

Promoting Human Health *and* the Functioning of the Internal Market: The Reaffirmation of the Tobacco Products Directive's Key Objectives in *Poland v Parliament and Council, Pillbox 38* and *Philip Morris Brands and Others*

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Abstract

The regulation of tobacco in the EU has a history of tough negotiations and legal challenges and the new 2014 Tobacco Products Directive has already proven to be no exception. Striving to promote the functioning of the internal market, yet at the same time maintain high level of health protection, this piece of legislation proliferated from international standards under the WHO Framework Convention for Tobacco Control and introduced more stringent marketing requirements for tobacco and its products than its predecessor. However, the Directive was immediately challenged by the industry and some Member States, which claimed that the new requirements on packaging and labelling as well as trade of tobacco and related products were inconsistent with the primary law. This analysis provides an insight into three recent parallel judgments of the European Court of Justice in cases *Poland v Parliament and Council, Pillbox 38* and *Philip Morris Brands and Others*, which upheld the legality of the Tobacco Products Directive and reaffirmed the importance of preserving the balance between the smooth functioning of the internal market and the promotion of human health within the EU.

1. Introduction

Although smoking has long been identified as one of the major lifestyle threats to human health and the campaigns – both social and legal – against it have significantly thwarted the positions of the tobacco industry, the persisting trend of a society with a large number of smokers has been successfully carried into the 21st century. In that regard, Europe has traditionally been a region with a high prevalence of tobacco users; nevertheless, through a combination of policy measures adopted at the European Union (EU) and at Member State level coupled with the increased public awareness, the prevalence of smokers in the EU has been on the decline.¹

Yet, despite this seemingly positive trend, the regulation of tobacco and its products in the EU has been all but a smooth process.² Thus, throughout its history, the multi-pronged EU policy on tobacco products' labelling, taxation, advertising and sponsorship was scattered across different pieces of legislation, which were subject to fierce institutional debates and litigation.³ In 2001, after a sequence of tough negotiations, a new directive on tobacco products was adopted, consolidating and strengthening the pre-existing legislation on labelling and tar yield; however, the Directive had

¹ See Alemanno, 'Nudging smokers – The behavioural turn of tobacco risk regulation', 3 *European Journal of Risk Regulation* (2012), 32-42.

² Opinion of AG Kokott in Case C-477-14, *Pillbox 38 (UK) Limited*, EU:C:2015:854, para. 1.

³ See, in general, Alemanno, 'Out of Sight, Out of Mind – Towards a New EU Tobacco Products Directive', 18 *Columbia Journal of European Law* (2011), 197-241. See also C-376/98, *Germany v Parliament and Council*, EU:C:2000:544.

to undergo substantial court challenges almost immediately upon its adoption and afterwards.⁴

Similarly, when the 2001 Directive was repealed by the new 2014 Tobacco Products Directive,⁵ the latter, which introduced even more stringent requirements for the marketing of tobacco and related products, was immediately challenged in its turn. The paper provides an insight into three recent parallel judgments of the European Court of Justice (ECJ) in cases *Poland v Parliament and Council*,⁶ *Pillbox 38*⁷ and *Philip Morris Brands and Others*,⁸ which upheld the legality of the Tobacco Products Directive and reaffirmed the importance of preserving the balance between the smooth functioning of the internal market and the promotion of human health within the EU.

2. The 2014 Tobacco Products Directive: A Brief Overview

The Tobacco Products Directive builds on the premise that tobacco products are no ordinary commodities, thus due to their harmful effect on human health, such products should be subject to particular scrutiny in accordance with Art. 114(3) of the Treaty of the Functioning of the European Union (TFEU),⁹ which requires a high level of health protection as a base for legislation.¹⁰ The objectives of the Directive are, therefore, threefold: to facilitate the smooth functioning of the internal market for tobacco and related products, to ensure a high level of protection of human health, especially for young people, and to meet the obligations of the EU under the WHO Framework Convention for Tobacco Control (FCTC),¹¹ which is binding on the Union and its Member States.¹² To achieve those objectives, the key regulatory requirements of the Directive include, *inter alia*, the prohibition to place on the market tobacco products with a characterizing flavour¹³ and certain additives (e.g. vitamins, caffeine, etc.), which may render such products more attractive to tobacco users¹⁴ and tobacco for oral use;¹⁵ furthermore, the Directive sets limits for emission levels from cigarettes,¹⁶ detailed requirements for health warnings on products and packaging¹⁷ as well as product appearance and content¹⁸ and prohibition of certain elements on labelling.¹⁹ The requirements of the Directive also cover electronic cigarettes²⁰ as well as herbal products for smoking.²¹

A highly important feature of the Directive is its regulatory significance not only with regard to tobacco products, but to trade itself. Thus, for example, the Directive, apart from its regulation of

⁴ See C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, EU:C:2002:741; C-434/02, *Arnold André*, EU:C:2004:800; C-210/03, *Swedish Match*, EU:C:2004:802; C-380/03, *Germany v Parliament and Council*, EU:C:2006:772.

⁵ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1).

⁶ Case C-358-14, *Republic of Poland v European Parliament and Council of the European Union*, EU:C:2016:323.

⁷ Case C-477-14, *Pillbox 38 (UK) Limited, trading as Totally Wicked v Secretary of State for Health*, EU:C:2016:324.

⁸ Case C-547-14, *Philip Morris Brands SARL and Others v Secretary of State for Health*, EU:C:2016:325.

⁹ Consolidated Version of the Treaty on the Functioning of the European Union, 7 June 2016, 2016 O.J. (C 202) 47.

¹⁰ Recital 8.

¹¹ WHO FCTC, adopted on 21 May 2003, <http://www.who.int/fctc/en/> (last visited 3 August 2016).

¹² Art. 1.

¹³ Art. 7(1).

¹⁴ Art. 7(6).

¹⁵ Art. 17.

¹⁶ Art. 3(1).

¹⁷ Arts. 8-12.

¹⁸ Art. 14.

¹⁹ Art. 13.

²⁰ Art. 20.

²¹ Art. 21.

cross-border distance sales of tobacco products,²² grants Member States discretion to prohibit such sales.²³ Moreover, by way of derogation from the principle of free movement of goods²⁴ and on the grounds of public health, the Member States preserve a right to maintain or introduce further requirements for tobacco products²⁵ and even prohibit a certain category of products owing to the specific situation in a particular Member State.²⁶ This discretion, however, is conditional on specific circumstances laid down in Art. 24.

3. The Background to the Three Challenges

On 4th May 2016, the ECJ delivered its judgment in three separate parallel cases challenging the legality of the Tobacco Products Directive. The background to these cases are as follows.

3.1. *Poland v Parliament and Council*

In an action for annulment, the Republic of Poland (supported by Romania, the intervener) challenged the Directive's restrictions on placing on the market of tobacco products with a characterizing flavour, namely, menthol, by alleging that such restrictions infringed Art. 114 TFEU and the principles of proportionality and subsidiarity.²⁷ According to the applicant, the EU legislature should have distinguished products containing menthol from those with another characterizing flavour because of the alleged 'traditional' nature, different qualities in terms of taste, and unattractiveness to young people of the former.²⁸ Furthermore, the applicant claimed that there were no divergences between the national rules with regard to the use of menthol in tobacco products when the Directive was adopted, nor were there any objective reasons for those divergences to emerge in the future, save for the ones potentially arising from the ambiguous concept of 'characterising flavour' in the Directive.²⁹ For its part, the intervener claimed that the above-mentioned restrictions principally sought to ensure a high level of health protection and not to improve the conditions for the functioning of the internal market as required by Art. 114 TFEU.³⁰

3.2. *Pillbox 38*

In this case, which was a reference for a preliminary ruling, *Pillbox 38 (UK) Ltd* – a manufacturer and marketer of electronic cigarettes – brought a claim before the High Court of Justice of England and Wales, Queen's Bench Division, seeking judicial review of the 'intention and/or obligation' of the UK to implement the Tobacco Products Directive in national law. Specifically, it challenged the Directive's regulation of electronic cigarettes in Art. 20 (such rules were introduced in the EU for the first time), claiming that it infringed the principles of proportionality, legal certainty, equal treatment, free competition and subsidiarity as well as Arts. 16 and 17 of the Charter of Fundamental Rights of the EU (the Charter).^{31,32}

3.3. *Philip Morris Brands and Others*

Similar to *Pillbox 38*, *Philip Morris Brands and Others* (reference for a preliminary ruling) originated from two sets of proceedings brought by Philip Morris Brands SARL and Philip Morris

²² Art. 18.

²³ Art. 18(1).

²⁴ Art. 24(1).

²⁵ Art. 24(2).

²⁶ Art. 24(3).

²⁷ *Poland v Parliament and Council*, para. 19.

²⁸ *Ibid*, para. 24.

²⁹ *Ibid*, para. 25.

³⁰ *Ibid*, para. 26.

³¹ Charter of Fundamental Rights of the European Union, 7 June 2016, 2016 O.J. (C 202) 389.

³² *Pillbox 38*, paras. 10 and 11.

Ltd, and British American Tobacco UK Ltd – companies engaged in manufacturing and marketing of tobacco products – against the Secretary of State for Health, concerning UK's implementation of the Directive.³³ However, unlike *Poland v Parliament and Council* and *Pillbox 38*, this case revolved around much more substantial and sweeping challenges to the Tobacco Products Directive, raising in essence, the question of how to practically maintain the proper balance between the smooth functioning of the internal market for tobacco products and the fundamental objective of a high level of health protection, enshrined in the EU primary law.³⁴ Specifically, it questioned the validity of Arts. 24(2) and (3), the Directive's provisions on packaging and labelling under Chapter II and Arts. 7 and 18 in the light of Art. 114 TFEU; furthermore, the compliance of various provisions on ingredients as well as labelling and packaging with the principles of proportionality and subsidiarity and/or Art. 11 of the Charter was also put to the test.³⁵

4. The Position of the ECJ: Backing the Directive

4.1. Admissibility

The court declared all three cases admissible; however, it rejected the admissibility of nearly a half of all the questions raised in *Philip Morris Brands and Others*, which referred to the Directive's provisions empowering the European Commission to adopt various delegated and implementing acts, as not related to the implementation of the Directive.³⁶ Furthermore, the ECJ found no concrete reason for questioning the validity of Directive's provisions on health warnings, product presentation as well as appearance and content in the light of compliance with the principle of subsidiarity; consequently, these questions were declared inadmissible too.³⁷

4.2. The Challenges to the Directive under Art. 114 TFEU and the Principle of Proportionality

As pointed out by the Advocate General, Art. 114 TFEU specifies 'whether the Union actually has a competence to adopt internal market harmonisation measures'.³⁸ Hence, according to the settled case-law, this article may be invoked when the existing disparities between national rules obstruct (or are likely to obstruct in the future) the fundamental freedoms, thus having a direct effect on the functioning of the internal market.³⁹ Furthermore, the Court stressed that the EU legislature is free to rely on that legal basis on the ground that public health protection is a decisive factor in the choices to be made,⁴⁰ and used this occasion to reiterate the objective of a high level of human health protection established in the primary law.⁴¹ Accordingly, the measures adopted under Art. 114(1) TFEU may lead to certain limitations and even up to the definitive prohibition of the marketing of specific products.⁴² The Court, therefore, went on to examine the challenges to the Directive under Art. 114 TFEU in the light of these considerations.

First, with regard to Member States' discretion under Art. 24(2), it acknowledged the precise

³³ *Philip Morris Brands and Others*, para. 2.

³⁴ Opinion of AG Kokott in Case C-547-14, *Philip Morris Brands and Others*, EU:C:2015:853, para. 4.

³⁵ *Philip Morris Brands and Others*, paras. 28.

³⁶ *Ibid*, paras. 42-46.

³⁷ *Ibid*, paras. 47-53. It is worth mentioning that in determining the competences of the EU legislature and the Member States in the light of this principle, the ECJ concluded, in all three cases, that the two key objectives of the Directive (particularly, the smooth functioning of the internal market) could not have been achieved better at national level, thus adopting all the contested measures was clearly advantageous. *Poland v Parliament and Council*, paras. 116-123; *Pillbox 38*, paras. 149-150; *Philip Morris Brands and Others*, paras. 219-224.

³⁸ See Opinion of AG Kokott in Case C-477-14, *Pillbox 38*, EU:C:2015:854, para. 164.

³⁹ See the cited case-law in *Philip Morris Brands and Others*, paras. 58-59.

⁴⁰ *Ibid*, para. 60.

⁴¹ *Ibid*, para. 61. See in particular, Arts. 9, 114(3) and 168(1) TFEU and Art. 35 of the Charter.

⁴² *Ibid*, para. 64.

extent of it as 'not entirely unambiguous' and not directly indicating whether or not Member States have discretion to maintain or introduce further requirements for packaging of tobacco products.⁴³ Thus, the ECJ held that the encroachment of such discretion on the aspects harmonized by the Directive would indeed undermine the harmonizing effect of the Directive and replace it with national requirements, which would be incompatible with Art. 114 TFEU.⁴⁴ On the contrary, since the Directive regulates 'certain' aspects of labelling and packaging and does not bring about full harmonisation, the Court emphasized that Member States should remain free to use their discretion with regard to elements that are not harmonized by it, even despite the fact that it might pose some obstacles to free movement of the products at issue.⁴⁵ Similarly, Art. 24(3) of the Directive does not interfere with Member States' policies on the lawfulness of tobacco products as such, but rather concerns an aspect not covered by the harmonisation measures, thus it is not subject to the rules laid down in Art. 114 TFEU.⁴⁶

Second, the ECJ availed itself of the above-mentioned line of reasoning in responding to the allegations brought in *Philip Morris Brands and Others* and *Poland v Parliament and Council* that the Directive's requirements on labelling and packaging, and cross-border distance sales as well as the restriction on placing on the market of tobacco products with a characterizing flavour, namely, menthol, create an unnecessary obstacle to the internal market. Thus, for example, the Court consistently stated that divergences did exist in national rules with regard to labelling and packaging of the tobacco products prior to the adoption of the 2014 Directive, as demonstrated in the impact assessment of 2012⁴⁷ and, moreover, such divergences would only be exacerbated in the future.⁴⁸ At the same time, the Court backed the Advocate General's position that the persisting differences in some aspects of labelling, for example the appearance of health warnings in different languages, are not substantial and, in general, the contested provisions harmonize the essential elements of labelling and packaging, namely the shape of the unit packets, the minimum number of cigarettes per unit packet and the size and nature of health warnings.⁴⁹ Meanwhile, the contested rules on cross-border distance sales were not harmonized at all prior to the Directive, thus laying down common rules, combined with the Member States' right to prohibit such sales with regard to products that do not comply with the Directive, is an adequate addition to the harmonizing effect of the latter and the means of insuring that the risk of young people getting access to those products is decreased.⁵⁰

Identically, the Court was not persuaded that the above-mentioned provisions of the Directive infringed the principle of proportionality. Thus, it was observed that such allegations basically revolved around the interpretation of the objective of health protection without paying heed to the objective of promoting the functioning of the internal market.⁵¹ Indeed, the elements in question,

⁴³ Ibid, para. 69.

⁴⁴ Ibid, paras. 71-72.

⁴⁵ Ibid, paras. 73-79. The Court therefore agreed with Advocate General that the Directive 'undeniably offers advantages for the functioning of the internal market, since, whilst it does not eliminate all obstacles to trade, it does eliminate some' (para. 81). See Opinion of AG Kokott in *Philip Morris Brands and Others*, para. 119.

⁴⁶ *Philip Morris Brands and Others*, paras. 88-90. In other words, what Art. 24(3) of the Directive does do, is that it clarifies 'that tobacco and related products which comply with the requirements laid down by the directive may move freely on the internal market, provided that those products belong to a category of tobacco products or related products which is, as such, lawful in the Member State in which they are marketed.' (para. 91)

⁴⁷ EU Commission's impact assessment of 19 December 2012, accompanying 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. SWD (2012) 452 final.

⁴⁸ *Philip Morris Brands and Others*, paras. 98-99.

⁴⁹ Ibid, paras. 102-103. See Opinion of AG Kokott in *Philip Morris Brands and Others*, para. 98.

⁵⁰ *Philip Morris Brands and Others*, paras. 129-133.

⁵¹ Ibid, paras. 193-194.

such as the requirement for a unit packet to contain at least 20 cigarettes, or for the combined health warnings to cover 65% of the unit packet, were dedicated to ensure a high level of health protection; however, they were also meant to harmonize the requirements at the EU level and fulfil the Union's obligations under FCTC.⁵²

The challenges to the prohibition of mentholated tobacco products and the regulation of electronic cigarettes under Arts. 7 and 20 respectively of the Directive were resolved in a similar manner, only this time with an additional scientific background to it. Thus, the ECJ maintained, first and foremost, that the approach to menthol originated from blanket rules on all characterizing flavours, which stemmed from the FCTC Guidelines,⁵³ calling for, *inter alia*, 'the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties' and directly referring to menthol as such an ingredient.⁵⁴ The scientific reason for that was, as may be easily understood, the expected reduction of the products' attractiveness to consumers, owing to the natural harshness of the tobacco smoke, otherwise masked by the pleasant taste of menthol or some other flavour.⁵⁵ In other words, the above-mentioned blanket ban had a clear goal of promoting human health by tackling the potential initiation and sustainability of tobacco consumption.⁵⁶ For the same reasons, the Court rejected the three arguments brought by Poland in favour of distinguishing mentholated tobacco products from others with a characterizing flavour as unsubstantiated.⁵⁷

Moreover, the ECJ stated that the proposed more lenient measures, such as raising the age limit from which the consumption of flavoured tobacco products would be permitted, organizing information campaigns on such products or adopting the lists of prohibited/permitted flavours would not add to the functioning of the internal market.⁵⁸ In the meantime, with regard to the alleged negative economic and social consequences of such prohibition, the Directive itself provided both the industry and the consumers with enough time to adapt by maintaining that 'in the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.'⁵⁹ Therefore, given the expected reduction in cigarette consumption within the EU, following from the Directive's approach to flavouring, the ECJ concluded that the prohibition was proportionate and in line with the provisions of the primary law.⁶⁰

With regard to the alleged infringement of the principle of proportionality in case of new rules on electronic cigarettes the ECJ considered, first of all, that the persisting scientific uncertainty – acknowledged both by the EU institutions, governments and the WHO on one hand, and the industry itself on the other – on the health impact and consumption habits of these products does not lead to any decisive conclusion.⁶¹ Therefore, the EU legislature was prompted to have recourse to the precautionary principle, which justifies the adoption of restrictive measures.⁶² However, the ECJ disagreed with the statement that these measures – such as, for example, the contested notification scheme, enabling Member States to monitor those products – were in any way stricter than those

⁵² Ibid, paras. 196-211.

⁵³ Guidelines available at http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf (last visited 3 August 2016).

⁵⁴ See *Poland v Parliament and Council*, paras. 42-44 and 53 and *Philip Morris Brands and Others*, paras. 108-110.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ See *Poland v Parliament and Council*, paras. 50-54. Similarly, the Court remained unpersuaded by the argument that the alleged 'traditional' nature of such products should render them exceptional with regard to general restrictions.

⁵⁸ See *Poland v Parliament and Council*, paras. 92-96 and 53 and *Philip Morris Brands and Others*, paras. 180-184.

⁵⁹ Art. 7(14).

⁶⁰ *Philip Morris Brands and Others*, paras. 189-190 and *Poland v Parliament and Council*, paras. 101-102.

⁶¹ *Pillbox 38*, paras. 50-54.

⁶² Ibid, paras. 55.

applicable to tobacco products.⁶³ The Court did acknowledge that in general, the objective characteristics of electronic cigarettes – their composition, consumption pattern and novelty, including the unclear risks to human health – render them different from tobacco products; therefore, such products are not in the same situation and it is only appropriate for them to be covered by a separate legal regime.⁶⁴ An example of such different regulation is the requirement for manufacturers and importers to submit each year to the Member States certain data on sales, enabling the authorities to monitor the market, which, nevertheless, does not infringe the principle of proportionality.⁶⁵

At the same time, other specific requirements, including those on the composition of electronic cigarettes (for example, maximum nicotine value), their packaging (for example, the inclusion of a leaflet with information on use and storage, possible adverse effects, toxicity, etc.), promotion and cross-border distance sales were all proportionate in the light of the Directive's objectives – much like the case of their tobacco counterparts.⁶⁶ Overall, the Court remained adamant of the fact that the establishment of a specific legal regime on such products was entirely justified, given the differences in national rules, the growing market, the engagement in the FCTC platform as well as the level of scientific evidence and novelty.⁶⁷

4.3. The Challenges to the Directive under the Charter

The challenges under the Charter included the alleged infringement of the freedom of expression and information with regard to Directive's prohibition to include any information on labelling and packaging of tobacco products that could promote them or encourage their consumption,⁶⁸ and the freedom to conduct a business as well as a right to property with regard to broad-natured restrictions on commercial communications and any public/private promotion of electronic cigarettes.⁶⁹

In the first case, the Court, emphasized that the nature of the prohibition is such as to cover every aspect of information, even one that is factually accurate, since its appearance might trigger the undesirable consumption among particularly vulnerable potential consumers.⁷⁰ While it is true that such prohibition interferes with Art. 11 of the Charter,⁷¹ Art. 52(1) of the same Charter allows for limitations on the exercise of the granted rights and freedoms if these are provided for by law and serve the greater general interests of others, subject to the principle of proportionality. The Court held that the above-mentioned criteria were met, putting a particular emphasis on the EU objective of promoting human health, which outweighs the commercial interests of the claimants due to the undisputed harmfulness of tobacco products and exposure to tobacco smoke and the related mortality and morbidity.⁷² The Court, therefore, concluded that the Directive's requirements struck a fair balance between the contested interests.⁷³

The challenges in the second case were resolved in a very similar manner. The ECJ observed that the restriction at hand did constitute an interference with the freedom to conduct a business; yet, it refused to accept that such freedom constituted an 'unfettered prerogative' in the light of the above-mentioned Art. 52(1) of the Charter and maintained that the intellectual property (the use of

⁶³ Ibid, paras. 70-75.

⁶⁴ The Court referred to this with regard to the alleged infringement of principles of equal treatment and free competition. Ibid, paras. 35-44.

⁶⁵ Ibid, paras. 132-140.

⁶⁶ Ibid, paras. 81-131.

⁶⁷ Ibid, paras. 57-68.

⁶⁸ *Philip Morris Brands and Others*, para. 137.

⁶⁹ *Pillbox 38*, para. 152.

⁷⁰ *Philip Morris Brands and Others*, paras. 138-145.

⁷¹ Ibid, para. 148.

⁷² Ibid, paras. 150-158.

⁷³ Ibid, para. 161.

the brand name) was in no way hindered by Art. 20 of the Directive, thus the right to property under the Charter remained intact.⁷⁴

5. The Regulatory Significance of the Three Rulings

Given an all-out green light from the ECJ, the new Tobacco Products Directive came into effect on 20th May 2016. In itself though, the Court's assessment of the Directive in the three cases can hardly be regarded as something of a groundbreaking novelty. Indeed, apart from the evident example of electronic cigarettes,⁷⁵ the nature of the three cases was rather trivial and the essence of the challenges was very much close to the 'classical' EU tobacco litigation of the early 2000s. Therefore, it is not surprising that throughout its rulings, the Court extensively referred to those cases. What does give the rulings a considerable element of novelty, is the presence and impact of international law in the face of FCTC, which appears to have given the EU tobacco law a strong impetus.⁷⁶ Thus, for instance, the influence of the FCTC is corroborated by the shift in national legislation, not only of the EU Member States, but worldwide, as seen in the example of plain packaging regulation.⁷⁷ This influence is based on the fact that apart from its regulatory effect, the FCTC provides a consensus-based scientific approach – a factual reference – to the harmful effects of tobacco and the importance of considering it while assessing the relationship between the health and economic objectives.⁷⁸ So far, it should be acknowledged that references to the FCTC have appeared in the ECJ case-law before, namely in cases concerning the taxation of tobacco;⁷⁹ nevertheless, the nature and the extent of the Court's (and indeed the Directive's) reliance on the Convention in present cases were unprecedented. However, whether or not this would lead to any further decisive strengthening of the anti-tobacco stance in Europe is yet to be seen.

At the same time, the Court's backing of the Directive falls within the EU lifestyle risk regulation scheme⁸⁰ and, speaking in broader terms, within the general architecture of the Union's health policy,⁸¹ ranging from regulation of foods and other nutritional substances to air pollution controls.⁸² Furthermore, the three rulings made a clear reinforcement of the commitment to promote both public health and the smooth functioning of the internal market in tobacco regulation simultaneously, without any implied dichotomy.⁸³ The Court's rulings, therefore, are in line with the established perception that the promotion of the internal market does not constitute the promotion of

⁷⁴ *Pillbox* 38, paras. 153-165.

⁷⁵ For more on electronic cigarettes see e.g. Syx, 'The case of the electronic cigarette in the EU', 21 *European Journal of Health Law* (2014), 161-175; Oliver, 'Regulations Are a Drag: The WHO Framework Convention on Tobacco Control and Its Potential Application to Electronic Cigarettes', 16 *Chicago Journal of International Law* (2015), 185-214.

⁷⁶ Elsmore, 'Does the Judicial Clean Sweep for the New EU Tobacco Directive Mean a New-Fangled Mirth of May?' Available at SSRN 2809137 (2016).

⁷⁷ See Berger-Walliser and Bird, 'The Impact of Plain Packaging Regulation on Illicit and Non-Illicit Tobacco Products in the European Union' 38 *North Carolina Journal of International Law & Commercial Regulation* (2012), 1015-1060. See also Ritwik, 'Tobacco Packaging Arbitration and the State's Ability to Legislate', 54 *Harvard International Law Journal* (2013), 523-538.

⁷⁸ See Berger-Walliser and Bird, at 1023 and Mitchell and Voon, 'Regulating Tobacco Flavors: Implications of WTO Law' 29 *Boston University International Law Journal* (2011), at 412-413.

⁷⁹ See C-197/08, *Commission v France*, EU:C:2010:111; C-198/08, *Commission v Austria*, EU:C:2010:112; C-221/08, *Commission v Ireland*, EU:C:2010:113.

⁸⁰ See Alemanno and Garde, 'The emergence of an EU lifestyle policy: The case of alcohol, tobacco and unhealthy diets', 50 *Common Market Law Review* (2013), 1745-1786.

⁸¹ See, e.g. Greer et al. 'Health law and policy in the European Union', 381 *The Lancet* (2013), 1135-1144.

⁸² See, e.g. Varvaštian, 'Achieving the EU Air Policy Objectives in Due Time: A Reality or a Hoax?', 24 *European Energy and Environmental Law Review* (2015), 2-11; Varvaštian, 'A Review of EU Regulation of Sports Nutrition: Same Game, Different Rules', 16 *German Law Journal* (2015), 1293-1315.

⁸³ See, e.g. Marchetti and Nicola, 'Constitutionalizing Tobacco: The Ambivalence of European Federalism' 46 *Harvard International Law Journal* (2005), 507-526.

business *per se*, as clearly demonstrated in the parts referring to the Charter. Rather, it reflects the objective – scientific – criterion, which becomes (or at least, should become) dominating in the process of decision-making, particularly in such a sensitive area.⁸⁴ Understandably, it might be tempting to dub the regulation of tobacco as a 'conflict between trade and health',⁸⁵ especially in the context of human rights.⁸⁶ But then, so are many other fields of risk regulation, including regulation of alcoholic beverages, unhealthy foods, etc. And if the traditional legislative mechanisms fail to properly address these challenging areas, the regulatory vacuum is likely to be filled with individual, or even governmental-scale litigation.⁸⁷

So far as it concerns the present cases though, the new Directive withstood the examination of balancing the economic and health interests. Still, the story of tobacco litigation in Europe is probably far from over. Thus, for example, in terms of recent litigation at Member State level, a decision was issued by France's Constitutional Council, backing the standardized packaging legislation earlier this year, and two weeks after the ECJ rulings, the English High Court made its ruling upholding similar provisions in the UK national law.⁸⁸ And just a month later on, the 'Brexit' referendum took place, dwarfing many, if not all, political processes within the EU and leaving some wondering on the very future of the Union. In some related areas, namely environmental protection, concerns have already been expressed on the future policy.⁸⁹ In case of tobacco regulation though, the potential laxity of UK's standards, given its unclear future relationship with the EU, does not seem obvious. After all, it might be recalled that the UK was on the pro-regulatory side in the relevant ECJ cases; moreover, the above-mentioned decision of the domestic court also supported more stringent regulatory measures.⁹⁰ A point of concern for the future, however, certainly remains. Nevertheless, the gradual tightening of the tobacco legislation seems once again to speak in favour of the FCTC and, ultimately, scientifically-based approach, which becomes more prevalent as states gradually embrace the idea of promoting public health in all policy spheres⁹¹ including, of course, the regulation of tobacco.

⁸⁴ For more on the use of science see Schrefler and Pelkmans. 'Better Use of Science for Better EU Regulation' 5 *European Journal of Risk Regulation* (2014), 314-323.

⁸⁵ For more on this see Lester, 'Domestic Tobacco Regulation and International Law: The Interaction of Trade Agreements and the Framework Convention on Tobacco Control', 49 *Journal of World Trade* (2015), 19-47.

⁸⁶ See, e.g. Petersmann, 'How to Reconcile Health Law and Economic Law with Human Rights? Administration of Justice in Tobacco Control Disputes', 10 *Asian Journal of WTO & International Health Law and Policy* (2015), 27-78.

⁸⁷ See, e.g. the case of the US in Luff, 'Regulating Tobacco Through Litigation' 47 *Arizona State Law Journal* (2015), 125-181.

⁸⁸ See Elsmore, *supra* note 76.

⁸⁹ See e.g. a review by Burns et al. 'The EU Referendum and the UK Environment: An Expert Review. How has EU membership affected the UK and what might change in the event of a vote to Remain or Leave?' (2016). See also the position of the environmental law NGO ClientEarth: 'Brexit 'challenge' to politicians over UK environmental laws', 24 June 2016, <http://www.clientearth.org/brexit-challenge-politicians-uk-environmental-laws/> (last visited 3 August 2016).

⁹⁰ It would fair to observe that this case concerned the challenge to the national legislation, which sought to implement certain provisions of the Tobacco Products Directive as well as FCTC; thus, technically speaking, it was both FCTC- and EU-driven. See *British American Tobacco (UK) Limited and Others v Secretary of State for Health* [2016] EWHC 1169 (Admin) (19th May 2016). See also Elsmore, *op. cit.*

⁹¹ See, e.g. Alemanno, 'Balancing Free Movement and Public Health: The Case of Minimum Unit Pricing of Alcohol in Scotch Whisky' 53 *Common Market Law Review* (2016), 1037-1063.