The New EU Tobacco Products Directive and Standardized Packaging: [in the Name of 'Smooth Functioning of the Internal Market']

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Salus populi suprema lex esto (Cicero, Marcus Tullius, De Legibus (book III, part III, sub. VIII). From Latin: 'The Health of the People Should Be the Supreme Law'.)

This article conducts a selective legal analysis of the new Tobacco Products Directive 2014/40/EU, which was formally adopted in April 2014 and which, except for a few provisions, should be implemented in all EU Member States by 20 May 2016. The dominant focus of the article is on the labelling and packaging requirements (including standardized packaging). The labelling and packaging measures, despite ambitious and noble targets, have raised controversial debates about their effect in decreasing tobacco consumption. It has also begged the question whether these rules will contribute to facilitating free movement of tobacco products in the internal market as planned. In light of recent legal challenges and the ECJ's Preliminary Ruling in Philip Morris Brands SARL and Others v. Secretary of State for Health*, the article assesses the validity of the proposed measures under the principles of subsidiarity, proportionality and fundamental rights, as well as the chosen legal basis for the Directive. It continues with the examination of the minimum requirement of the Directive and the possibility for Member States to introduce further requirements relating to packaging.*

Overall, the article concludes that the Directive's chosen model of partial harmonization presents a fresh approach to the regulation of labelling and packaging of tobacco products in the internal market. However, it might generate the same results as in the case of minimum harmonization. Namely, further standardization of packaging of tobacco products at the national level will lead to the lack of a harmonized approach, thereby affecting the smooth functioning of the internal market. As a result, new harmonizing rules will be required in the future.

1 INTRODUCTION

On 3 April 2014, the European Parliament and the Council of the European Union (EU) adopted a new Tobacco Products Directive (2014/40/EU; further, the Directive). The Directive is part of comprehensive tobacco control legislation in the EU. Alongside the increase of public awareness of the health risks of tobacco use, the EU and its Member States have undertaken a wide range of tobacco control

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activities in different forms of legislation,[1] recommendations[2] and information campaigns[3] in order to address tobacco consumption across the EU. Those undertakings are aimed at establishing a harmonized approach to the tobacco products trade in the internal market, while at the same time securing that consumption remains within certain boundaries for public health reasons.

The revision of the old Tobacco Products Directive (2001/37/EC; further, TPD 2001) was proposed to reflect scientific and market developments as well as international agreements under the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC). Except for those provisions where an additional transitional period exists,[4] the Directive should be implemented by the Member States by 20 May 2016. The process of the revision of the old Directive and the adoption of the new Directive was not smooth. The revision process lasted almost five years,[5] forced the responsible Health Commissioner to 'voluntarily'[6] resign in light of a tobacco lobbying scandal and attracted considerable legal and economic scrutiny.[7] As a follow-up, the adopted Directive soon faced 'fierce'[8] legal challenges in the courts (see section 3). With the announced aim of facilitating the smooth functioning of the internal market for tobacco and related products while ensuring a high level of health protection of individuals,[9] the Directive intends to remove any loopholes of the TPD 2001, expand its scope, update old provisions and go further with the libertarian paternalistic-inspired[10] regulations[11] in regard to labelling and packaging requirements aimed at decreasing tobacco consumption. Among many others provisions, the new Directive includes measures for

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1 The Tobacco Tax Directives, the Tobacco Advertising Directive, the Common Agricultural Policy.

2 Council Recommendations Nr. 2003/54 (02 Dec. 2002), Nr. 2009/C 296/02 (30 Nov. 2009)

3 E.g. campaign *Ex-Smokers Are Unstoppable (2014–2016).*

4 An additional transitional period includes a ban on menthol cigarettes, the traceability and security features, and electronic cigarette product regulations.

5 According to the DG SANCO roadmap 'Revision of the TPD' the work for the impact assessment started mid-2009.

6 ECJ Press release, No 40/16 Luxembourg, Case C-394/15P, *Dalli v. Commission*, 14 Apr. 2016.

7 *See* more Matthew J. Elsmore & Viktoria Obolevich, *Thank You for Not Smoking: The Commission's Proposal for a New Tobacco Products Directive – Legally Sound, but Does It Hit the Spot?*, 4 Eur. L. Rev. 552–572 (2013).

8 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853, para. 2.

9 TPD 2014/40/EU, Recital 21.

10 Libertarian paternalism is a concept introduced by the economist Richard Thaler and the legal scholar Cass Sunstein. The concept suggests regulations that direct (or 'nudge') individuals towards positive decisions while preserving their freedom of choice. *See* more Cass R. Sunstein, & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. Chi. L. Rev.1159 (2003). Richard H. Thaler & Cass R. Sunstein, *Libertarian Paternalism*, 93 Am. Econ. Rev. 175 (2003). Richard H. Thaler & Cass R. Sunstein, *Nudge: Improving Decisions About Health, Wealth and Happiness* (New Haven, CT: Yale University Press 2008).

11 *See* more Alberto Alemanno, *Nudging Smokers – The Behavioural Turn of Tobacco Risk Regulation*, 3 Eur. J. Risk Reg. (2012).

products that are not specifically regulated such as e-cigarettes and herbal smoking products,[12] and updates legal rules on ingredients and emissions.[13] It also obliges manufacturers to submit a notification of novel tobacco products before placing them on the EU market,[14] introduce a ban on characterizing flavours (such as menthol, vanilla or candy),[15] as well as preserve the ban (except for Sweden) for oral tobacco (snus).[16] In addition, it includes EU-wide tracking and tracing technical features to combat illicit trade of tobacco products,[17] and includes rules for cross-border internet sales.[18]

Probably the most noticeable and most controversial aspect for the affected actors, but at the same time the most promising policy area in the EU lawmakers' eyes,[19] is the labelling and packaging provisions. Specifically, the Directive aims to reduce smoking prevalence among young people by making tobacco products less appealing to them. In order to achieve that, the Directive aims to ensure that 'tobacco products look and taste like tobacco products'[20] and 'the appearance of the package reflects the characteristics inside the package'.[21] Thus, the Directive updates a set of minimum rules concerning tobacco packaging and labelling,[22] and allows Member States, following a set of conditions,[23] to introduce provisions for further standardization of the packaging of tobacco products[24] and even to introduce plain packaging or standardized packaging.

However, packaging and labelling measures, including plain packaging, raise serious questions regarding legal norms, such as fundamental rights, free movement and illicit trade. There are also questions as to whether they are the best and less intrusive instruments and will prove as effective as planned.

This article examines the packaging and labelling provisions of the Directive, including the Member States' option to follow further measures relating to standardization of packaging. Contemplating the conformity of the chosen provisions with the principles of conferral, subsidiarity and proportionality, the article highlights how well placed the EU is to intervene in tobacco laws, and how effective it is in doing so. A Preliminary Ruling delivered by the European Court of Justice (ECJ) in 2016, in a

12 TPD 2014/40/EU, Arts 20–22.
13 *Ibid*., Arts 3–7.
14 *Ibid*., Art. 19.
15 *Ibid*., Art. 7.
16 *Ibid*., Art. 17.
17 *Ibid*., Arts 15 and 16.
18 *Ibid*., Art. 18.
19 According to the impact assessment SWD (2012) 452 final, 19 Dec. 2012, A.5.2.1., Table 2.1. The packaging and labelling provisions will decrease cigarette consumption for 1–1.5%.
20 Commissioner Borg´s statement on the revision of the TPD 2001, 26 Feb. 2014, Brussels.
21 Proposal for a directive COM (2012) 788 final, 19 Dec. 2012, at 7.
22 TPD 2014/40/EU, Chap. 2 Labelling and packaging.
23 TPD 2014/40/EU, Art. 24(2).
24 *Ibid*., Recital 53.

legal challenge brought by Philip Morris and Others[25] (further, Philip Morris Brands SARL case) against the new Directive, elucidates the Court's position regarding the proposed labelling and packaging measures and adds to the legal analysis. The article furthermore discusses the legal implications of the adoption of plain packaging at national level, and observes recent developments of other Member States in this field.

Considering the recent legal cases and the Member States' developments towards plain packaging for tobacco products, the article might be informative for those Member States that are heading towards plain packaging legislation for cigarettes, plus those that might be interested in applying similar regulations to other 'unhealthy' consumer products, such as alcohol and sugary and fatty foods.[26]

Section 2 outlines, the new Directive's packaging and labelling provisions. Section 3 assesses the compatibility of the mentioned rules with EU law provisions. Section 4 discusses the possible impact of the labelling and packaging and the legal implications of the adoption of standardized packaging at the national level. Section 5 concludes.

2 THE DIRECTIVE'S PACKAGING AND LABELLING PROVISIONS

This section describe in detail the mandatory and optional requirements for the packaging and labelling of cigarettes set out in the Directive. By giving a brief overview of the rules existing in previous directives, particularly under the TPD 2001, the discussion broaches the question of why there was a need to update the previous labelling and packaging provisions. It continues with the examination of the minimum requirements set for the Member States and considers the plain packaging option.

2.1. TPD 2001 AND THE NEED FOR A NEW DIRECTIVE

Labelling and packaging provisions for tobacco products are not new for the EU. In the late 1980s and early 1990s, the EU introduced a couple of Directives on labelling that brought some degree of standardization to tobacco packages.[27] These Directives required displaying information on tar and nicotine yields on cigarette packages and health warnings covering at least 4% of the pack. The TPD 2001 amended existing

[25] Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325.

[26] E.g. a recent report from the government advisory body Public Health England already suggested that bottles of alcohol could be sold in plain packaging and carry larger health warnings. *See* The Public Health Burden of Alcohol and the Effectiveness and Cost-Effectiveness of Alcohol Control Policies. An evidence review. Public Health England. Dec. 2016.

[27] Council Directive 89/622/EEC of 13 Nov. 1989 and Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC.

health warning labels on cigarette packs on the grounds that different presentations in different Member States were 'liable to constitute a barrier to trade'.[28] It required that all tobacco products carry a general health warning (e.g. 'Smoking kills/ Smoking can kill') covering not less than 30% of the front side, and a specific text warning covering not less than 40% of the back. In addition, the TPD 2001 introduced maximum yields on nicotine and carbon monoxide.[29]

As regards the provision of displaying information on the maximum limits for the tar, nicotine and carbon monoxide (TNCO) yields of cigarettes, these requirements were introduced despite the fact that at that time no Member States imposed carbon monoxide limits and no Member States imposed limits on nicotine levels, and the risk that different nicotine levels in Member States would create a hindrance to trade was not apparent.[30]

A few years later, reports on the application of the TPD 2001[31] concluded that there was a need for further harmonization of labelling rules. One reason for that was that, under the TPD 2001, some countries could not make changes to the packaging or labelling rules even if they were required to do so by the WHO FCTC.[32] In particular, it was not possible to change the size or location or replace the health warnings on the TNCO emission labels,[33] which, moreover, proved to be misleading as they made people believe that some products are less risky to their health.[34]

The TPD 2001, despite its benevolent intentions, unintentionally raised obstacles for the smooth functioning of the market. While Article 5 of the TPD 2001 allowed Member States to adapt the labelling of tobacco products to the requirement of public health protection, Article 13(1) of the same Directive stated that Member States cannot, for considerations relating to TNCO, to health warnings and to other requirements to this Directive, prohibit or restrict the importation, sale or consumption of tobacco products that comply with the Directive. This resulted in a situation where, while Member States were allowed to take actions with respect to domestically produced products, they could not impose the same requirements on imported products.[35] This created problems for national health regulations.

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28 TPD 2001/37/EC, Recital 19.

29 *Ibid*., Art. 3.

30 Scott Crosby, *The New Tobacco Control Directive: An Illiberal and Illegal Disdain for the Law*, 27 Eur. L. Rev. 181 (2002).

31 First Application Report COM(2005)339; Second Application Report COM(2007)754.

32 WHO FCTC Art.11.

33 TPD 2014/40/EU, Recital 3.

34 *See* Karine Gallopel-Morvanet et al., *Consumer Understanding of Cigarette Emission Labelling*, 21(3) Eur. J. Pub. Health 373–375 (2011) ; and, Abraham Brown et al., *Do Smokers in Europe Think All Cigarettes Are Equally Harmful?*, 22(S1) Eur. J. Pub. Health 35–40 (2012).

35 IA SWD (2012) 452 final, 19 Dec. 2012, at 2.2.2.

All these shortcomings, along with several legal challenges to the TPD 2001,[36] brought policymakers to the conclusion that the TPD 2001 needed substantial changes.[37] The new Directive announced that its target is to facilitate the smooth functioning of the internal market for tobacco and related products while taking as a base a high level of health protection, especially for young people.[38]

Compliance with the obligations of the Union under the WHO FCTC is mentioned as an objective of the Directive, alongside the removal of obstacles to the functioning of the internal market.[39] This is reinforced by Article 168(3) of the Treaty on the Functioning of the European Union (TFEU), which stipulates that the EU and Member States shall cooperate with competent international organizations in the field of public health.[40]

The FCTC is the world's first international public health treaty, and is one of the most widely adopted treaties in the history of the United Nations. Like the EU, all Member States are parties of the WHO FCTC. The Convention contains a broad framework of legally binding and non-binding control measures aimed at reducing both the demand and supply of tobacco. Among many other measures, it requires that each cigarette packet carries health warnings that cover at least 30% of the tobacco packaging, with encouragement for larger graphic warnings.[41] Numerous FCTC measures were already covered by the TPD 2001, but the new Directive went even further.

2.2 Minimum requirements of the directive

The main provisions on labelling and packaging in the new Directive dictate common minimum requirements regarding the size, shape, material and information displayed on the packaging of tobacco products. According to them, cigarette packets must come in a carton or soft material of cuboid shape, and include at least twenty cigarettes.[42]

Each unit packet of a tobacco product is required to contain textual and pictorial information. Specifically, each cigarette packet must carry the following message, 'Tobacco smoke contains over 70 substances known to cause cancer',[43] and one of the following sentences, 'Smoking kills – quit now' or 'Smoking kills'.[44]

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36 Case C-491/01, British American Tobacco (Investments) Ltd and Imperial Tobacco [2002], ECR I-11453; Case C-210/03, Swedish Match [2004], ECR I-11893.
37 TPD 2014/40/EU, Recital 1.
38 *Ibid*., Recital 21.
39 *Ibid*., Recital 24, Art. 1.
40 TFEU Art. 168(3).
41 WHO FCTC, Art. 11.
42 TPD 2014/40/EU, Art. 14(1).
43 *Ibid*., Art. 9(2).
44 *Ibid*., Art. 9(1).

Additionally, the package must include smoking cessation information such as telephone numbers, e-mail addresses or internet sites intended to inform consumers about the programmes that are available to support persons who want to stop smoking.[45]

Learnt from bitter experience, the Directive prohibits labels that include any information about the TNCO content of the tobacco product or any information that promotes or encourages tobacco consumption by creating a misleading impression about its health effects and characteristics.[46]

With regard to pictorial information, it is required that any outside packaging carry indelible, irremovable and visible health warnings that cover 65% of the surface.[47] The remaining 35% of the package surface still belongs to the tobacco companies for their trademark purposes. Health warnings may not be modified or paraphrased.[48] Those warnings include colour photographs and other illustrations aimed at affecting consumers emotionally and raising the smoker's awareness of the damage smoking brings.

The new EU packaging rules only establish a regime of minimum harmonization, meaning that Member States are entitled to apply more stringent standards than those required by EU law. Article 24(2) specifically reserves to Member States the power to maintain or introduce further requirements regarding the standardization of packaging of tobacco placed on their market, including plain packaging. The consequences of this minimum harmonization are analysed in section 4.

2.3 Plain packaging option

'Plain packaging' is the most rigorous form of package standardization since it requires full standardization of the package and almost eliminates the manufacturers' freedom to present their product in the manner of their choice. Plain packaging requires the removal of all attractive promotional elements – trademarks, logos, colour schemes and promotional graphics are prohibited. The brand name can appear, but it is presented in a uniform typeface for all brands, and appears along with information permitted by the regulations (such as health warnings, tax-paid stamps and marking for traceability and security purposes).[49] This definition is similar to the WHO FCTC guidelines, which recommends that its parties adopt plain packaging to decrease the effects of advertising and promoting smoking.[50]

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45 *Ibid*., Art. 10(b).
46 *Ibid*., Art. 13(a).
47 *Ibid*., Arts 8–14.
48 *Ibid*., Art. 8(2).
49 IA SWD(2012) 452 final, 19 Dec. 2012, glossary of terms and 5.3.3., at 93.
50 Guidelines for implementation of Art. 11 of WHO FCTC, para. 46, and Guidelines for implementation of Art. 13 of WHO FCTC, paras 16 and 17.

The introduction of plain packaging at the EU level was one of the policy options during the revision of the Directive. Among many other positive attainments, plain packaging had been seen as an instrument capable of increasing the noticeability of health warnings and saving Member States the expenditures required for developing their own plain packaging legislation.[51] The most positive effect would probably be that the homogenous appearance of the cigarette packs throughout the EU would remove all discrepancies between national legislations and would prevent new ones from appearing, since the rules would be the same for all Member States. As some scholars acknowledged, plain packaging requirements would harmonize the fragmented national laws,[52] thus providing the basis for the creation and smooth functioning of the internal market.

However, plain packaging has also been seen as the most intrusive option as it could negatively affect brand differentiation and would heavily affect tobacco companies' revenues due to the drop in consumption.[53] In addition, the real consequences of plain packaging were difficult to estimate because of a lack of empirical data and experience with plain packaging in Member States.[54]

A less intrusive alternative in the form of large mandatory pictorial warnings with the prohibition of promotional and misleading elements was preferred. However, the EU reserved the power to the Member States to introduce plain packaging under certain conditions, and indeed, many countries are proceeding in that direction; see section 4.2.

Chiefly we can observe that under the new Directive, the concept of the cigarette packaging has been changed. Instead of being an effective selling instrument the packaging has become an instrument intended to discourage people from buying the product, which, as a logical consequence, would shrink the trade in tobacco products. The EU has not previously included an aim to shrink the market for any other so generally accepted and widely legally produced and sold product.

3 VALIDITY OF LABELLING AND PACKAGING PROVISIONS

Developing policies for tobacco products has always been a complicated and meticulous process for policymakers, especially for the EU. It is each Member State's responsibility to organize healthcare and to ensure that it is provided. The EU's role in those questions can only be complementary – seeking to support, coordinate or

51 IA SWD(2012) 452 final, 19 Dec. 2012, 5.3.3. at 92.
52 Peter K. Henning & Leonid Shmatenko, *Plain Packaging on Its Way to Europe: Competence Issues and Compatibility with European Fundamental Rights*, 9(5)Transnat'l Disp. Mgmt. 3 (2012).
53 IA SWD(2012) 452 final, 19 Dec. 2012, 5.3.5., at 95.
54 *Ibid*., 5.3.3., at 92.

supplement Member States' actions[55] and not go beyond what is necessary and allowed.

Besides the complications in balancing diverse targets of the functioning of the internal market and public health, the tobacco industry has a long practice of challenging all new regulations in the courts. It is abundantly clear that the tobacco companies' target, like all businesses, is to increase their profits by both protecting their interests and maintaining or increasing new users of their products. This contradicts health policies aimed at decreasing the existing amount of smokers and preventing new smokers from developing this habit. That goal would inevitably lead to the decrease of tobacco product sales. The latest data indicates that from 2007 until 2013, the prevalence of smoking had already declined worldwide by 2%.[56] However, that positive tendency does not stop policymakers from introducing new policy instruments in the field of tobacco control. This duly leads the tobacco industry to engage the courts in order to protect its interests.

3.1 Recent legal challenges

Like its predecessors, Directive 2014/40/EU was 'fiercely' challenged in the courts,[57] and this became 'a kind of general onslaught' calling into question a large number of its provisions.[58]

For this article, the Philip Morris Brands SARL case[59] is of particular interest because it encompasses the main topic of discussion of this article – packaging and labelling rules. In its Preliminary Ruling, the ECJ addresses the appropriateness of Article 114 TFEU as the legal basis of the Directive, and its compliance with the principles of proportionality, subsidiarity and fundamental rights.[60] Interestingly, the European Parliament's own legal body – the Committee on Legal Affairs of the European Parliament (further, JURI) – raised legal concerns during the Directive's

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55 TFEU, Arts 2(5) and 6(a).

56 WHO report on the Global Tobacco epidemic, 2015. Raising taxes on tobacco. Smoking prevalence has declined worldwide from 23% in 2007 to 21% in 2013.

57 Firstly, Case C-358/14 [2016], ECLI:EU:C:2016:323, brought by the Republic of Poland against Parliament & Council, asked for the annulment of the prohibition on menthol cigarettes. Menthol cigarettes were known in Poland since 1953 and account for almost 40% of Poland's production. In the next case C-477/14 [2016], ECLI:EU:C:2016:324, Pillbox 38 (UK) Ltd, a wholesaler and retailer of electronic cigarettes, challenged the legal validity of Art. 20 concerning the domestic implementation of the Directive's rules concerning e-cigarettes.

58 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853, para. 2.

59 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325.

60 Besides the above-mentioned provisions, tobacco companies claimed the Directive improperly delegates certain powers to the European Commission, and infringes Arts 290 and 291 TFEU. However, since these provisions are not addressed to the Member States and therefore do not relate to the implementation of the Directive in the Member States, the ECJ found them inadmissible.

revision regarding the legal base, fundamental rights and the principle of proportionality,[61] arguing that some of the measures proposed by the Commission did not aim at improving the conditions of the internal market but had as their only objective the protection of public health.

These questions will be addressed in the following sections of the article. First, the issue of a legal basis will be analysed, then the principles of subsidiarity, proportionality and fundamental rights will be discussed.

3.2. Article 114 as a legal basis for the TPD

Among the range of arguments raised by the tobacco industry against the Directive was the inappropriate choice of a legal basis. Like its predecessor, the Directive has been adopted on the legal basis of Article 114 TFEU (ex Article 95 TEC). Article 114 TFEU empowers the EU institutions to adopt measures for the harmonization of national provisions that have the establishment and functioning of the internal market as their object.[62] In adopting such measures, the EU institutions shall ensure a high level of protection of human health.[63] This requirement might intertwine with Article 168 of the TFEU that formulates the basis for public health regulation in the EU, and assigns a carefully circumscribed role to the EU.[64] Considering the principle of conferral,[65] the EU action directed towards improving public health shall merely complement national policies[66] and leave the fundamental choices to be decided by the Member States. The EU cannot 'self-authorize' to act in areas which do not belong to it.[67] Moreover, Article 168(5) particularly excludes any harmonization of the laws and regulations of the Member States regarding tobacco. This vague nature of the Treaty Articles results in a lack of clarity in the regulation of tobacco products and makes it more vulnerable to opposition from the tobacco industry.

Not surprisingly, the claimants used it and argued that the Directive is invalid because Article 114 TFEU does not provide an adequate legal basis for it.

The Directive's aim is clearly health-orientated, and is very much influenced by the WHO FCTC whose main target is to reduce the *continual and substantial* use of tobacco products[68] until the trade of tobacco disappears completely. Even though

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61 JURI opinion, Committee on Legal Affairs, 2012/0366(COD), 25 June 2013.
62 TFEU, Art. 114(1).
63 *Ibid*., Art. 114(3).
64 Peter Oliver, *Oliver on Free Movement of Goods in the EU* 13.52 (5th ed., Hart Publishing 2010).
65 Art. 5(2) TEU establishes the principle of conferral, according to which the EU may act only within the limits of the competences conferred upon it by the Member States. The competences not conferred remain with the Member States.
66 TFEU, Art. 168(1).
67 Stephen Weatherill, *EU Consumer Law and Policy*, Elgar Eur. L. Series 5 (2013).
68 WHO FCTC Art. 3.

the Directive did not state as its target to eliminate of tobacco use, and the declared target is to facilitate the smooth functioning of the internal market for tobacco products, while taking a high level of health protection as a base, the importance of health reasons for such regulation prevails. With the available data on the harmful effects of tobacco products and with the WHO FCTC requirements, we would expect more initiative from the Member States to introduce stricter regulation based on public health protection measures, but not from the EU policymakers by adapting the internal market legal basis for regulating the movement of tobacco products in the internal market and promoting health purposes simultaneously. To the Member States' credit, the so-called 'tobacco endgame' concept had already occupied the mind of some of them. For example, Ireland declared it would stop[69] the use of tobacco products by 2025,[70] Denmark by 2030,[71] Scotland by 2034[72] and Finland by 2040.[73]

However, as case law has established, Article 168(5) does not restrict the scope of Article 114.[74] Provided that the harmonizing measures contribute to the conditions of the internal market, the EU cannot be prevented from relying on Article 114 TFEU on the grounds that public health protection is a decisive factor to be pursued.[75]

Overall, the ECJ as well as the Advocate General took the standpoint that the main target of the Directive is to improve the conditions for the establishment and functioning of the internal market,[76] and a high level of health protection is an indispensable part of the internal market. This conclusion reveals the ECJ's increased interest towards public health, and highlights the wide application of Article 114 TFEU.

3.3 Subsidiarity

The principle of subsidiarity requires the EU, in areas which do not fall within EU exclusive competence, to act only when the actions of individual states are

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69 Less than 5% of the population is smoking.

70 Tobacco Free Ireland, Report of the Tobacco Policy Review Group, Department of Health, Oct. 2013.

71 Patienternes Kræftplan, Kræftplan IV, Regeringen, Aug. 2016.

72 Tobacco Control Strategy – Creating a Tobacco-Free Generation, the Scottish Government, Edinburgh 2013.

73 Roadmap to a Tobacco-free Finland. Action Plan on Tobacco Control. Publications of the Ministry of Social Affairs and Health 2014:12.

74 Oliver, *supra* n. 64.

75 Case C-376/98, *Germany v. Parliament and Council*, [2000], ECR I-08419, para. 88; Case C-491/01, British American Tobacco (Investments) Ltd and Imperial Tobacco [2002], ECR I-11453, para. 62.

76 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853; Judgment Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325.

insufficient.[77] In relation to the questions of labelling and packaging due to free movement of tobacco goods across the borders, the EU asserts itself as being in a better position to regulate the above-mentioned measures than the Member States.[78] Philip Morris and British American Tobacco challenged this, arguing that the Member States are in a better situation to determine the shape, appearance and content of cigarette packs, as well as the requirements for the health warnings. In response to this, the ECJ stated that the Directive has two targets: 'to facilitate the smooth functioning of the internal market', while 'ensuring a high level of protection of human health, especially for young people'.[79] Even if the health protection objective might be better achieved at the level of Member States,[80] the interdependence of these two objectives allows the EU legislature legitimately to take the initiative and establish a set of rules for placement on the EU market of tobacco products.[81] Moreover, the ECJ found that the Commission's proposal for a directive and its impact assessment included sufficient information, showing clearly and unequivocally that it is better to take actions at the EU level rather than at Member State level.[82]

3.4 Proportionality

In the legal proceedings the proportionality of various requirements of the labelling and packaging provisions of tobacco products was called into question. Specifically the plaintiffs questioned the appropriateness and necessity of large warnings and the shape, size and the minimum number of cigarettes per packet.[83] According to the plaintiffs' opinion, for the purpose of health protection it would be sufficient for health warnings to have the general visibility requirement, without being distorted by packet shapes.[84] In addition, they consider the warnings' obligation to cover 65% of the surface to be 'arbitrary and disproportionate'[85] and 'not scientifically proven'.[86] Furthermore, the plaintiffs argued that the proposed requirements will impede the differentiation of tobacco products and will distort the competition.[87] As to the minimum number of

77 TEU Art. 5(3).
78 Alberto Alemanno & Amandine Garde, *European Union*, in *Regulating Tobacco, Alcohol and Unhealthy Foods* Ch. 13, 265 (Tania Voon et al. eds, Routledge 2014).
79 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, paras 143 and 220.
80 *Ibid*., para. 221.
81 *Ibid*., para. 222.
82 *Ibid*., para. 226.
83 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 28(3) (b),(c).
84 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853, para. 188.
85 *Ibid*., para. 195.
86 *Ibid*., para. 196.
87 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 193.

cigarettes, in their view, the requirement to include at least twenty cigarettes per pack is not justifiable on the grounds of public health protection.[88]

Addressing the plaintiffs' arguments in such complicated areas that involve 'political, economic and social choices' the EU legislature acted within the bounds of its broad discretion.[89] This implies that the principle of proportionality can be infringed by the EU legislature only when the provision concerned is *manifestly disproportionate*.

The ECJ maintained that the requirements contained in the Directive relating to the shape, size and minimum content of cigarette packets contribute to the effectiveness of the health warnings.[90] The Advocate General acknowledged that the standardization of the shape, size and minimum content of cigarette packets affects the diversity, marketing opportunities and competitiveness of manufacturers of tobacco products; however, the protection of human health must prevail over purely economic interest,[91] and may justify 'even substantial negative economic consequences for certain economic operators'.[92] The judgment added to that, that the requirements still allow tobacco companies' 'opportunities for product differentiation'.[93]

As to the appropriateness and the necessity of large warnings, the judgment referred to the Guidelines for Implementation of Article 11 of the WHO FCTC, which states that big pictorial warnings are 'more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption'.[94]

Generally, in addressing the plaintiffs' arguments, the ECJ found the mentioned rules neither *arbitrary* nor *manifestly disproportionate*.[95]

While one should not underestimate the possible positive effect of pictorial warnings, such as making cigarette packs more visible and, probably, better memorized,[96] it does not necessarily mean that such practice will affect actual

88 *Ibid*.

89 Case C-491/01, British American Tobacco (Investments) Ltd and Imperial Tobacco [2002], ECR I-11453, para. 123; Case C-558/07, S.P.C.M. and Others [2009], ECR I-05783, para. 42; Case C-58/08, Vodafone and Others [2010], ECR I-04999, para. 52; and Case C-62/14, Gauweiler and Others [2015], ECLI:EU:C:2015:400, para. 67.

90 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853, para. 190.

91 *Ibid*., para. 193.

92 *Ibid*., para. 204.

93 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 199.

94 Guidelines for Implementation of Art. 11 of the WHO FCTC, point 7.

95 Opinion of AG Kokott Case C-547/14, Philip Morris Brands SARL [2015], ECLI:EU:C:2015:853, para. 209. Judgment Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, paras 200 and 211.

96 *See* more; Noar SM, Hall MG, Francis DB, et al., *Pictorial Cigarette Pack Warnings: A Meta-Analysis of Experimental Studies*, Tobacco Cont. (2015).

behaviour. For example, Joel Monárrez-Espino et al. in their systematic review of the effect of pictorial warnings on cigarette packages in smoking behaviour 'purposely excluded outcomes not related to behavior change, such as those looking at perceptions, attitudes, reactions, knowledge, or even motivation and intention to quit'.[97] They determined the evidence for the use of pictorial warnings is insufficient and if it does influence behaviour, the effect is modest compared with other tobacco control policies.[98] As Howells stated in his book on tobacco: 'Warnings may be necessary and valuable, but are not necessarily a sufficient form of protection', and to be efficient they need to be as firm as possible with no possibility for misinterpretation.[99] However, the modern behavioural approach[100] allows us to assume the cognitive limitations of consumers, and hence we can no longer assume that even clear and firm information presented for consumers will guarantee that consumers will not misinterpret it.

It is entirely possible that different health hazards displayed on the packs might raise an erroneous impression about the same product. Pictorial warnings are more vulnerable to different interpretations[101] and depend on how we perceive the information and what kind of information we consider risky for us. For example, the pictorial warning 'smoking can make you impotent' and cigarette packs stating 'smoking causes heart attacks' might have a different level of impact on different consumers. As a consequence thereof, they might choose the same product – cigarettes, but with the pictorial warning they deem less risky for them.

3.5 Proportionality and fundamental rights

During the litigation process, the plaintiffs invoked their right to freedom of expression and information.[102] In particular, they argued that Article 13 of the Directive violates Article 11 of the EU Charter of Fundamental Rights (further, EU CFR) and the principle of proportionality, by prohibiting certain design elements of the packs, including displays on the labelling's factually accurate information, such as

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97 J. Monárrez-Espino, B. Liu, F. Greiner, S. Bremberg & R. Galanti , *Systematic Review of the Effect of Pictorial Warnings on Cigarette Packages in Smoking Behavior*, 104(10) Am. J. Pub. Health e12 (2014).

98 *Ibid*.

99 Geraint Howells, *The Tobacco Challenge: Legal Policy and Consumer Protection*, 275 (Surrey: Ashgate Publishing 2011).

100 *See* more; Daniel Kahneman & Amos Tversky, *Subjective Probability: A Judgment of Representativeness*, 3 Cognitive Psychology 430–454 (1972); Dan Ariely, *Predictably Irrational* (New York: Harper Collins 2008); Cass R. Sunstein & Richard H. Thaler, *Nudge: Improving Decisions About Health, Wealth, and Happiness* (New York: Penguin Books 2009).

101 *See* more; *Warnings and Risk Communication* 294 (Michael S. Wogalter et al. eds, London: Taylor & Francis 2005).

102 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 146.

information about the TNCO content of the tobacco product[103] – information which could help consumers to make a more informed choice on purchase.

The EU Charter of Fundamental Rights[104] (further, EU CFR) and the European Convention on Human Rights[105] (further, ECHR) provide that everyone has the right to freedom of expression and information. Commercial information used by tobacco companies on cigarette packs also falls under the scope of the EU CFR and ECHR.[106] The ECJ held that it is true that the above-mentioned measures constitute an interference with a business' freedom of expression and information.[107] However, these rights are not absolute,[108] and according to the established case law, restrictions may be imposed provided these restrictions are in accordance with the general interests of the EU, and do not form disproportionate and unreasonable intervention impairing the essence of those rights.[109]

The ECJ pointed out that the Directive is not prohibiting all information about the product, but only certain elements and features of labelling[110] and that they are justified by the general interest of the whole EU – the protection of health. In addition, the ECJ concluded that considering the proven harmfulness of tobacco consumption, these prohibitions are proportionate and do not go beyond what is necessary. In proving the proportionality, the ECJ mostly based its argumentation on health reasons.[111]

Nevertheless, taking into account all the complications mentioned and some degree of uncertainty of the proposed measures, the ECJ dismissed all presented arguments and the plaintiffs met a 'crushing defeat'.[112]

4 THE LEGAL IMPLEMENTATION AND IMPLICATIONS OF LABELLING AND PACKAGING PROVISIONS

The following sections discuss the possible consequences of the chosen method of harmonization; specifically how it will affect the free movement of goods in the

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103 TPD 2014/40/EU Art. 13(1).
104 EU CFR Art. 11.
105 ECHR Art. 10.
106 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 147.
107 *Ibid.*, para. 148.
108 Elsmore & Obolevich, *supra* n. 7, at 28.
109 Case C-292/97, Kjell Karlsson and Others [2000], ECR I-02737, para. 45; Case 5/88, Wachauf [1989], ECR 2609, para. 18.
110 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 151.
111 *Ibid.*, paras 152 and 153.
112 ASH (Action on Smoking and Health) Chief Executive Deborah Arnott (19 May 2016) http://ash.org.uk/media-and-news/press-releases-media-and-news/tobacco-companies-legal-challenge-to-standardised-tobacco-packaging-fails-other-countries-to-follow-uk-lead/ (accessed 8 June 2017).

Member States' choices of going further and introducing additional labelling and packaging requirements.

4.1 Harmonization – to what extent?

When introducing the new Directive, the European Commission stated that some labelling and packaging requirements, which had not been fully harmonized under the TPD 2001, became a subject of important disparities between national regulations and created obstacles for the free movement of goods.[113] In addition, those requirements became outdated and no longer on a par with scientific evidence. Thus, the Commission concluded there was a necessity to adopt new internal market harmonization measures in order to eliminate existing obstacles to trade and prevent new ones.

The complication in relation to the European Commission initiative arises from the dual nature of the Directive, which intertwines the EU's and Member States' competences. The internal market is an area of shared competence between the EU and the Member States.[114] In its turn, the protection and improvement of human health belongs to the supporting competence,[115] i.e. the EU can only intervene to support, coordinate or complement the action of EU countries, and therefore the EU cannot require harmonization of the Member States' laws or regulations.

Thus, to ensure the facilitation of the internal market while ensuring the high level of protection of human health, the new Directive needed to find a proper balance between the EU intervention in harmonization with the internal market and the Member States' initiatives in the field of public health.

Minimum harmonization would allow Member States to maintain a higher degree of consumer protection by introducing stricter national measures.[116] However, the approach based on minimum harmonization would also assume that certain disparities will remain[117] whereas full harmonization would be more in line with the idea of the internal market[118] because it would ensure the free movement of goods, but it would also limit autonomous policy choices by Member States.

Finally, the Directive offered an intermediate approach, namely partial harmonization based on Article 114 TFEU, according to which Member States are allowed

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113 IA SWD(2012) 452 final, 19 Dec. 2012, 2.4.2., at 45.
114 TFEU Art. 4.
115 *Ibid.*, Art. 6.
116 *Consumer Law: Ius Commune Casebooks for a Common Law of Europe* 60 (Hans-W. Micklitz, Jules Stuyck & Evelyn Terryn eds, Oxford 2010).
117 *The Oxford Handbook of EU Law* 528 (Anthony Arnull & Damian Chalmers eds, 2015).
118 Micklitz et al., *supra* n. 116, at 60.

to apply stricter national measures than those prescribed in the Directive by ensuring that certain conditions are fulfilled.[119]

In many respects, the Directive is inspired by the WHO FCTC, but exceeds its minimum requirements; i.e. the Directive introduced mandatory health warnings covering 65% of the top surface of both the front and back of cigarette packages, while the FCTC required that health warnings should be 50% or more, but not less than 30%.[120] In addition, the Directive requires health warnings to include pictures and text[121] while the FCTC suggests only that health warnings may be in the form of or include pictures or pictograms.[122] Following the FCTC plain packaging idea,[123] Article 24(2) of the Directive allows Member States to introduce further measures relating to the presentation and packaging of tobacco products.[124]

However, as the Philip Morris Brands SARL case demonstrated, the Directive is vague as to whether Article 24(2) allows Member States to introduce further requirements to all aspects relating to the packaging of tobacco products, including harmonized ones, or only to those aspects which have not been harmonized by the Directive.[125] In the ECJ interpretation, Article 24(2) could be perceived as being in favour of further requirements for the packaging issues which have not been harmonized by the Directive.[126] Otherwise, as the ECJ indicated, it would undermine the regulations harmonized by the Directive[127] and would allow Member States to avoid the Commission notification procedure and further requirements prescribed in Article 114(4) to (10) TFEU.

After clarifying that Article 24(2) applies only to aspects of the packaging that have not been harmonized by the Directive, the ECJ scrutinized Article 24(2)'s alignment with Article 114 TFEU. The ECJ admitted that Article 24(2) does not ensure that 'products whose packaging complies with the requirements of the Directive may move freely on the internal market'[128] and it is 'the inevitable consequence' of the chosen method of harmonization.[129] However, it also added that while the chosen method of harmonization does not remove all obstacles to trade, it does remove some, and can be considered as an advantage for the functioning of the internal market.[130]

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119 TFEU Art. 114 (4–9).
120 WHO FCTC Art.11(1)(iv).
121 TPD 2014/40/EU, Art. 10.
122 WHO FCTC Art. 11(1)(v).
123 Guidelines for implementation of Art. 11 and Art.13 of WHO FCTC
124 TPD 2014/40/EU Art. 24(2).
125 Case C-547/14, Philip Morris Brands SARL [2016], ECLI:EU:C:2016:325, para. 68.
126 *Ibid.*, para. 73.
127 *Ibid.*, para. 71.
128 *Ibid.*, para. 79.
129 *Ibid.*, paras 80 and 81.
130 *Ibid.*, para. 81.

Drawing a parallel with the first Tobacco Advertising case,[131] which by rejecting Article 114 TFEU as a legal basis[132] for the Directive 98/43 on the advertising of tobacco products brought some dissonance in case law of the ECJ on minimum harmonization, we may say that the Philip Morris Brands SARL case may bring some clarity for future cases. In the first Tobacco Advertising case,[133] the Court held that minimum harmonization without a free movement clause would not contribute to the elimination of obstacles to free movement, and would not ensure the establishment or functioning of the internal market, thus it cannot use Article 114 TFEU as a legal basis. A similar approach was applied in the second Tobacco Advertising case.[134] At the same time, the EU has many minimum harmonization directives that do not contain a free movement clause.[135] The Philip Morris Brands SARL case offers the middle ground in that twofold view. The new TPD includes a free movement clause in Article 24(1), but it is highly stipulated by Article 24(2) and (3) of the Directive.

It may be argued that Article 114 TFEU might be used as a valid legal basis for harmonizing directives, without necessarily ensuring the free movement of all products in the internal market as in the first Tobacco Advertising case. Nevertheless, it should ensure the prohibition of the introduction of stricter domestic regulations on the issues already harmonized by the directives, as well as it should ensure the refraining from the regulation of issues which have not yet been harmonized.

However, the offered model of partial harmonization, the same as the model of minimum harmonization in the first Tobacco Advertising case, achieves similar results; it does not remove all obstacles to trade but only some of them. At the same time, the minimum harmonization model in the first Tobacco Advertising case was rejected, and in the Philip Morris Brands SARL case was accepted.

4.1[a] *Free Movement of Goods*

The Treaty provisions on free movement of goods still apply, unless there is full harmonization.[136] Consequently, any rules adopted by a Member State to

131 Case C-376/98, *Germany v. Parliament and Council* (Tobacco Advertising I) [2000], ECR I-08419.

132 *Ibid.*, para. 104.

133 *Ibid.*

134 Case C-380/03, *Germany v. Parliament and Council* (Tobacco Advertising II) [2006], ECR I-11573, paras 73 and 74.

135 Package Holidays Directive 90/314, 1990 O.J. (L 158/59); Unfair Contract Terms Directive 93/13, 1993 O.J. (L 95/29); Timeshare Directive 94/47, 1994 O.J. (L 280/83); Distance Contract Directive 97/7, 1997 O.J. (L 144/19); Sale of Consumer Goods Directive 99/44, 1999 O.J. (L 171/12).

136 *See* e.g. Case C-221/00, *Commission v. Austria* [2003], ECR I-01007, para. 42; Case C-99/01, Linhart and Biffl [2002], ECR I-09375, para. 18; Case C-421/04, Matratzen Concord [2006], ECR I-02303, para. 21.

implement packaging and labelling measures should comply with Articles 34–36, since packaging and labelling rules, as product requirements, fall within the scope of Article 34 TFEU.

Furthermore, 'quantitative restrictions' and 'measures having equivalent effect' – all trading rules of Member States which are capable to impede, directly or indirectly, actually or potentially, the EU trade[137] – shall be prohibited in order to ensure the free movement of goods within the EU.

Surely, any rule exceeding the minimum requirements of the Directive (including standardized packaging), implemented only by a few Member States, may contribute to the non-uniform development of the tobacco products market and constitute potential obstacles to free movement of goods in the EU, since the importer may have to change the packaging and labelling to secure access to the market. This issue arose in the Philip Morris Brands SARL case, where the tobacco industry claimed that the standardized packaging regulation infringes Article 34 because it restrains import of cigarettes from other countries.[138]

However, an infringement of Article 34 TFEU can be justified on the grounds of public health according to Article 36 TFEU and market requirements fulfilling certain conditions. Firstly, Member States must provide evidence that there exists a 'real risk' to human health and the proposed measures are directed to decrease or eliminate such risk. Secondly, such restrictions should not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Thirdly, these provisions should be proportional.

4.1[b] *Article 24(2) TPD*

Article 24(2) of the Directive allows Member States to introduce further measures relating to the presentation and packaging of tobacco products[139] following a set of conditions.

In particular, further measures shall be 'applicable to all products placed on its market', they shall be 'justified on grounds of public health, and be proportionate', and may not constitute 'a means of arbitrary discrimination or disguised restriction on trade between Member States'.[140] And finally, Member States are obliged to notify

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137 Case C -8/74, Dassonville [1974], ECR I-00837, at 852.

138 *R (on the application of British American Tobacco (UK) Limited) v. The Secretary of State for Health* [2016] EWHC 1169 (Admin), at 368.

139 According to Art. 24(2) TPD 2014/40/EU 'shall not affect the right of a Member State to maintain or introduce further requirements […] in relation to the standardisation of the packaging of tobacco products'.

140 TPD 2014/40/EU, Art. 24(2).

the Commission if they intend to exceed the mandated minimum provisions following the procedure stated in the Directive.[141]

According to Directive 2015/1535, in order to prevent technical barriers to trade, Member States must inform the European Commission of any draft technical regulation for products, including technical specifications regarding packaging and labelling requirements. In doing so, Member States should provide reasons for their actions and prove that those actions are necessary to fulfil 'essential requirements' in the public interests.[142] The notification procedure includes a transaction period of three months during which the European Commission and other Member States examine the proposed regulation. If the European Commission or a Member State argue that the notified regulation may constitute a barrier to trade, the procedure extends for another three months. Additionally, if Member States fail to notify the European Commission, they cannot enforce the regulations.[143]

With Article 24(2) the Directive introduces the parallel requirements to the principles of free movement of goods. While Articles 34–36 would probably allow justification of the stricter labelling and packaging rules based on a public health aim, Article 24(2) includes grounds for justification where principles of free movement of goods are supplemented by additional control from the European Commission.

4.2 Different solutions adopted by member states

Although the Directive came into force relatively recently, many Member States had already decided to go beyond the Directive's minimum requirements, and plain packaging legislation is spreading around the EU. On 20 May 2016, the United Kingdom[144] and France[145] became the first countries in the EU to implement plain packaging. Ireland is in the process of finalizing plain packaging requirements. Hungary[146] and Slovenia[147] provided

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141 The Directive refers to Directive 98/34/EC, which was amended by the Directive 2015/1535 on 9 Sept. 2015.

142 Directive 2015/1535, Art. 4.

143 Case C-194/94, *CIA Security International SA v. Signalson SA* and Securitel SPRL [1996], ECR I-02201.

144 Regulations adopted in Mar. 2015; came into force on 20 May 2016. Regulations apply to England, Wales, Northern Ireland and Scotland. Legislation applies to cigarettes and hand-roll tobacco. Transitional period until 20 May 2017.

145 The Assemblée Nationale, on 24 Nov. 2015, the legislation was held to be compliant with the constitution by the Constitutional Council on 21 Jan. 2016; the detailed decree and Ministerial Order were published on 22 Mar. 2016 and came into force 20 May 2016. Legislation applies to cigarettes and hand-roll tobacco. Transitional period until 1 Jan. 2017.

146 Notification provided to the European Commission on 21 Sept. 2015. http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2015&num=529 (accessed 8 June 2017).

147 Draft Act restricting the use of tobacco and related products. Notification provided to the European Commission on 26 May 2016. http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=135 (accessed 8 June 2017).

notification to the European Commission for drafting plain packaging legislation. Belgium,[148] Sweden[149] and Finland[150] are formally deliberating the introduction of plain packaging.

In going beyond the Directive's minimum requirements, the UK and France standardize packaging in terms of colour – all packs have the same uniform colour (Pantone 448 C, also known as 'opaque couché' or the 'ugliest colour in the world'),[151] the same shape and size, the same inscription of the brand and name, requiring removal of logos or other distinctive marks. And, no noise, no smell,[152] no additional effects after retail sale (such as inks that appear over time, after heat or in certain light).[153] This has been done because of a belief that neutralizing the style of packaging will help in changing behavioural intentions.[154]

When the UK considered plain packaging regulation, it had three options:[155]

(1) follow the Directive's minimum requirements, i.e. the 'do nothing option'
(2) go beyond the Directive and require standardized tobacco packaging of cigarettes
(3) wait for Australia's experience on this issue.

During the litigation process, Philip Morris International insisted there is another – less restrictive and more effective - alternative to plain packaging: taxation.[156] However, it was declined by the High Court of Justice of England and

148 Minister of Social Affairs and Public Health, *Anti-Tobacco Plan with Smoking Ban in Vehicles with Children and Excise Increases* (9 Apr. 2016), news release. http://www.deblock.belgium.be/fr/plan-anti-tabac-avec-interdiction-de-fumer-en-voiture-en-pr%C3%A9sence-d%E2%80%99enfants-et-augmentation-des (accessed 8 June 2017).

149 Swedish Government Official Reports 2016:14 http://www.regeringen.se/contentassets/a6818bf095a24080a5770001d0ea40b5/en-oversyn-av-tobakslagen_nya-steg-mot-ett-minskat-tobaksbruk.pdf, at 531. Government Bill 2015/16:82 http://www.regeringen.se/contentassets/6d8ca69aa46047bfaa19923695a6f390/atgarder-for-okad-folkhalsa-pa-tobaksomradet_genomforandet-av-eus-tobaksproduktdirektiv.pdf (accessed 8 June 2017).

150 Finland Ministry of Social Affairs and Health, *Roadmap to a Tobacco-Free Finland: Action Plan on Tobacco Control* (2014), published 27 June 2014. https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/70305/URN_ISBN_978-952-00-3513-6.pdf?sequence=1 (accessed 8 June 2017).

151 GfK Blue Moon Report, Market Research to Determine Effective Plain Packaging of Tobacco Products (Aug. 2011).

152 Public Health: The Standardized Packaging of Tobacco Products Regulations, 2015 No. 829, sec. 11, at 8.

153 *Ibid.*, sec. 12, at 8.

154 France's notification to the European Commission No. 2015/109/F (France), Government amendment relating to the introduction of neutral packets for tobacco products.

155 Department of Health, Impact Assessment 3080, Standardized Packaging of Tobacco Products 17 June.2014.

156 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWHC 1169 (Admin), at 652.

Wales, arguing that there is no evidence that tax increase will achieve the aim of standardized packaging.[157]

Between possible alternatives, the UK chose to follow Australia's example and implemented standardized tobacco packaging. In 2012, Australia[158] became the first country to introduce the plain packaging of tobacco products. This legislation was challenged from the three possible angles. It successfully survived a constitutional challenge in the High Court of Australia, a case[159] brought by four major tobacco companies.[160] It underwent an investment challenge by Philip Morris Asia under the 1993 Agreement between the Government of Australia and the Government of Hong Kong for the Promotion and Protection of Investments.[161] And it is awaiting the report of the World Trade Organization (further, WTO) regarding disputes brought by Ukraine, Honduras, the Dominican Republic, Cuba and Indonesia.[162]

Similar to Australia's case, the UK withstood the challenge brought by the tobacco industry against its innovative regulation.[163] Since Australia is the only country to have implemented plain packaging long enough to generate the first results, the High Court of Justice of England and Wales questioned whether the plain packaging regulation in Australia was able to generate positive public health effects so fast and whether we can apply Australia's experience to the EU Member States. These concerns are supported by recent research, which concluded that so far there is no evidence that plain packaging affected smoking 'in any jurisdiction'.[164] At the same time, the UK collected and investigated a solid base of evidence, and even attracted an independent reviewer, Emeritus Professor Sir Cyril Chantler, a paediatrician and medical researcher, to give his view of public health evidence for plain packaging. Sir Cyril Chantler concluded that there is sufficient evidence from independent sources that the standardized packaging in conjunction with other tobacco control measures in time would contribute to a 'modest but important' reduction of tobacco consumption especially among youth.[165]

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157 *Ibid.*, at 666–668.

158 Tobacco Plain Packaging Act, No. 148, 2011.

159 Case S409/2011, *JT International SA v. Commonwealth of Australia* [2012].

160 British American Tobacco, Imperial Tobacco, Japan Tobacco and Philip Morris.

161 PCA Case No. 2012-12, *Philip Morris Asia Limited (Hong Kong) v. The Commonwealth of Australia*.

162 Ukraine launched a legal challenge against Australia through DSB in Mar. 2012 (DS434), Honduras (DS435) in Apr. 2012, Dominican Republic (DS441) in July 2012, Cuba (DS458) in May 2013, and Indonesia (DS467) in July 2013. The WTO decided to consider these five complaints together. In 2015 Ukraine suspended its proceedings.

163 *R (on the application of British American Tobacco (UK) Limited) v. The Secretary of State for Health* [2016] EWHC 1169 (Admin).

164 Neil McKeganey & Christopher Russell, *Tobacco Plain Packaging: Evidence Based Policy or Public Health Advocacy?*, Elsevier 567 (2015).

165 Standardized packaging of tobacco, Report of the independent review undertaken by Sir Cyril Chantler (Apr. 2014), at 6.11.

This might inspire other countries to follow the UK example. However, some Member States found difficulties determined by constitutional restrictions when evaluating their possibilities of introducing plain packaging. Sweden, for example, concluded that plain packaging would require a change to the Swedish Constitution that may take several years.[166] More specifically, under the Freedom of the Press Act, public institutions are prohibited from intervening against abuses of freedom of expression. Even in relation to the Directive's requirements, the Swedish Government found that the size of health warnings may violate the Swedish Constitution by restricting a trader's ability to choose text content, although the Government dismissed that doubt later on.[167]

Some Member States have already implemented plain packaging regulation although other Member States might never follow that path and will settle for implementing the minimum requirements only. And some of the countries have already met difficulties in following the further requirements and implementing plain packaging in their national laws; hence we may expect that under the new Directive the internal market will become more fragmented than ever before in relation to the appearance of cigarette packs.

5 CONCLUSION

Essentially we can see that the EU and ECJ are very confident in their views regarding the regulation of tobacco products and a new approach is emerging in which the protection of human health is increasingly taken into account.

Particular attention of the Directive is dedicated to the promising area of labelling and packaging. Specifically, through the new provisions the EU aims to turn cigarette packs into a dissuasive instrument that would deter smoking initiation. Such a move by a confident EU legislator towards an alternative demand-side regulation to change consumer behaviour in relation to smoking certainly inspires a partial respect. However, it also raises questions about the effectiveness of the proposed measures. In particular, the lack of factual evidence on plain packaging raises uncertainty about whether standardized packaging would serve a useful public health purpose. In that regard, the UK experience and collected empirical evidence might serve as a template for other Member States and encourage those countries that hesitate to go further with standardized packaging to proceed with it.

By following this path, the EU chooses a partial harmonization approach. In tight entwinement of Article 168 TFEU, which requires the EU to merely complement national policies and leave the fundamental choices for the Member States to

166 Swedish Government Official Reports 2016:14, *supra* n. 149, at 531.
167 Government Bill 2015/16:82, *supra* n. 149.

decide, and Article 168(5) that particularly excludes any harmonization of the laws and regulations of the Member States regarding tobacco, yet again Article 114 TFEU gets the upper hand, proving its powerfully broad applicability.

The chosen regime of partial harmonization might mean a never-ending story for policymakers in their initiatives to harmonize the market of tobacco products. By setting up minimum requirements on the cigarette packs' appearance, the Directive certainly made one step forward towards stricter regulation of tobacco products that is stricter than that required by the TPD 2001. From another perspective, the Directive allows, fulfilling certain requirements, the introduction of further measures in the area of labelling and packaging. Some Member States already implemented plain packaging in their laws, some met difficulties, and some Member States will probably follow the minimum requirements only. Although it is constrained by Article 24 of the Directive, further standardization of the packaging of tobacco products at the national level could raise more disparities between national provisions regarding the labelling and packaging of tobacco.

Considering the current regulations and countries' different initiatives of following the minimum requirements or going further in standardization of packaging, there is a high probability that the new Directive's labelling and packaging provisions are awaiting the same destiny as the TPD 2001, and a new Directive will be required. Again Member States will implement different laws, which would result in a non-homogenous appearance of cigarette packs throughout the EU, raise obstacles for the free movement of goods and require harmonization measures in the immediate future. All these beg the question about the effectiveness of the proposed 'smooth' harmonization approach in the regulation of tobacco products. Particularly, it may be asked to what extent the regulations that allow maintenance of old or creation of new trade obstacles can be named as an effective legal instruments for the internal market.