report, FCTC/COP6(10), at paras. 2 and 23–24 (Nov. 2014).

[164] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report, FCTC/COP6(10), at para. 14 (Nov. 2014).

[165] *See* Directive 2014/40, *supra* note 6, at recital 43 ("gateway to nicotine addiction . . . mimic and normalize the action of smoking").

[166] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report FCTC/COP6(10), at paras. 23–24 (Nov. 2014).

[167] Pillbox stressed, however, their lower levels in e-cigarettes than in tobacco products, and recognized the need for further scientific studies).

[168] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 47–56, Opinion of Advocate General Kokott at paras. 61–67 (the Advocate General devoted a sub-section to the precautionary principle); Case C-157/14, *Société Neptune Distribution v. Ministre de l'Economie et des Finances*, ECLI:EU:C:2015:823, paras. 81-82; Case C-269/13P, *Acino AG v. Commission*, ECLI:EU:C:2014:255, paras 57–58.

[169] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 25–26, part 4 at 2; Directive 2014/40, *supra* note 6, at recital 36; Committee on Proposal on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, at 79.

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conditions to be satisfied by these products,[170] liable to result in obstacles to free movement, considering their growing market, stressed in the preamble and ENDS report.[171] The Court, also noting FCTC recommendations to ban or restrict these products, their advertising and sponsorship,[172] the need for the Union legislature to act consistently with the precautionary principle, and take into consideration FCTC requirements—again referring to internal market and health objectives resulting from the mainstreaming provision, and young people—considered that the EU legislature had not manifestly infringed the scope of its discretion.[173] Another issue concerned the adoption of comparable or even stricter rules to those applicable to—more harmful—tobacco products. In this respect, the Court reiterated differences in terms of objective characteristics and market novelty, justifying specific rules, and the irrelevance of a comparison between these products.[174] It should also be noted that the JURI and ENVI Committees had inserted a recital demanding that Member States "ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products or related products,"[175] adopted at the European Parliament partial vote,[176] yet

[170] As regards compliance with the principle of subsidiarity, the Court referred to its proportionality assessment of Article 20 as a whole and paras. 2, 3, 4(a) and 5 as to the existence of national differences: *see Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 142-151.

[171] *See* Directive 2014/40, *supra* note 6, at recital 43; World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report FCTC/COP6(10), at para. 27(a) (Nov. 2014); Case C-491/01, *supra* note 4, at para. 64, Opinion of Advocate General Geelhoed at para. 61, on tobacco.

[172] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems, Decision FCTC/COP6(9), at para. 4 (Oct. 2014).

[173] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 57–61.

[174] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 62–66. As regards the absence of proportionality assessment of the provisions on electronic cigarettes in the impact assessment, as not initially envisaged in the Commission proposal, the Court noted the lack of binding nature of impact assessments: *see* Case C-343/09, *Afton Chemical Limited v. Secretary of State for Transport*, 2010 E.C.R. I-7027, para. 57. It also stressed the discretion of the Union legislature to adopt different measures to those envisaged in the impact assessment, including stricter measures, without manifestly exceeding what was necessary to achieve the objective pursued. The Court noted that scientific evidence and opinions of the parties had been taken into consideration by the Union legislature, and that consultations and meetings had taken place later, organized by the Commission and the ENVI Committee. *Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 64-66, Opinion of AG Kokott at paras. 68-72.

[175] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Draft EP Legislative Resolution, Amendments 15 (recital 35a) and 65 (art. 18(1e)); Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 59 (art. 18(1e)) (on a minimum age for nicotine-containing products).

[176] *See* Amendments adopted by the European Parliament, P7_TA(2013)0398, *supra* note 27 (EP Partial Vote), Amendment 36 (recital 35a).

not included in Directive 2014/40, which does not provide an age limit for electronic cigarettes.[177]

3. Proportionality of Specific Provisions on Electronic Cigarettes

The validity of specific provisions on electronic cigarettes in light of proportionality and legal certainty was also considered in *Pillbox*. Article 20(2) requires the notification by manufacturers and importers of information on the product to national authorities,[178] six months prior to its placing on the market.[179] Regarding the argument that this notification regime was stricter than that for tobacco products, the Court stressed that it merely constituted a notification, rather than a more onerous authorization regime requiring approval prior to the placing on the market. It considered the obligation appropriate to achieve the objective, stated in the preamble,[180] of allowing Member States to ensure surveillance and control, in accordance with the precautionary principle and the FCTC recommendation to monitor product use. The Court further dismissed as inadequate the alternative, less onerous measure consisting in establishing common standards at EU level for these products, in the absence of "sufficiently substantive data." It did not deem the length of the six months period envisaged manifestly excessive, in light of the amount of data and uncertainties as to consumption of the product, or hindering innovation, considering the impact on innovation of other Directives providing similar or stricter regimes. With regard to information to be provided and compliance with the principle of legal certainty, the Court noted that it concerned average, minimum and maximum levels, and that the general framework was supplemented by a common notification format provided by an implementing act.[181]

Similarly, concerning the Article 20(7) reporting obligations, requiring manufacturers and importers of electronic cigarettes and refill containers to submit every year market data to national authorities, the argument that manufacturers and importers of tobacco products were not subject to such a requirement was dismissed. The Court considered that this

[177] *See* Directive 2014/40, *supra* note 6, recital 48 (on electronic cigarettes and refill containers), and recital 21, (encouraging Member States to "lay down and enforce age limits" for tobacco and related products).

[178] *See* Directive 2014/40, *supra* note 6, at art. 20(2) subpara. 2 (including information as to ingredients and emissions (b), toxicological data (c), nicotine doses/ uptake (d), product components (e), production process (f)).

[179] Or six months prior to the transposition deadline for products already on the market: *see* Directive 2014/40, *supra* note 6, at art. 20(2) subpara. 1. This subparagraph also provides for a new notification "for each substantial modification of the product".

[180] *See* Directive 2014/40, *supra* note 6, at recital 36.

[181] *See* Directive 2014/40, *supra* note 6, at art. 20(13), providing for the adoption of an implementing act establishing a common notification format, adopted as Commission Implementing Decision 2015/2183, 2015 O.J. (309) 15 (EU); *Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 69–80, Opinion of Advocate General Kokott at paras. 75–94.

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obligation did not go manifestly beyond what was necessary to attain the objective of allowing the Commission and Member States to collect information on market development to carry out their regulatory tasks. It noted again the "long-standing presence [of tobacco products] on the market and the scientific studies of which they were the subject," to be contrasted with the "novelty . . . and . . . uncertainties" as to health risks of electronic cigarettes and refill containers. The Court stressed that manufacturers and importers were better placed to provide such data—and often already collected such information as part of their strategic development—thus not constituting a manifestly excessive burden on these actors. Additionally, market surveys were inadequate as an alternative less onerous measure, constituting only part of the required information,[182] direct data providing "more accurate, reliable and exhaustive information." Considering that the provision was also sufficiently clear—as a Union legislative measure did not need to provide technical details, Member States remaining free to decide the appropriate method to be used—it was held that the provision complied with proportionality and legal certainty.[183]

With regard to the Article 20(3) volume and nicotine concentration requirements,[184] relying on the internal market and high level of health protection objective,[185] the Court considered those provisions to be appropriate to remove obstacles to the free movement of goods relating to the composition of these products, and limit risks associated with nicotine exposure, consistently with high level of health protection required. As to whether provisions on volume limits went beyond what was necessary to achieve the measure's objective, and the argument that these amounted to a stricter regime for electronic cigarettes and refill containers than for tobacco products, it referred back to its comments on different product characteristics in terms of composition, consumption pattern, and novelty. Regarding the necessity assessment of provisions on the nicotine yield, the claimant in the main proceedings had argued that these were based on an erroneous scientific premise based on the "'physical' quantity of nicotine" in the liquid rather than the "amount of metabolized nicotine delivered into the smoker's bloodstream," as measured for cigarettes, thus reducing the effectiveness of these products as substitutes to tobacco. This was in fact one of three elements considered in the Commission proposal for the application of Directive 2001/83.[186] The Court nonetheless referred to scientific

[182] *See* Directive 2014/40, *supra* note 6, at art. 20(7) subpara. 1(iv).

[183] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 132–41, Opinion of Advocate General Kokott at paras. 149–55.

[184] *See* Directive 2014/40, *supra* note 6, at art. 20(3)(a)-(b).

[185] *See* Directive 2014/40, *supra* note 6, at art. 1 (referring to the mainstreaming provision and young people).

[186] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 18(1)(c).

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evidence relied upon by the Union legislature and the risk of overdose or poisoning identified in the ENDS report.[187] It further noted that the nicotine yield of most electronic cigarettes in the internal market was lower than 30 mg/ml, and that a smoker smoking a packet a day needed between 18 and 24 mg/ml of nicotine. However, this argument tends to demonstrate that Article 20(3)(b) does not ensure that electronic cigarettes constitute adequate substitutes to tobacco, in limiting the nicotine yield to 20 mg/ml, thus removing strong cartomizers of 24 mg/ml from the market unless authorized. The possibility remains for electronic cigarettes above 20 mg/ml to be placed on the market in accordance with Directives 2001/81 and 93/42, as noted by the Court, which concluded that the Union legislature had not exceeded limits of its broad discretion or acted arbitrarily, again with reference to high level of health protection and young people. Finally, as regards the requirement of consistent levels in nicotine delivery,[188] the provision was considered sufficiently clear and compliant with legal certainty, leaving to Member States or manufacturers the choice of assessment method.[189]

Concerning the leaflet required by Article 20(4)(a), and the argument based on the absence of a similar requirement for tobacco products, it was held that the Union legislature had not manifestly exceeded the limits of what was appropriate and necessary. The provision complied with principles of proportionality and legal certainty, on the basis of differences in product characteristics, the amount of information required, not sufficiently visible on packaging, which already includes the list of ingredients, and the concern that consumer information should be available after the removal of packaging.[190] Leaflet references to contra-indications, risk groups, adverse effects,[191] or toxicity, [192] and the list of ingredients on packaging,[193] provide useful information for consumers. Notification by manufacturers and importers of data as to ingredients, emissions, components of devices,[194] data

[187] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems Report FCTC/COP6(10), at para. 14 (Nov. 2014).

[188] *See* Directive 2014/40, *supra* note 6, at art. 20(3)(f).

[189] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 81–102 and 36–43, Opinion of Advocate General Kokott at paras. 95-112.

[190] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 103–08, Opinion of Advocate General Kokott at paras. 113–19.

[191] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(a)(ii)-(iv).

[192] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(a)(v) ("addictiveness and toxicity"). Article 2(27) defines toxicity as "the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure."

[193] *See* Directive 2014/40, *supra* note 6, at art. 20(4)(b)(i).

[194] *See* Directive 2014/40, *supra* note 6, at art. 20(2) subpara. 2(b) ("list of all ingredients contained in, and emissions resulting from the use of, the product"), (c) ("toxicological data regarding the product's ingredients and emissions, including when heated"), and (e) ("description of the components of the product, including . . . the

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collection on adverse effects on health, safety and quality,[195] research on health risks,[196] and the possibility to extend to the whole Union provisional national prohibitions of specific or types of devices potentially presenting serious health risks,[197] constitute further constructive provisions aimed at minimizing health risks of these relatively new products, especially considering the diversity of products available. This should be the primary concern, before analysis of the impact on initiation of consumption and cessation.[198]

D. Prohibition of Cross-Border Advertising and Sponsorship of Electronic Cigarettes

I. Provisions and Added Legal Bases Reflecting the Tobacco Advertising and AMS Directives

Directive 2014/40 prohibits a number of forms of advertising and sponsorship concerning electronic cigarettes and refill containers. The preamble refers to existing national disparities, resulting in obstacles to the free movement of goods and services, and creating an appreciable risk of distortions of competition, furthermore likely to increase in light of the growing market in these products. In addition to internal market considerations, the same recital stresses public health concerns relating to "normalization" and "gateway" to addiction.[199] The Directive does not harmonize national rules on "domestic sales

opening and refill mechanism"). Article 20(8) subpara. 1 requires that information be "made publicly available on a website."

[195] *See* Directive 2014/40, *supra* note 6, at art. 20(9) subparas. 1 ("system for collecting information about all of the suspected adverse effects on human health of these products") and 3 ("may also request additional information . . . for example on the safety and quality aspects or any adverse effects"), applying to manufacturers, importers and distributers; Directive 2014/40, *supra* note 6, recital 45.

[196] *See* Directive 2014/40, *supra* note 6, at art. 20(10)*; Report from the Commission to the European Parliament and the Council on the Potential Risks to Public Health Associated with the use of Refillable Electronic Cigarettes* COM (2016) 269 final (May 20, 2016).

[197] *See* Directive 2014/40, *supra* note 6, at art. 20(11), if such prohibitions have been adopted by at least three Member States (subpara. 2); Directive 2014/40, *supra* note 6, at recital 46.

[198] *See* Directive 2014/40, *supra* note 6, art. 20(7) (on submission of market data by manufacturers and importers including "preferences of various consumer groups, including young people, non-smokers and the main types of current users" (ii)), recital 44, article 28(2) subpara. 1(g) (Commission report to "pay special attention to . . . market developments . . . including on the initiation of consumption . . . by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavors").

[199] *See* Directive 2014/40, *supra* note 6, at recital 43, (stating that "electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking," justifying a "restrictive approach" to advertising, referring to the high level of health protection).

arrangements or domestic advertising, or brand stretching."[200] Article 20(5) focuses on cross-border advertising and sponsorship.[201] What distinguished the two Tobacco Advertising Directives, resulting in different outcomes as to their validity in the Tobacco Advertising rulings, was, in addition to provisions on diversification products,[202] the distinction between "static" and "non-static" advertising,[203] as well as the presence of a free movement clause.[204] Article 20(5) prohibits commercial communications of electronic cigarettes and refill containers in information society services, press and other printed publications,[205] radio,[206] and audio-visual commercial communications to which Directive 2010/13 applies,[207] as well as public or private contributions to radio programs,[208] events, activities, or individual persons, "involving or taking place in several Member States or otherwise having cross-border effects" promoting these products.[209] Articles 53(1) and 62 TFEU were added to Article 114 as legal bases as a result of amending the Commission proposal substantially in relation to these products—including this provision on advertising and sponsorship—consistently with the legal bases of the Tobacco Advertising Directive and the Audiovisual Media Services Directive applicable to tobacco advertising and sponsorship. The JURI Committee, in its opinion on the legal basis of the measure, while

[200] *See* Directive 2014/40, *supra* note 6, at recital 48, as well as age limit. It also provides that the "presentation and advertising of those products should not lead to the promotion of tobacco consumption or give rise to confusion with tobacco products".

[201] *See* Directive 2014/40, *supra* note 6, at recital 43.

[202] *See Germany*, Case C-376/98, *supra* note 4, at para. 102; Directive 98/43, *supra* note 4, at art. 3(2). *See below* on bans.

[203] *See Germany*, Case C-376/98, *supra* note 4, at paras. 15–16 and 97–99; Directive 98/43, *supra* note 4, at art. 3(1); *Germany*, Case C-380/03, *supra* note 4, at paras. 53–54, 59 and 70–71; Directive 2003/33, *supra* note 4, at art. 3.

[204] *See Germany*, Case C-376/98, *supra* note 4, at paras. 101, 104; *Germany*, Case C-380/03, *supra* note 4, at paras. 73–75; Directive 2003/33, *supra* note 4, at art. 8.

[205] *See* Directive 2014/40, *supra* note 6, at art. 20(5)(a), except for "publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market"). *See* the equivalent provisions for tobacco advertising: Directive 2003/33, *supra* note 4, at art. 3.

[206] *See* Directive 2014/40, *supra* note 6, at art. 20(5)(b); Directive 2003/33, *supra* note 4, art. 3.

[207] *See* Directive 2014/40, *supra* note 6, at art. 20(5)(e); Directive 2010/13 2010 O.J. (L 95) 1 (EU).

[208] *See* Directive 2014/40, *supra* note 6, at art. 20(5)(c); Directive 2003/33, *supra* note 4, at art. 4(2).

[209] *See* Directive 2014/40, *supra* note 6, at art. 20(5)(d); Directive 2003/33, *supra* note 4, at art. 5(1).

skeptical as to the Article 114 legal basis, approved the two legal bases added, to reflect those of these two Directives.[210]

II. Proportionality of the Prohibitions

In *Pillbox*, it was argued that these prohibitions were disproportionate for the "developing market" in electronic cigarettes, while tobacco products had "benefited for years from advertising enabling them to establish themselves on a long-term basis on the market", prior to the Tobacco Advertising measures. The Court, however, dismissed this argument on the basis of scientific allegations as to health risks, the precautionary principle, and the high level of health protection required by the four mainstreaming provisions. The prohibition was considered necessary in light of the FCTC recommendation to prohibit or restrict advertising and sponsorship of such products.[211] The provision was also deemed appropriate to achieve the internal market objective, considering national disparities impeding free movement of goods and services and resulting in an appreciable risk of distortions of competition, with a likely increase in such disparities in an expanding market, as stated in the Directive's preamble,[212] as well as health protection of potential consumers, with reference to young people's vulnerability to advertising.[213]

Another element at issue in *Pillbox* was compliance of Article 20 of Directive 2014/40, and more specifically the prohibition of commercial communications in Article 20(5), with Articles 16 and 17 of the Charter of Fundamental Rights.[214] As to Article 16 on freedom to conduct a business, the Court conceded the presence of an interference, but held that, accordingly with Article 52(1) of the Charter, the limitation was laid down by law—the Directive—respected the essence of the freedom to conduct a business—as it did not prevent the manufacturing and marketing of products complying with the Directive—and was appropriate and necessary to attain its objectives, considered in the proportionality assessment above. In regards to Article 17(2) of the Charter on the right to property—including the protection of intellectual property—it was held that Article 20 did not hinder intellectual property rights as to marketing, the essence of the undertaking's property right

[210] *See* Committee on Legal Affairs, Opinion on the Legal Basis of the Proposal (EP) PE527.873 of 24 Jan. 2014, at 1-3 and 5; Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932; Directive 2003/33, *supra* note 4; Directive 2010/13, *supra* note 207.

[211] *See* World Health Organization Framework Convention on Tobacco Control Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems, Decision FCTC/COP6(9), at para. 3 (Oct. 2014).

[212] *See* Directive 2014/40, *supra* note 6, at recital 43.

[213] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 109–18, Opinion of Advocate General Kokott at paras. 120–33.

[214] *See Pillbox 38*, Case C-477/14, *supra* note 6, at sub-question 4 and para. 153.

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was unaffected, and again that the interference did not exceed the limits of what was appropriate and necessary to achieve the Directive's objectives.[215]

E. Cross-Border Distance Sales, Flavored Tobacco Products, and Electronic Cigarettes

I. The Possibility to Prohibit Cross-Border Distance Sales and the Article 114 TFEU Legal Basis

Article 18 of Directive 2014/40 provides the possibility for Member States to prohibit cross-border distance sales of tobacco products[216]—as envisaged in the Council general approach.[217] It also provides common rules applicable in the absence of distance sales prohibitions,[218] registration of retail outlets engaging in cross-border distance sales with national authorities,[219] and an age verification system requirement,[220] already envisaged in the Commission proposal,[221] which did not refer to the possibility to ban such sales.[222] Following the opinions of most European Parliament committees, however, the ENVI Committee Report envisioned a general prohibition of cross-border distance sales, adopted

[215] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 152–66, Opinion of Advocate General Kokott at paras. 181–201.

[216] *See* Directive 2014/40, *supra* note 6, at art. 18(1) 1st sentence; *Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 4 at 45–58 (on national provisions as to cross-border sales).

[217] *See Council of the European Union General Approach*, *supra* note 20*,* annex, at recital 30, and art. 16(1).

[218] *See* Directive 2014/40, *supra* note 6, at recital 33.

[219] *See* Directive 2014/40, *supra* note 6, at art. 18(1) 4th and 5th sentences (for retail outlets established in the EU, to national authorities of the Member States where it is established and where its consumers are located; for retail outlets established outside the EU, to those of the Member States where its consumers are located).

[220] *See* Directive 2014/40, *supra* note 6, at art. 18(4); Council Recommendation 2003/54, sec. 1(d), 2003 O.J. (L 22) 31 (EC) (recommending the adoption of national measures "to prevent tobacco sales to children and adolescents, including . . . restricting tobacco distance sales for general retail, such as sales via the Internet, to adults by using adequate technical means").

[221] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 16(1) 1st and 2nd sentences and art. 16(4); *Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 45 (on the analysis of subsidiarity as regards internet distance sales).

[222] *See Commission Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, *supra* note 27, at art. 16; *Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 56–57, 104–07, 119, part 5 at 8 (on policy options and impacts) part 4 at 7. On public health derogations to the freedom to provide information society services between Member States: Directive 2000/31, art. 3(2) and 3(4)(a)(i) point 2, 2000 O.J. (L 178) 1 (EC) on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.

at the European Parliament partial vote, rather than a possibility to prohibit such sales.[223] The rationale was the protection of minors and difficulty of age verification, in particular for internet sales.[224] The provision was amended again by the European Parliament following the trialogue to the possibility for Member States to ban cross-border distance sales.[225] Article 18 is made applicable to electronic cigarettes and refill containers by Article 20(6) of the Directive.

In *Poland v. EP and Council*, the prohibition of cross-border distance sales was suggested as an alternative measure to the prohibition of flavors, yet discarded by the court alongside other less restrictive measures in its proportionality assessment, noting the possibility for Member States to do so under Article 18 of the Directive, which in fact reflects the *status quo*.[226] The validity of Article 18 and adequacy of Article 114 TFEU as its legal basis were examined in *Philip Morris*. As with Article 24(2) and (3), the Court declared the question admissible,[227] whereas the Advocate General did not, distinguishing the question referred from the points at issue in *Pillbox*.[228] It was argued in *Philip Morris* that the possibility for Member States to prohibit cross-border distance sales would result in divergences in national legislation, and thus impede rather than facilitate trade. The Court held that

[223] *See* Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013, at 4, Amendments 13 and 65-66; Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendments 7, 13, 45; Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 14, 23 and 51. The Committees refer to the prohibition of cross-border distance sales alongside that of distribution of free or discounted tobacco products through distance sales and "in public places for promotional purposes", as well as bartering/ swapping. *See also* Directive 2003/33, *supra* note 4, at art. 5(2) (prohibiting free distribution in the context of event sponsorship), and the general ban of free distribution promoting tobacco products in article 3(4) of the annulled Directive 98/43 1998 O.J. (L 213) 9 (EC)); Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, Draft EP Legislative Resolution/ P7_TA(2013)0398 (EP partial vote), Amendments 29, 45, 68 and 69 (art. 16a).

[224] *See* Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, Amendments 29 and 79; Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013 at 4, Amendments 13, and 65–66; Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, at 3-4; Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013 Amendment 7; *Council of the European Union General Approach*, *supra* note 20*,* annex, at recital 30; Directive 2014/40, *supra* note 6, at recital 33; *Commission Staff Working Document Impact Assessment*, *supra* note 22, at part 1 at 36–37, 42, 56, 105–07, part 4 at 8 (on different national provisions on internet sales); Guidelines for Implementation of Article 13, WHO FCTC, Decision FCTC/COP3(12) paras. 18–21 (Nov. 2008).

[225] Council, Press Release 17905/13, at 2; Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932, at art. 16(1).

[226] *See Poland*, Case C-358/14, *supra* note *6,* at para. 94.

[227] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 37–41.

[228] *See Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 40–43, nonetheless addressed by the Advocate General; *Pillbox 38*, Case C-477/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 134–48 (on Directive 2014/40, *supra* note 6, at art. 18 and 20(6).

Article 18 sought to prevent circumvention of the Directive's free movement provisions, the preamble referring to the fact that cross-border distance sales facilitate access of non-compliant tobacco products.[229] The case law provides, in this respect, that an Article 114 TFEU measure "may incorporate [a provision not aimed directly at improving the conditions for the functioning of the internal market] so long as its purpose is to ensure that certain prohibitions concerning the internal market and imposed in pursuit of that object are not circumvented."[230] This was held to be the case in *British American Tobacco* in relation to the application of tar, nicotine, and carbon monoxide yield requirements to cigarettes exported to non-member countries in order to prevent unlawful reimports or deflections of trade,[231] but not in relation to "static" advertising in the first *Tobacco Advertising* case.[232] Along with this internal market objective of preventing circumvention of the Directive's provisions, the judgment in *Philip Morris* once again referred to the required high level of health protection particularly for young people, the recital stressing also the "increased risk" of access for these potential consumers.[233]

The Court considered the absence of EU harmonization rules on distance sales, with national differences, existing prior to the adoption of Directive 2014/40, rather than resulting from its provision—the Advocate General having noted that Article 18(1) was merely a "declaratory clause confirming the *status quo*." The impact assessment had identified such national divergences, with some Member States already prohibiting such sales, while others subjected them to authorization.[234] Regarding common rules on distance sales for Member States not having banned such sales,[235] the Court relied again on the legislature's discretion under Article 114 TFEU, the possibility of partial and gradual

[229] *See* Directive 2014/40, *supra* note 6, at recital 33. The Advocate General noted that prohibition of cross-border distance sales was "the price for the circulation in the European internal market of [compliant] tobacco products"). *See also Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 44–45, 56, 104–07, part 3 at 11–12.

[230] *See* Case C-491/01, *supra* note 4, at para. 82; *Germany*, Case C-376/98, *supra* note 4, at para. 100 ("provisions which do not contribute to the elimination of obstacles to exercise of the fundamental freedoms"); Case C-180/96, *United Kingdom v. Commission of the European Communities*,1998 E.C.R. I-2265, para. 109 (on the common agricultural policy).

[231] *See* Case C-491/01, *supra* note 4, at paras. 81–91; *United Kingdom*, Case C-180/96, *supra* note 230, at para. 109 (on animals and meat in the context of the BSE crisis, and risks as to reimports of meat and deflections of trade).

[232] *See Germany*, Case C-376/98, *supra* note 4, at paras. 99–100.

[233] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 127-131, Opinion of Advocate General Kokott at paras. 133–34 and 136–39.

[234] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 4 at 8 (prohibition: France and Lithuania; authorization: Austria, Bulgaria, Hungary, Latvia, and Spain).

[235] *See* Directive 2014/40, *supra* note 6, at art. 18(1)-(5).

harmonization of some but not other aspects of distance sales,[236] and concluded in the validity of the provision.[237]

II. Proportionality of the E-Cigarettes Cross-Border Distance Sales Provision

In *Pillbox*, the proportionality and legal certainty of Article 20(6) of the Directive—providing for the application of Article 18 on cross-border distance sales to electronic cigarettes and refill containers—was examined. Concerning the argument based on lack of reasoning justifying the extension of provisions on cross-border distance sales to electronic cigarettes, the preamble referring only to tobacco products in this respect,[238] the Court noted that its reasoning applied to electronic cigarettes, and that, consistently with its case-law,[239] statements of reasons could focus on the general situation and general objectives.[240] As for tobacco products, it was held that Article 20(6) ensured that the Directive's rules on conformity as to electronic cigarettes were not circumvented, preventing facilitated access of non-complying products, and limited the risk of young people having access to such products—again with reference to the high level of health protection—concluding in the appropriateness of the provision. Regarding its necessity, the Court considered the absence of prohibition at Union level, the discretion left to Member States in imposing a prohibition or restrictions on cross-border distance sales, in light of scientific and market developments, and the inadequacy of age limits as a less onerous measure for electronic cigarettes, considering the facility of their circumvention in the context of such sales.[241]

F. Retaining the Prohibition of Tobacco for Oral Use: Health and Competence Issues

I. Reproduction of the Prohibition of Oral Tobacco and Pending Preliminary Ruling Reference

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[236] *See* Case C-37/83, *Rewe-Zentral AG v. Direktor der Landwirtschaftskammer Rheinland*, 1984 E.C.R. 1229, para. 20; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 63, 134 ("harmonization only in stages" and "gradual abolition of unilateral measures").

[237] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 132–36, Opinion of Advocate General Kokott at para. 135.

[238] *See* Directive 2014/40, *supra* note 6, at recital 33.

[239] *See Inuit Tapiriit Kanatami*, Case C-398/13P, *supra* note 5, at para. 29; Case C-5/67, *Beus GmbH & Co v. Hauptzollamt München*, 1968 E.C.R. 125, para. 95, and additional subsequent case-law on the duty to state reasons.

[240] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 129–30, Opinion of Advocate General Kokott at paras. 135–39.

[241] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 120–28, Opinion of Advocate General Kokott at paras. 140–47.

The prohibition of tobacco for oral use was established by Directive 92/41, which inserted Article 8a into Directive 89/622. [242] This ban was reproduced in Article 8 of Directive 2001/37, and now in Article 17 of Directive 2014/40, repealing and replacing the previous Tobacco Products Directive, both provisions referring to the Swedish exemption.[243] The European Parliament voted against amendments to lift the snus prohibition at the partial vote. However, the European Parliament amended the measure to exempt snus, allowed only in Sweden, from the article on ingredients.[244] The INTA Committee would have removed the prohibition of tobacco for oral use.[245] The JURI and ITRE Committees, although upholding the prohibition, would have let Member States allow "historically traditional tobacco products for oral use."[246] The AGRI Committee would have provided for national regulation of snus, rather than its prohibition,[247] and the IMCO Committee would have imposed "maximum limits for toxic or carcinogenic substances" to all smokeless tobacco products rather than prohibiting oral tobacco. The latter Committee noted that, instead of prohibiting "the least hazardous smokeless tobacco products," this would have provided "product quality standards for all smokeless tobacco" and "remov[ed] the most

[242] *See* Council Directive 92/41, art. 1(5), 1992 O.J. (L 158) 30 (EEC), amending Council Directive 89/622 1989 O.J. (L 359) 1 (EEC) on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products.

[243] *See* Directive 2001/37 2001 O.J. (L 194) 26 (EC); Article 151 of the Act of Accession of Austria, Finland and, Sweden O.J. 1994 C 241/3.

[244] *See* Directive 2014/40, *supra* note 6, at art. 7(15) and (12); Amendments adopted by the European Parliament, P7_TA(2013)0398, *supra* note 27 (EP Partial Vote), Amendments 17, 28 (recital 29a–"there is no cross-border interest in regulating the content of snus . . . responsibility for regulating the content of snus lies with the Member State where snus is permitted") 50, 87 and 95 (Article 6(10c) and 6(10)—initially substituting smokeless tobacco with waterpipe tobacco, consumed by young people); Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013, Amendments 17, 28, 50 and at 78; Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 26 (art. 18(1e)); Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 39; Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendment 6 (distinguishing oral from nasal and chewing smokeless tobacco, confined to few European regions and consumed by older people); Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendment 3 (excluding nasal tobacco, consumed by older people); Council Doc 11483/13, *General Approach*, annex, recital 18; Amendments by the European Parliament to the Commission Proposal, AM\P7_AMA(2013)0276(190-190) – (EP) PE515.932, art. 6(12a) and (10).

[245] *See* Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013 Amendment 44.

[246] *See* Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendments 10 and 62 ("This ban should, however, not affect traditional products for oral use, which may be allowed by individual Member States on cultural or historical grounds."); Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendment 11.

[247] *See* Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013 Amendment 64.

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hazardous from the market."[248] Regarding labelling of smokeless tobacco—including Swedish tobacco for oral use[249]—Article 12 of the new Tobacco Products Directive provides for the same percentage of surfaces for warnings as Article 5 of the previous Tobacco Products Directive, although no longer a minimum,[250] but on the two largest surfaces rather than the most visible surface only,[251] as well as a change in formulation of the warning from a possibility to an assertion.[252]

Swedish Match has again recently challenged the snus ban, now in regulation 17 of the Tobacco and Related Products Regulations 2016,[253] incorporating Article 17 of Directive 2014/40. The Administrative Court of the High Court QBD made another preliminary ruling reference to the Court of Justice in Case C-151/17 *Swedish Match* concerning the validity of Articles 1(c) and 17 of the new Tobacco Products Directive, with questions on principles of non-discrimination, proportionality, subsidiarity and Article 5(3) TEU, Articles 34 and 35 TFEU, the Article 296(2) TFEU duty to state reasons, and Articles 1, 7, and 35 of the Charter. The issue was whether the prohibition was still valid "in the light of developments in scientific knowledge and the regulatory framework applicable to tobacco and related products since [the previous rulings]."[254] The New Nicotine Alliance intervened alongside Swedish Match to challenge the validity of the prohibition of oral tobacco. This reference could arguably result in a different outcome than previous cases, considering public

[248] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 49, 50 (art. 15(1a)-1b)) and 72 (annex IIa - NNN, NNK, B(a)P limits, based on WHO Technical Report No. 955 toxicity recommendations, subject to adaptation by delegated acts). On the diversity of smokeless tobacco in terms of TSNA: *see* SCENIHR, see *Health Effects of Smokeless Tobacco Products* (2008), at 119; WHO Study Group on Tobacco Product Regulation, *Report on the Scientific Basis of Tobacco Product Regulation* (2009), at 26–29, 32–34, 36.

[249] *See* Directive 2014/40, *supra* note 6, at art. 2(5) (defining "smokeless tobacco product" as a "tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use"); Directive 2001/37, *supra* note 4, art. 5(4) subpara. 1.

[250] *See* Directive 2001/37, *supra* note 4, art. 5(5) subpara. 1 ("not less than"); Directive 2014/40, *supra* note 6, at art. 12(2) subpara. 2(b) (30% of the surfaces, increased to 32% or 35% for Member States with two or three more languages).

[251] *See* Directive 2001/37, *supra* note 4, art. 5(4) subpara. 2; Directive 2014/40, *supra* note 6, at art. 12(2) subpara. 2(a).

[252] *See* Directive 2001/37, *supra* note 4, art. 5(4) subpara. 1 ("This tobacco product can damage your health and is addictive."); Directive 2014/40, *supra* note 6, at art. 12(1) ("This tobacco product damages your health and is addictive", subject to adaptation by delegated acts under article 12(3)).

[253] The Tobacco and Related Products Regulations 2016, c. 507 (Eng.), http://www.legislation.gov.uk/uksi/2016/507/contents/made.

[254] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 3 and 17–19. Articles 1 and 7 CFREU concern respectively human dignity and respect for private and family life, article 35 CFREU constitutes the health care mainstreaming provision.

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consultation results,[255] alleged limits of impact assessment justifications,[256] subsidiarity, proportionality and non-discrimination, in light of provisions on novel tobacco products and e-cigarettes.[257] However, the Opinion delivered by Advocate General Saugmandsgaard Øe on April 12, 2018—which focused on compliance with the proportionality and non-discrimination principles—concluded in the validity of provisions on oral tobacco.[258] In addition to compliance with EU law, questions of conformity with the GATT and TBT Agreements have also been raised by the INTA Committee.[259]

II. The Article 114 TFEU Legal Basis and Prohibition of a Product

The prohibition in Article 8 of Directive 2001/37 was at issue in Cases C-434/02 and C-210/03 *Arnold André/Swedish Match*. In these cases, the Court held that the then Article 95 EC—now Article 114 TFEU—constituted an appropriate legal basis for the provision,[260] again relying on the two mainstreaming provisions, the "decisive factor" formula,[261] and types of appropriate approximation measures, including "provisionally or definitively prohibiting the marketing of a product or products."[262] It noted that two Member States already had prohibitions in force, and a third had adopted such provisions which were not yet in force, at the time of adoption of Directive 92/41.[263] Lifting the prohibition would

[255] *See Commission Report on the Public Consultation on the Possible Revision of the Tobacco Products Directive*, at 11–13, 2001/37 (July 2011).

[256] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 22–24, 50–52, 61–76, 117, part 5 at 3 (on the various options and their impacts).

[257] *See* Directive 2014/40, *supra* note 6, at art. 19–20; C. Bates, *A Strong Case to Overturn the EU Snus Ban*, CLIVEBATES.COM (July 4, 2016).

[258] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 4–5, 89.

[259] *See* Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendment 44 (art. 2.1, 2.2, TBT Agreement, art. I and III GATT).

[260] On the inappropriateness of the then Article 133 EC—now art. 207 TFEU—as a secondary legal basis yet validity of the measure, as in *British American Tobacco*: *see* Swedish Match, Case C-210/03, *supra* note 4, at paras. 43–44.

[261] *See Arnold André*, Case C-434/02, *supra* note 4, at paras. 32–33; *Swedish Match*, Case C-210/03, *supra* note 4, at paras. 31–32.

[262] *See Arnold André*, Case C-434/02, *supra* note 4, at para. 35; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 34; *Germany*, Case C-359/92, *supra* note 51, at paras. 4, 33; *Germany*, Case C-380/03, *supra* note 4, at para. 43; *Alliance for Natural Health*, Joined Cases C-154 and 155/04, *supra* note 5, at para. 33.

[263] The Court also noted the likelihood of future obstacles considering "the public's growing awareness of the dangers to health of the consumption of tobacco products". *See Arnold André*, Case C-434/02, *supra* note 4, at para. 38, 40; *Swedish Match*, Case C-210/03, *supra* note 4, at paras. 37, 39.

have risked "reintroduc[ing that] fragmentation of the market."[264] Similar national differences with regard to nasal and chewing tobacco[265]—products less attractive to young people—did not, however, lead the Union legislature to prohibit these types of smokeless tobacco, which testifies to the purely public health purpose of the provision on snus.

As with some prohibitions of components of a product, facilitating free movement of compliant products, bans of a "free standing product" at Union level may also in some circumstances facilitate free movement of compliant products, complying for instance with certain safety requirements.[266] However, the ban of tobacco for oral use, "prohibition outright of a product," rather than facilitating free movement, "prohibited the subject-matter of the trade in question."[267] Such a prohibition, as noted by the claimants and acknowledged by Advocate General Geelhoed in *Arnold André/ Swedish Match*, "exclud[ing the product] from the market . . . can hardly be regarded as the removal of barriers to the marketing of these products, since it makes the existence of a market impossible . . . it prevents a lawful market from coming into being and, by so doing, establishes a barrier to trade."[268]

III. Persisting Health Issues—Proportionality, Broad Discretion, and Precautionary Principle

Beside the questionable nature of its internal market objective, the prohibition may also be considered problematic in terms of the requirement to take as a base a high level of health protection. While, on one hand, banning a tobacco product that presents a number of

[264] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 62; *Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at para. 23.

[265] Some Member States have banned chewing and nasal tobacco: *see Commission Staff Working Document Impact Assessment*, *supra* note 22, part 4 at 2. Directive 2014/40, *supra* note 6, at art. 2(8) (defines oral tobacco as "all tobacco products for oral use, except those intended to be inhaled or chewed").

[266] Wyatt, *supra* note 53, at 7 (on Council Directive 88/378 1988 O.J. (L 187) 1 (EC) concerning the safety of toys or Council Directive 92/59 1992 O.J. (L 228) (24) (EC) on general product safety, based on Article 100a (now art. 114 TFEU). However, see Advocate General Geelhoed on other smokeless tobacco products.

[267] Wyatt, *supra* note 53, at 25–26. *Germany*, Case C-376/98, *supra* note 4, at para. 102 (on diversification products).

[268] *See Arnold André*, Case C-434/02, *supra* note 4; Swedish Match, Case C-210/03, *supra* note 4, at para. 78. *See however* paragraph 79 on the improvement of internal market conditions not being required "in respect of every individual product" and the argument as to "diminish[ed] enforcement costs and . . . even diminish[ed] . . . of the enforcement of regulations on related products . . . if snus is not on the market . . . the effort to control the marketing of other smokeless tobacco products can be reduced." The Union legislature and the Court provided no such justification, yet even such an interpretation of the prohibition "as part of a wider regime dedicated to freeing trade in other kinds of products which were regarded as less harmful," rather than as a "free standing ban," is problematic as "it invites strategic drafting . . . it encourages the drafting of legislative measures that are broad not targeted." *See* Weatherill, *supra* note 102, at 836–37.

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health risks, such as esophageal or pancreatic cancer and myocardial infarction,[269] it prohibits, on the other hand, a potentially lower risk alternative to tobacco for smoking, without tar and carbon monoxide, less nitrosamines and "considerably lower carcinogenic potential,"[270] no risk of lung cancer or chronic obstructive pulmonary disease, and with an impact on the number of smokers, being used both as a cessation tool and as an alternative to taking up smoking, and on lung cancer mortality.[271]

The Court in *Arnold André/Swedish Match* had considered the measure proportionate and compliant with the requirement to take into account "any new development based on scientific facts" in the mainstreaming provision,[272] relying again on the EU legislature's broad discretion, where "political, economic and social choices" and "complex assessments" are involved, and unlawfulness only of manifestly inappropriate measures.[273] This classic formula was reiterated by AG Saugmandsgaard Øe in Case C-151/17, who noted that this discretion was unaffected by the right to health in Article 35 CFREU, "requir[ing] complex assessments in the interests of not only smokers, but also the population as a whole," and the importance of this broad discretion in the application of the precautionary principle.[274] He also relied on the twofold internal market/health objective and health mainstreaming, with reference to young people—in accordance with recitals of Directives 92/41 and 2014/40.[275]

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[269] Britton & Bogdanovica, *supra* note 145, at 11; Luo et al., *Oral Use of Swedish Moist Snuff (Snus) and Risk for Cancer of the Mouth, Lung, and Pancreas,* 369 LANCET 2015 (2007); Hansson et al., *Use of Snus and Acute Myocardial Infarction*, 27 EUR. J. EPIDEMIOLOGY 771 (2012)*; Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 64–65 (more generally on smokeless tobacco products).

[270] Coggins et al., *The In Vitro Toxicology of Swedish Snus*, 42 CRITICAL REV. TOXICOLOGY 304 (2012); Osterdahl et al. *Decreased Levels of Tobacco-Specific N-Nitrosamines in Moist Snuff*, 52 J. AGRI. & FOOD CHEMISTRY 5085 (2004); Colilla, *An Epidemiologic Review of Smokeless Tobacco Health Effects and Harm Reduction Potential*, 56 REG. TOXICOLOGY & PHARMACOLOGY 197 (2010); Lee, *Summary of the Epidemiological Evidence Relating Snus to Health*, 59 REG. TOXICOLOGY & PHARMACOLOGY 197 (2011).

[271] Britton and Bogdanovica, *supra* note 145, at 11; Foulds et al., *Effect of Smokeless Tobacco (Snus) on Smoking and Public Health in Sweden*, 12 TOB. CONTROL 349 (2003); Stegmayr et al., *The Decline of Smoking in Northern Sweden*, 33 SCANDINAVIAN J. PUB. HEALTH 321 (2005); Commission, Special Eurobarometer 385, *Attitudes of Europeans Towards Tobacco* (2012); Rodu and Cole, *Lung Cancer Mortality: Comparing Sweden with Other Countries in the European Union*, 37 SCANDINAVIAN J. PUB. HEALTH 481 (2009).

[272] *See Arnold André*, Case C-434/02, *supra* note 4, at paras. 44 and 52; *Swedish Match*, Case C-210/03, *supra* note 4, at paras. 46, 54.

[273] *See Arnold André*, Case C-434/02, *supra* note 4, at para. 46; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 48; Case C-491/01, *supra* note 4, at para. 123; *Germany*, Case C-380/03, *supra* note 4, at para. 145.

[274] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 28-30, 40-42, 47-48, 50 and 57.

[275] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 22, 58, 60; Directive 2014/40, *supra* note 6, at recitals 8, 21; Council Directive 92/41, at recitals 3, 13, 15; *Arnold André*, Case C-434/02, *supra* note 4, at para. 47; *Swedish Match*, Case C-210/03, *supra* note 4, at para. 49.

The aim of the Union legislature was to prevent access to an addictive and harmful product, as is clear from recital 32 of Directive 2014/40. The *Swedish Match* opinion pointed out the EU legislature's emphasis on oral tobacco's "intrinsic harmfulness," its "initiation effect," especially for young people, snus amounting to a "new form of nicotine addiction," its "gateway effect" to smoking tobacco—risks of preventing smokers' cessation efforts potentially leading to dual use, with the possibility of using snus in smoke-free environments—combined to the absence of a proven "substitution effect" as cessation aid. Swedish Match and the NNA had considered the provision disproportionate, relying on the substitution effect and lower "relative harm," the absence of evidence of a gateway effect, and difference in treatment with other products. The applicant argued that the Court's analysis in the previous *Swedish Match* ruling was no longer applicable considering evolutions in scientific data and market characteristics since that judgment. Nevertheless, the Advocate General in Case C-151/17 considered that scientific and legal developments since *Arnold André/Swedish Match* did not put into question the suitability of oral tobacco provisions to achieve the "twofold" internal market and public health objective.[276]

In *Arnold André/Swedish Match*, the Court had noted persisting doubts as to mouth cancer and the role of snus as a substitute for cigarettes, the presence of nicotine, of a toxic nature, causing addiction, and absence of a proven less harmful character of oral tobacco, contrasting with the presence of proven health risks.[277] In his evaluation of suitability in the Case C-151/17 *Swedish Match* opinion—concerning first scientific developments—the Advocate General, in line with the impact assessment, noted persisting uncertainty as to both some harmful effects of snus and the impact of its availability on consumption patterns. Case law on the Article 191(2) TFEU precautionary principle excluding "purely hypothetical considerations," precautionary measures having to be based on risk assessments identifying an "impossib[ility] to determine with certainty the existence or extent of the alleged risk," the Opinion stressed the need to take into consideration the Union legislature's broad discretion in the scientific risk evaluation and adoption of precautionary measures setting the appropriate level of protection, based on its appraisal of the acceptable level of risk.[278]

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[276] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 24–7, 43, 16, 34.

[277] *See Arnold André*, Case C-434/02, *supra* note 4, at paras. 49-51; *Swedish Match*, Case C-210/03, *supra* note 4, at paras. 51–53; *Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 32–33.

[278] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 35–43.

Regarding the potentially harmful and addictive nature of the product, while the impact assessment identified uncertainties as to increased risks of oral, esophageal, pancreatic cancers, and myocardial infarction, Swedish Match and the NNA emphasized lower risks involved in snus consumption, conceded in the impact assessment, and referred to alternative studies. The Advocate General considered, however, that these were insufficient to question the conclusion of the harmful nature of oral tobacco, relying again on the Union legislature's discretion, in its evaluation of the persistence of these uncertainties, its appraisal of the importance and reliability of studies, its assessment of risks involved, the need to take action, and to take into consideration all rather than individual risks.[279] Concerning consumption patterns and the impact of lifting the prohibition, the question was the respective importance of potential initiation, gateway effects, coupled with a risk of dual use, and substitution effect allowing smoking cessation. For the EU legislature, the risk of the former outweighed the latter, while Swedish Match and the NNA argued for cessation virtues of snus and its absence of gateway effect. Risks on consumption patterns having been examined, the Advocate General considered that remaining scientific uncertainties did not preclude adoption of precautionary measures by the Union legislature, with analogy to e-cigarettes and *Pillbox*.[280] As regards the measure itself, arguments in favor of maintaining the prohibition could once again be found in the twofold objective, the four mainstreaming provisions requiring a high level of health protection,[281] the precautionary principle, and the EU legislature's discretion for a "political, economic and social choice" including evaluation of the tolerated level of risk by balancing concomitant health risks. The legislature was thus entitled to consider that risks of negative health effects outweighed a possible substitution/cessation effect, choosing to prevent a "new source of nicotine addiction, particularly among young people" and a potential gateway effect.[282]

Secondly—in terms of legal developments and non-discrimination—the issue was whether evolutions since *Arnold André* and the previous *Swedish Match* case, and the difference in

[279] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 43–50, 57.

[280] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 50–55 and 60; *Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 51–57.

[281] The Advocate General noted the objective of the new TPD to ensure the high level of health protection "for the population as a whole [rather than] in relation to a single category of consumers", as stressed in Philip Morris and Poland v EP and Council: *see Philip Morris*, Case C-547/14, *supra* note 6, at para. 176; *Poland,* Case C-358/14, *supra* note *6,* at para. 86.

[282] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 58–63. The Advocate General also refuted *Swedish Match's* argument as to a "zero risk" requirement that snus be harmless for lifting its prohibition, resulting from a misinterpretation of the case-law—absence of risk evaluation and of "threshold of certainty" as to their probability and gravity—and of the rationale behind the Union legislature's decision to ban the product—presence of "demonstrated/ duly assessed" risks of a harmful character rather than proven harmlessness): paras. 64–68.

treatment with other tobacco and related products, rendered the provisions inappropriate to achieve the measure's objective "in a consistent and systematic way." In relation to other smokeless tobacco products, the Advocate General surprisingly stressed the presence of national prohibitions of snus in some Member States at the time of adoption of the original prohibition. He did not, on the other hand, consider differences in national legislation on chewing and nasal tobacco when the new Tobacco Products Directive was adopted. Some Member States had already banned these products,[283] which did not, however, lead to their prohibition, as noted above. The difference in treatment was considered further justified in light of the novelty of snus at the time and its popularity among young people. Moreover, nasal and chewing tobacco constitute "only niche markets [with] limited potential for expansion on account of, *inter alia*, their costly, and in part artisanal, production methods." The concern once again appears to be public health, rather than the internal market, excluding regulation of less popular products with an older consumer base. Regarding tobacco for smoking—as for other smokeless tobacco products—the Advocate General referred to the novelty of oral tobacco at the time of adoption of the prohibition, the "new source of addiction" and appeal for young people argument, still relevant at the time of the new Tobacco Products Directive's adoption, and risk of a black market emerging if a similar prohibition were applicable to smoking tobacco, considering the number of consumers. Snus was distinguishable from novel tobacco products—for which Directive 2014/40 envisages a system of notification with studies on health and consumption effects, otherwise unknown—whereas those of oral tobacco were arguably "sufficiently identified and substantiated scientifically," given its long-term availability on the Swedish market and the presence of studies on its effects. Difference in treatment with e-cigarettes was also considered justified, based on their lack of tobacco and combustion, their novelty and persisting uncertainty of risks involved—elements identified in *Pillbox*.[284]

With regard to the necessity of maintaining the prohibition, again in light of the Union legislature's broad discretion, the Opinion in Case C-151/17, referring to rulings in *Arnold André*/*Swedish Match*, considered that alternative measures, such as technical standards, labelling, or conditions of sale including to minors were still inadequate, not as effective as preventing access to the market altogether. This was supported by arguments as to the "difficult[y] to reverse" public health effects, commercial potential with smoke-free environments, and the "ambiguous message" of harmlessness that would result from removing a prohibition in place for a long time, with a potential impact on young people.[285]

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[283] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 4 at 2. Five Member States have banned chewing tobacco: Greece, Ireland, Latvia, Lithuania, and Poland; two Member States have banned nasal tobacco: Latvia and Lithuania.

[284] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 70–77.

[285] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 80–83.

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Finally, concerning proportionality *stricto sensu*—once again with reference to the twofold objective and the Union legislature's broad discretion—Advocate General Saugmandsgaard Øe dismissed economic operator's negatively affected interests. These arguably "must take a back seat in matters concerning the general interest of public health," considering case law on the possibility for a measure to have "even substantial negative economic consequences for certain economic operators,"[286] the "objective of health protection tak[ing] precedence over economic interests,"[287] and even Advocate General Kokott's point as to "protection of human health ha[ving] considerably greater importance in the value system under EU law than such essentially economic interests,"[288] which, despite mainstreaming provisions, is problematic for an internal market measure.[289]

[286] *See Vodafone*, Case C-58/08, *supra* note 5, at paras. 53 and 69.

[287] *See Philip Morris*, Case C-547/14, *supra* note 6, at para. 156, Opinion of Advocate General Kokott at paras. 183, 209; *Poland*, Case C-358/14, *supra* note 6, Opinion of Advocate General Kokott, at para. 134.

[288] *See Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 179, 193, 204; *Poland*, Case C-358/14, *supra* note *6,* Opinion of Advocate General Kokott at para. 130; *Pillbox 38*, Case C-477/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 130, 190.

[289] *See Swedish Match AB*, Case C-151/17, *supra* note 16, Opinion of Advocate General Saugmandsgaard Øe at paras. 84–88.

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G. Article 114 TFEU and the Possibility to Prohibit Certain Categories of Tobacco or Related Products

Article 24(3) of Directive 2014/40 provides the possibility for Member States to prohibit a category of tobacco products—again justified by the protection of public health[290]—in presence of a "specific situation in [the] Member State," reminding the formulations in Article 114(5) and (8) TFEU.[291] Provisions adopted under Article 24(3) of the Directive should not constitute an "arbitrary discrimination or a disguised restriction on trade," as under Articles 36 and 114(6) TFEU, must be necessary and proportionate,[292] be notified to and approved by the Commission under a procedure similar to that in Article 114(6).[293] Unlike the EU-wide prohibition of snus—applicable to all but one Member State—approximating national legislations despite its questionable internal market aim, Article 24(3) of the Directive envisages the possibility for individual Member States to prohibit categories of products.

In *Philip Morris*, the Court examined the adequacy of Article 114 TFEU as legal basis for and validity of Article 24(3) of the Directive. Parties in the main proceedings claimed that the provision created—rather than removed—obstacles to free movement.[294] As with paragraph 2, the Advocate General considered the question inadmissible as a result of the potentially hypothetical nature of the question, in the absence of an obligation to adopt such national prohibitions and of indication as to the possible adoption of such measures in the Member State,[295] whereas the Court held that the silence of the order for reference as to the possibility of such national provisions—which could moreover depend on the preliminary ruling reference and outcome of the national proceedings—did not imply a purely hypothetical question, concluding in the admissibility of the question referred.[296]

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[290] *See also* the possibility under Article 24(2) to maintain/adopt further packaging requirements on grounds of public health, other exception to the Article 24(1) free movement clause. Article 24(2) and (3) require taking into account the high level of protection of human health).

[291] *See* TFEU art. 114(5) ("problem specific to that Member State"—environment or working environment); TFEU art. 114(8) ("specific problem on public health").

[292] Implicit in art. 114(6) TFEU subpara. 1: R. Verheyen, "Article 95 EC Treaty in Practice: The European Commission Decisions on Creosote, Sulphite, Nitrates and Nitrites", 9 RECIEL 71, 75 (2000).

[293] *See* TFEU art. 114(6), at subparas. 1–2.

[294] *See Philip Morris*, Case C-547/14, *supra* note 6, at question 1(b), Opinion of Advocate General Kokott at para. 122.

[295] *See Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at paras. 39, 41–43. The question was nonetheless examined by the Advocate General.

[296] *See Philip Morris*, Case C-547/14, *supra* note 6, at paras. 37–41.

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The Advocate General rejected the Union legislature's argument based on lack of EU competence as a result of the Article 168(5) TFEU express exclusion of harmonization, and the retention of Member States competence in defining their health policy under Article 168(7), stressing the internal market rather than public health nature of the measure.[297] The difficulty of reconciling the artificial exclusion of harmonization with the high level of health protection in the mainstreaming provisions prevents express reliance on this provision. The Court conceded that Article 24(3) could hinder free movement of such products complying with the Directive, yet noted that the measure did not aim to interfere with national policies on the lawfulness of tobacco products,[298] and did not harmonize smoke-free environment rules,[299] with national provisions that could range from prohibiting smoking in certain places to prohibiting categories of products. Article 24(3) applied, therefore, to an aspect not harmonized by the Directive, and the Article 114(4)-(10) TFEU derogation procedure was thus inapplicable to this provision.[300] The Court noted that an Article 114 measure could include provisions on "issues which are not the subject of the harmonizing measures adopted", as Article 24(3)—which specified the scope of the Directive and its paragraph 1 free movement clause—moreover prevented "arbitrary discrimination or a disguised restriction on trade," consistently with the internal market objective of this legal basis. The Advocate General, on the other hand, conceded that Article 114 TFEU should not in principle constitute a legal basis for provisions allowing Member States to derogate unilaterally from harmonization, including national measures to be adopted in order to adapt to "possible future market developments."[301] These were subject to Article 114(8), which envisages notification and consideration of further harmonization by the Commission in presence of a "specific problem on public health in a field which has been the subject of prior harmonization measures," and, under Article 114(10) TFEU on safeguard clauses, such national derogatory measures should be provisional.[302] She rebutted the argument that Article 24(3) could be used to ban a product already subject to harmonization—such as cigarettes—thus adopting a strict interpretation

[297]The Advocate General referred to the prohibition of flavors.

[298] The Court thus alluded to TFEU art. 168(7).

[299] *See* Directive 2014/40, *supra* note 6, at recital 48.

[300] *See* M. Dougan, *Minimum Harmonization and the Internal Market*, 37 COMMON MKT. L. REV. 853 (2000).

[301] Justification given in the preamble for the contested provision: *see* Directive 2014/40, *supra* note 6, at recital 54.

[302] *See* TFEU art. 114(8) (providing that "when a Member State raises a specific problem on public health in a field which has been the subject of prior harmonization measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council"); TFEU art. 114(10) (stipulating that "harmonization measures . . . shall, in appropriate cases, include a safeguard clause authorizing the Member States to take, for one or more of the non-economic reasons referred to in article 36, provisional measures subject to a Union control procedure").

of that provision, according to which national prohibitions could be adopted only for products not subject to harmonization, justifying once again reliance on Article 114 TFEU as legal basis for this provision.[303] The Advocate General noted the conditions for reliance on Article 24(3)—a public health ground, taking into account the high level of health protection, the specific national situation, and a Commission authorization procedure modelled on the Article 114(5)-(6) TFEU derogation procedure.[304]

Finally, as to the alleged inconsistency between Article 24(3) and the prohibition of flavors in Article 7 of the Directive, it was argued that the latter provision was unnecessary in the presence of a possibility for Member States to individually prohibit certain product categories, and that it was intended to abolish disparities in national legislation while Article 24(3) encouraged such national divergences. The Court considered the provisions complementary, noting the application of the Article 24(1) free movement clause to products complying with provisions of the Directive, including Article 7, provided the product category was not prohibited in that Member State under Article 24(3). The Advocate General opposed the specific national situation required by Article 24(3) to the cross-border nature of Article 7, and referred again to the Union legislature's broad discretion under Article 114 TFEU, including the possibility to rely on gradual harmonization.[305]

H. Concluding Remarks

As for other provisions of the new Tobacco Products Directive—and as in previous rulings on tobacco control measures—the Court relied once again on its traditional Article 114 TFEU artifices to justify provisions relating to alternative tobacco and related products.[306] References to mainstreaming provisions were made by the Court to uphold the Article 114 legal basis of the prohibition of flavors,[307] its proportionality,[308] as well as the proportionality of provisions on electronic cigarettes.[309] The classical "decisive factor"

[303] As with Directive 2014/40, *supra* note 6, at art. 24(2) (on packaging standardization).

[304] *See Philip Morris*, Case C-547/14 at paras. 85–92; Opinion of Advocate General Kokott at paras. 121–29.

[305] *See Philip Morris*, Case C-547/14 at paras. 93–94; Opinion of Advocate General Kokott at paras. 130–31.

[306] On use of the case-law formulations by the Union legislature to draft TFEU art. 114 measures, see Weatherill, *supra* note 102.

[307] *See Poland*, Case C-358/14, *supra* note *6,* at para. 35; *Philip Morris*, Case C-547/14 at para. 61; TFEU art. 168(1) and 114(3).

[308] *See Poland,* Case C-358/14, *supra* note *6,* at para. 102–TFEU art. 114(3); *Philip Morris*, Case C-547/14 at para. 190–Charter of Fundamental Rights, art. 35, Dec. 7, 2000, 2016 O.J. (C 202) 389; TFEU art. 9, 114(3) and 168(1).

[309] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 61 and 116–Charter of Fundamental Rights, art. 35, Dec. 7, 2000, 2016 O.J. (C 202) 389; TFEU art. 9, 114(3) and 168(1).

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formula, directly linked to the mainstreaming provisions, was used by the Court in order to justify the legal basis of the provisions on flavors.[310] On the other hand, with regard to the subsidiarity of provisions on flavors, the Court stressed that compliance with this principle should not be exclusively assessed on the basis of the public health objective of the measure, in light of the interdependence of its internal market and health objectives.[311] The Article 114(3) mainstreaming provision thus provided not only a justification for health-related measures based on the general internal market legal basis, but also prevented a detrimental subsidiarity assessment based exclusively on public health. The Court also noted the discretion of the Union legislature as regards the most appropriate method of approximation, in support of the Article 114 legal basis for the prohibition of flavors,[312] and relied upon its broad discretion in areas "entail[ing] political, economic and social choices" in the proportionality assessments of provisions on flavors,[313] and on electronic cigarettes.[314] Reliance on these elements by the Court in order to justify the validity of these provisions demonstrates the need to adapt the Article 168 TFEU legal basis on public health and address the Article 168(5) express exclusion of harmonization, to provide clarity and transparency, and bring the allocation of Union competences on paper in line with their exercise in practice.[315] Another point to be taken into consideration in terms of exercise of Union competences is Advocate General Kokott's comment on the Article 296 TFEU duty to state reasons and procedural compatibility with the subsidiarity principle, suggesting, rather than the use of "set formulas" in recitals, to "instead enhance . . . preamble[s] . . . with sufficiently substantial statements regarding the principle of subsidiarity . . . tailored to the measures in question."[316]

In terms of regulation of these products, some of the Union legislature's choices are justified, whereas others are questionable, as are some of the recommendations in the

[310] *See Poland*, Case C-358/14, *supra* note *6,* at para. 34; *Philip Morris*, Case C-547/14 at para. 60.

[311] *See Poland*, Case C-358/14, *supra* note *6,* at paras. 105 and 116–18; *Philip Morris*, Case C-547/14, *supra* note 6, at paras. 214 and 220–22.

[312] *See Poland*, Case C-358/14, *supra* note *6,* at paras. 37 and 68-69; *Philip Morris*, C-547/14, *supra* note 6, at para. 63.

[313] *See Poland*, Case C-358/14, *supra* note *6,* at para. 79; *Philip Morris*, Case C-547/14, *supra* note 6, at para. 166.

[314] *See Pillbox 38*, Case C-477/14, *supra* note 6, at paras. 49, 61, 96.

[315] For a general discussion of mainstreaming provisions, the EU legislature's discretion/broad discretion, public health legal basis, as well as provisions on labelling and packaging, see Abaquesne de Parfouru, *Choking Smokers Don't You Think The Joker Laughs At* You' – European Union Competence and Regulation of Tobacco Products Packaging under the New Tobacco Products Directive, MAASTRICHT J. EUR. & COMP. L. (forthcoming).

[316] *See Philip Morris*, Case C-547/14, *supra* note 6, Opinion of Advocate General Kokott at para. 301; *Poland*, Case C-358/14, *supra* note *6,* Opinion of Advocate General Kokott at para. 188.

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FCTC Partial Guidelines.[317] While the prohibition of characterizing flavors in tobacco products by Directive 2014/40 can be considered as the ban of a component of a product, despite differences in national legislation, it does not facilitate free movement, as flavored tobacco products constitute, in reality, a separate category of products, for instance mentholated cigarettes, and could be considered as the prohibition of a "free-standing" product.[318] The lack of specificity of the menthol flavor does not as such support different treatment from other characterizing flavors, in terms of internal market or even public health justifications, and is consistent with the FCTC Partial Guidelines recommendations regarding all flavors, including menthol. Consumers should not, however, be deprived of a product they are used to, and the distinction made by some European Parliament Committees, based on the traditional nature and time on the market of mentholated products, could in this respect justify different treatment of these products. Concerning health arguments based on the well-being of smokers and cost on society, provisions such as the prohibition of flavored products, or stringent labelling requirements, are hardly justifiable in light of excise duties levied and common knowledge of risks involved in smoking, which in most cases constitutes an informed lifestyle choice. Purchase and consumption age limits, display bans, provide useful means of preventing young people from taking up smoking. However, if the main concern is the protection of the young and prevention of smoking initiation, regulations should be aimed at education, as suggested in European Parliament Committees' opinions.[319] As regards concern for existing smokers, providing smoking cessation information and help for those intending to stop is more constructive than banning certain products or imposing pictures to consumers who do not.[320] Likewise, while prohibiting all characterizing flavors only reduces consumer choice,

[317] FCTC Partial Guidelines for Implementation of Articles 9 and 10, Decision FCTC/COP4(10) and Decision FCTC/COP5(6).

[318] *See* Wyatt, *supra* note 53.

[319] *See* Committee on International Trade Opinion (EP) PE510.734 of 19 June 2013, Amendments 8, 11; Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 2 and 15; Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013, at 3, 4, Amendments 3 and 14; Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendment 18; Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013/P7_TA(2013)0398 (EP partial vote), Amendments 4 and 40 ; *See* Guidelines for the Implementation of Article 12 of the WHO FCTC (Education, Communication, Training and Public Awareness), Decision FCTC/COP4(7).

[320] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 2; Committee on Agricultural and Rural Development Opinion (EP) PE507.956 of 27 June 2013 Amendment 3; Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013, Amendment 18; Committee on Proposal on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013/P7_TA(2013)0398 (EP partial vote), Amendment 40; Directive 2014/40, *supra* note 6, at art. 10(1)(b) (on smoking cessation information, which constitutes part of the combined health warnings). *See also* the amendment proposed by the European Parliament ITRE Committee of combined health warnings of "50% … with 50% of that area providing information on smoking cessation": Committee on Industry, Research, and Energy Opinion (EP) PE508.180 of 8 July 2013 Amendment 39.

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regulation of some harmful components of tobacco, beside general considerations of the harmfulness inherent to smoking, would be beneficial. This had been envisioned by the ENVI Report amendments adopted at the European Parliament partial vote, which had provided for an assessment of the safety of additives and a Union list of authorized additives, with conditions and restrictions of use, as well as a procedure for obtaining the approval of an additive and its addition to the list.[321] The question of a "European system for the regulation of ingredients . . . including the establishment of a Union [positive] list of ingredients" constitutes one of the elements to be considered in the Commission report five years after the implementation of the Directive.[322] Former Directives had similarly established tar and carbon monoxide yields.[323]

As regards regulation of alternatives to tobacco, the new Tobacco Products Directive's provisions on electronic cigarettes and refill containers constitute an improvement to those in the Commission proposal on nicotine-containing products, according to which most products would have required authorization under Directive 2001/83. This could be considered problematic for an arguably lower-risk alternative to tobacco and smoking cessation tool. Concerns as to these products constituting a "gateway" to smoking are for most part unjustified, as these products are mainly used by former or current smokers intending to stop or reduce their consumption, yet suggestions on age limits should be considered.[324] On the other hand, the novelty of such products, and persisting uncertainties as to health risks involved, justify strict provisions on electronic cigarettes and refill containers. In light of the chemical compounds discovered, further analysis and regulation of emissions would be welcome.[325] Some European Parliament committees also highlighted Union measures applicable to such products.[326] It is essential to ensure that e-cigarettes are safer and healthier. However, the chosen nicotine concentration limit, below

[321] *See* Committee on Environment, Public Health and Food Safety Report on the Proposal (EP) PE508.085 of 24 July 2013/P7_TA(2013)0398 (EP partial vote), Amendments 11 (recital 14a), 50/50–87–95 (art. 6(10a)) and 85 (annex I). *See* Amendments 7 (recital 10a) on Polonium 210, and 12 (recital 14b) on Regulation 1272/2008. *See also* COM(2005) 339 final, at 7–8; *Commission Staff Working Document Impact Assessment*, *supra* note 22, part 1 at 34, part 4 at 6, and 39–45.

[322] *See Council of the European Union General Approach*, *supra* note 20, annex, at recital 39, and art. 23(2)(d); Directive 2014/40, *supra* note 6, at recital 52 subpara. 2, and art. 28(2)(d).

[323] *See* Council Directive 90/239, art. 2(2), 1990 O.J. (L 137) 36 (EEC); Directive 2001/37, art. 3(1), 2001 O.J. (L 194) 26 (EC); Directive 2014/40, *supra* note 6, at art. 3(1).

[324] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013; Amendment 59 (art. 18(1e)).

[325] *See* Directive 2014/40, *supra* note 6, at art. 20(2) subpara. 1, 2(b)–(c), (e)–(g), (8)–(9); Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendment 59 (art. 18(2)).

[326] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013 Amendments 59 (art. 18(1b)–(1c)), 73 (annex IIb); Committee on Legal Affairs Opinion (EP) PE510.591 of 25 June 2013, Amendment 74 (annex Ia).

the average nicotine intake for heavy smokers, is inappropriate for alternative smoking cessation devices.

Finally, regarding alternatives to smoking tobacco, Directive 2014/40 reproduces the prohibition of tobacco for oral use, already in former tobacco control directives, which is problematic from a public health perspective for a lower risk substitute to tobacco for smoking. The proposal of the IMCO Committee to regulate the composition of all smokeless tobacco, instead of the snus ban, would have provided a more appropriate solution.[327] The prohibition of oral tobacco, retained in the new Tobacco Products Directive, also raises important questions as regards Union competences, in terms of proportionality, and of the internal market legal basis, as it constitutes the ban of a free-standing product perpetuating a trade barrier.[328] Moreover, comparison with nasal and chewing tobacco,[329] products used by older rather than younger generations, and which, although subject to divergent national legislation, are not subject to a similar prohibition, tends to indicate the purely public health purpose of the ban.

[327] *See* Committee on Internal Market and Consumer Protection Opinion (EP) PE508.048 of 20 June 2013, Amendments 49, 50 (art. 15(1a)–(1b)) and 72 (annex IIa).

[328] Wyatt, *supra* note 53, at 25–26; *Arnold André*, Case C-434/02, *supra* note 4, Opinion of Advocate General Geelhoed; *Swedish Match*, Case C-210/03, *supra* note 4, Opinion of Advocate General Geelhoed at para. 78.

[329] *See Commission Staff Working Document Impact Assessment*, *supra* note 22, part 4 at 2.

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