EUROPEAN COMMISSION

Brussels, 19 March 2015
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Court procedural documents

TO THE PRESIDENT AND MEMBERS OF THE COURT OF JUSTICE

WRITTEN OBSERVATIONS

submitted by the **EUROPEAN COMMISSION**, represented by Mr Marc VAN HOOF, Principal Legal Adviser, Ms Chiara CATTABRIGA and Mr Jonathan TOMKIN, Members of its Legal Service, acting as Agents, with an address for service at the office of Ms Merete CLAUSEN, also a Member of its Legal Service, Bech Building, L-2721 Luxembourg, who consent to service by e-Curia

in Case C-547/14

The Queen on the Application of

PHILIP MORRIS BRANDS SARL
PHILIP MORRIS LIMITED
BRITISH AMERICAN TOBACCO UK LIMITED

Claimants

- and –

THE SECRETARY OF STATE FOR HEALTH

Defendant

IMPERIAL TOBACCO LIMITED
BRITISH AMERICAN TOBACCO UK LIMITED
JT INTERNATIONAL SA
GALLAHER LIMITED
TANN UK LIMITED AND TANNPAPIER GMBH
V. MANE FILS
DEUTSCHE BENKERT GMBH & CO KG AND BENKERT UK LIMITED
JOH. WILH. VON EICKEN GMBH

Interveners

Concerning the validity of 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 L 127, 29.4.2014, p.1).

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A. The Legal framework

Union law

Directive 2014/40/EU

1. Directive 2014/40/EU of the European Parliament and of the Council[1], adopted on the basis of Articles 53(1), 62 and 114 TFEU, seeks to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.

2. As the first Recital of Directive 2014/40/EU makes clear, the Directive repeals and replaces Directive 2001/37/EC of the European Directive 2001/37/EC of the European Parliament and of the Council[2] in order to reflect scientific, market and international developments which have arisen in the period since that directive was adopted. As with the present Directive, the validity of Directive 2001/37/EC was previously the subject of a reference on validity by the High Court (England and Wales).[3]

3. According to the fourth recital of Directive 2014/40/EU, the substantial differences that exist between the Member States' rules on the manufacture, presentation and sale of tobacco and related products present obstacles to the smooth functioning of the internal market. That recital further provides that in the light of scientific, market and international developments such discrepancies are expected to increase.

4. Pursuant to the fifth recital of Directive 2014/40/EU, the approximation of Member States' rules governing the manufacture, presentation and sale of tobacco and related products serves the objectives of eliminating such obstacles to the functioning of the international market.

5. In sixth recital of Directive 2014/40/EU, the Union legislature observes the existence of an increasing tendency of manufacturers to concentrate production for

[1] 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 L 127, 29.4.2014, p.1, hereinafter "Directive 2014/40/EU", "the Tobacco Products Directive", or "the Directive").

[2] European Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ 2001 L 194, p. 26).

[3] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741.

the entire Union in only a small number of production plants within the Union, resulting in significant cross-border trade of tobacco and related products. It is considered that such a situation calls for stronger legislative action at Union rather than national level to achieve the smooth functioning of the internal market.

6. The seventh recital of Directive 2014/40/EU explains that Union action is also necessary in order to implement the WHO Framework Convention on Tobacco Control ("FCTC") of May 2003, the provisions of which are binding on the Union and its Member States.

7. The eight recital of Directive 2014/40/EU provides as follows:

"In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people."

8. In the 15th recital of Directive 2014/40/EU, the Union legislature observes as follows:

The lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. Some Member States have adopted legislation or entered into binding agreements with the industry allowing or prohibiting certain ingredients. As a result, some ingredients are regulated in certain Member States, but not in others. Member States also take differing approaches as regards additives in the filters of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles to the smooth functioning of the internal market are expected to increase in the coming years, taking into account the implementation of the FCTC and the relevant FCTC guidelines throughout the Union and in the light of experience gained in other jurisdictions outside the Union. The FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for 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.

9. The 22nd and 23rd recitals of Directive 2014/40/EU state that disparities continue to exist between national provisions regarding the labelling of tobacco products, which are liable to constitute a barrier to trade and to impede the smooth

functioning of the internal market in tobacco products and which should therefore be eliminated. Pursuant to the 24th recital, the adaptation of provisions on labelling is also necessary to align the rules that apply at Union level to international developments.

10. Pursuant to the 25th recital of Directive 2014/40/EU, labelling provisions should also be adapted to new scientific evidence. By way of example, it is observed that the indication of the emission levels for tar, nicotine and carbon monoxide on unit packets of cigarettes has proven to be misleading as it leads consumers to believe that certain cigarettes are less harmful than others. It is considered that minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness.

11. The 27th and 28th recitals of Directive 2014/40/EU read as follows:

Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for-one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products.

In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimensions of the health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including the shape and opening mechanism. When prescribing a cuboid shape for a unit packet, rounded or bevelled edges should be considered acceptable, provided the health warning covers a surface area that is equivalent to that on a unit packet without such edges. Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned.

12. In the 34th recital of Directive 2014/40/EU, the Union legislature observes that all tobacco products have the potential to cause mortality, morbidity and disability. It is therefore considered important to monitor developments as regards novel tobacco products.

13. Article 1 of Directive 2014/40/EU, entitled Subject Matter, provides as follows:

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;

(c) the prohibition on the placing on the market of tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the obligation to submit a notification of novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;

in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control.

14. Title II of the Directive is divided into 3 Chapters. Chapter 1, composed of Articles 3 to 7, regulates ingredients and emissions. Chapter 2, composed of Articles 8 to 16, governs Labelling and Packaging. Chapter 3, composed of Articles 17 to 19, concerns tobacco for oral use, cross-border distance sales of tobacco products and novel tobacco products.

15. Article 3 of Directive 2014/40/EU sets out, among others, maximum emission levels for tar, nicotine, and carbon monoxide. The methods by which such emissions are measured are laid down in Article 4 of the Directive.

16. Pursuant to Article 5 of Directive 2014/40/EU, Member States are required to impose certain reporting obligations on manufacturers and importers of tobacco products, in particular, as regards the ingredients and emissions of the products they manufacture or import, by brand name and type. Manufacturers or importers are also required to keep competent authorities informed of any modification to the composition of a product that affects the information provided in accordance with that Article.

17. Article 6 of Directive 2014/40/EU, provides for additional reporting requirements applicable in respect of certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list to be drawn up by the Commission. Pursuant to paragraph 2 of that Article, such an enhanced reporting obligation shall apply, among others, to additives that:

    (a) are considered to contribute to, and increase, the toxicity or addictiveness of the products concerned to a significant or measurable degree

    (b) result in a characterising flavour

    (c) facilitate inhalation or nicotine uptake

    (d) lead to the formation of substances that are carcinogenic, mutagenic or reprotoxic (CPR) properties and which increase the CMR properties of any of the products concerned to a significant or measurable degree.

18. Article 7 of Directive 2014/40/EU requires Member States to prohibit the placing on the market of tobacco products with a characterising flavour. Pursuant to point 25 of Article 2, such products are defined as having a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product.

19. Articles 8 to 16 of Directive 2014/40/EU, falling under Chapter II of the Directive, sets out requirements relating to the labelling, packaging and presentation of tobacco products, and in particular, the requirement for tobacco products to carry health warnings. As regards health warnings, Articles 8 to 12, specify, among others, the font, manner and dimensions according to which they are to appear on each unit packet.

20. Article 13 of Directive 2014/40/EU provides as follows:

1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:

(a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

(b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;

(c) refers to taste, smell, any flavourings or other additives or the absence thereof;

(d) resembles a food or a cosmetic product;

(e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

21. Pursuant to Article 14(1) of Directive 2014/40/EU, unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.

22. Pursuant the second paragraph of Article 14, a unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.

23. Article 17 of Directive 2014/40/EU provides for the prohibition by Member States of the placing on the market of tobacco for oral use. Such a prohibition does not extend to Austria, Finland and Sweden, by virtue of Article 151 of their Treaty of Accession.

24. Article 24 of Directive 2014/40/EU reads as follows:

> *1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.*
>
> *2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.*
>
> *3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.*

25. Article 27 of Directive 2014/40/EU regulates the conditions in which the Commission may exercise its power to adopt delegated acts. It provides as follows:

> *1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*

2. *The power to adopt delegated acts referred to in Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall be conferred on the Commission for a period of five years from 19 May 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. *The delegation of powers referred to in Articles 3(2) and(4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.*

4. *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*

5. *A delegated act adopted pursuant to Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.*

26. Pursuant to Article 29 of Directive 2014/40/EU, the provisions of the Directive are to be transposed into the national legal orders of the Member States by 20 May 2016 and shall be applied as of that date.

International Law

The WHO Framework Convention on Tobacco Control

27. The WHO Framework Convention on Tobacco Control ("FCTC") was adopted by the World Health Assembly in Geneva on 21 May 2003 and entered into force on 27 February 2005.

28. By Decision dated 2 June 2004, the Council approved the WHO Framework Convention on Tobacco Control[4] and authorised its ratification. Following the Union's formal accession on 30 June 2005, the Convention entered into force as regards the Union on 28 September 2005. The Convention has to date[5] been ratified by 180 Parties, including the Union and all the Member States.

29. Pursuant to its Article 3, the FCTC provides a framework for tobacco control measures to be implemented by the contracting parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

30. Article 5(2)(b) of the FCTC requires contracting parties to implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

31. The Convention envisages the adoption of a variety of different measures in support of its objectives. Contracting parties are required to adopt measures, *among others*, relating to the reduction of demand for tobacco, to include both 'price' and 'non-price' measures. While the former concerns measures affect the cost of tobacco products, the latter concerns, among others, measures relating to their composition, packaging and labelling.

32. Article 9 of the Convention, entitled "*Regulation of the contents of tobacco products*", provides for the adoption of guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of those contents and emissions. That Article further places a positive obligation on each contracting party to implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

33. Article 11 of the Convention is entitled "*Packaging and labelling of tobacco products*". Pursuant to that provision, each contracting party is required to adopt and implement, in accordance with its national law, effective measures to ensure, among others, that tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco

[4] Council Decision of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control (OJ L213 of 15.06.2004, p.8).

[5] As of 19 March 2015.

product is less harmful than other tobacco products. Article 11 expressly refers to the use of terms such as 'low tar', 'light', 'ultra-light' or 'mild' as examples of false, misleading, deceptive means by which tobacco products may be promoted. That Article further provides for the adoption of measures to ensure that each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages.

34. In accordance with Articles 9 and 10 of the Convention, the Conference of the Parties to the FCTC adopted partial guidelines for the implementation of those Articles.[6] The guidelines focus on the means by which the attractiveness of tobacco products may be reduced, in order to reduce the prevalence of tobacco use and dependence among new and confirmed users. The guidelines recommend that contracting parties regulate by means of prohibition or restriction, ingredients that may be used to increase palatability in tobacco products and that have colouring properties. The guidelines also recommend that contracting parties prohibit ingredients in tobacco products that may create the impression that they have a health benefit or that are associated with energy and vitality, such as stimulant compounds.

35. Section 3 of the Article 9 and 10 Guidelines propose measures to be adopted governing the content of tobacco products. Section 3.1.2.2. of the Guidelines makes the following observation:

> *The harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. Tobacco industry documents have shown that significant effort has been put into mitigating these unfavourable characteristics. Harshness can be reduced in a variety of ways including: adding various ingredients, eliminating substances with known irritant properties, balancing irritation alongside other significant sensory effects, or altering the chemical properties of tobacco product emissions by adding or removing specific substances.*
>
> *Some tobacco products contain added sugars and sweeteners. High sugar content improves the palatability of tobacco products to tobacco users. Examples of sugars and sweeteners used in these products include glucose, molasses, honey and sorbitol.*

[6] Partial guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures) (the "Article 9 and 10 Guidelines"). The Guidelines were adopted by the Conference of the Parties at its fourth session (15 to 20 November 2010), with amendments adopted at its fifth session (12 to 17 November 2012).

Masking tobacco smoke harshness with flavours contributes to promoting and sustaining tobacco use. Examples of flavouring substances include benzaldehyde, maltol, menthol and vanillin.

Spices and herbs can also be used to improve the palatability of tobacco products. Examples include cinnamon, ginger and mint.

Recommendation:

Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products.
Ingredients indispensable for the manufacturing of tobacco products and not linked to attractiveness should be subject to regulation according to national law.

36. The Conference of the Parties to the FCTC also adopted guidelines on the implementation of Article 11 of the WHO Convention.[7] The guidelines contain detailed measures on packaging and labelling intended to ensure the effective implementation of the obligations set out in Article 11.

37. Point 3 of the Article 11 Guidelines observes that "*globally, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality due to tobacco use and exposure to tobacco smoke*". It further states that effective health warning and messages and other tobacco product packaging and labelling measures are key components of a comprehensive, integrated approach to tobacco control.

38. Point 7 of the Article 11 Guidelines notes that evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. According to such evidence, larger warnings with pictures 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. It is further noted that larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people.

39. Points 8 to 35 of the Article 11 Guidelines propose measures regulating the design of packaging and labelling of tobacco products. Such proposals cover, among other,

[7] Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products) (the "Article 11 Guidelines"). The Guidelines were adopted by the Conference of the Parties at its third session (17 to 22 November 2008).

specifications governing the size, language, location, rotation and content of health warnings, as well as the use and presentation of pictures of pictograms.

40. Points 36 to 42 of the Article 11 Guidelines contain proposals governing the process by which effective packaging and labelling requirements are developed and recommends, among others, that there should be no exemptions for small-volume companies or for different types and categories of tobacco products, in order to better focus on the specific health effects related to each product.

41. Point 46 of the Article 11 Guidelines proposes that Parties consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). It is considered that such measures may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from such warnings and messages, and address industry package design techniques that may suggest that some products are less harmful than others.

B. The facts and the procedure

42. By two applications lodged before the Administrative Court of the High Court of Justice (England and Wales), Philip Morris Brands SARL and Philip Morris Limited, on the one hand, and British American Tobacco UK Limited, on the other, instituted judicial review proceedings against the Secretary of State for Health. The Claimants, who are tobacco manufacturers established in the United Kingdom, sought to challenge the intention and obligation of the United Kingdom government to adopt legislation transposing Directive 2014/40/EU into national law.

43. In support of its claim, the Claimants submitted that the Directive constituting the basis of the national implementing measure to be adopted was invalid. In particular, they claimed that the Directive did not have a sufficient legal basis. In addition, the Claimants submitted that the Directive breached the principles of proportionality and subsidiarity. The Applicant further submitted the Directive breached provisions of the Charter of Fundamental Rights, in particular the rights conferred by Articles 16 and 17 to conduct a business and the right to property as well as Treaty provisions governing the use of delegated acts or powers.

44. The High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) decided to join and stay the two sets of proceedings and refer the following questions to the Court for a preliminary ruling:

Legal basis

1. Is the Directive invalid in whole or in part because Article 114 TFEU does not provide an adequate legal basis? In particular:

   (a) In relation to Article 24(2) of the Directive:
      (i) on its proper interpretation, to what extent does it permit Member States to adopt more stringent rules in relation to matters relating to the "standardisation" of the packaging of tobacco products; and,
      (ii) in light of that interpretation, is Article 24(2) invalid because Article 114 TFEU does not provide an adequate legal basis?

   (b) Is Article 24(3) of Directive 2014/40/EU, which allows Member States to prohibit a category of tobacco or related products in specified circumstances, invalid because Article 114 TFEU does not provide an adequate legal basis?

   (c) Are the following provisions invalid because Article 114 TFEU does not provide an adequate legal basis:
      (i) the provisions of Chapter II of Title II of Directive 2014/40/EU, which relate to packaging and labelling;
      (ii) Article 7 of Directive 2014/40/EU, insofar as it prohibits menthol cigarettes and tobacco products with a characterising flavour;
      (iii) Article 18 of Directive 2014/40/EU, which allows Member States to prohibit cross-border distance sales of tobacco products; and,
      (iv) Articles 3(4) and 4(5) of Directive 2014/40/EU, which delegate powers to the Commission in relation to emission levels?

   Proportionality and Fundamental Rights

2. In relation to Article 13 of Directive 2014/40/EU:
   (a) on its true interpretation, does it prohibit true and non-misleading statements about tobacco products on the product packaging; and,
   (b) if so, is it invalid because it violates the principle of proportionality and/or Article 11 of the Charter of Fundamental Rights?

3. Are any or all of the following provisions of Directive 2014/40/EU invalid because they infringe the principle of proportionality:
   (a) Articles 7(1) and 7(7), insofar as they prohibit the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components;
   (b) Articles 8(3), 9(3), 10(1)(g) and 14, insofar as they impose various pack standardisation requirements; and,

(c) Articles 10(1)(a) and (c), insofar as they require health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging?

Delegation/Implementation

4. Are any or all of the following provisions of Directive 2014/40/EU invalid because they infringe Article 290 TFEU:
   (a) Articles 3(2) and 3(4) concerning maximum emission levels;
   (b) Article 4(5) relating to measurement methods for emissions;
   (c) Articles 7(5), 7(11) and 7(12) concerning the regulation of ingredients;
   (d) Articles 9(5), 10(1)(f), 10(3), 11(6), 12(3) and 20(12) concerning health warnings;
(e) Article 20(11) concerning the prohibition of electronic cigarettes and/or refill containers; and/or,
(f) Article 15(12) concerning data storage contracts?

5. Are Articles 3(4) and 4(5) of Directive 2014/40/EU invalid because they breach the principle of legal certainty and/or impermissibly delegate powers to external bodies that are not subject to the procedural safeguards required by EU law?

6. Are any or all of the following provisions of Directive 2014/40/EU invalid because they infringe Article 291 TFEU:
(a) Article 6(1) concerning reporting obligations;
(b) Article 7(2)-7(4) and 7(10) concerning implementing acts relating to the prohibition of tobacco products in certain circumstances; and/or,
(c) Articles 9(6) and 10(4) concerning health warnings?
Subsidiarity

7. Is Directive 2014/40/EU and in particular Articles 7, 8(3), 9(3), 10(1)(g), 13 and 14 invalid for failure to comply with the principle of subsidiarity?

C. The preliminary reference

Admissibility

45. At the outset, the Commission has serious doubts as to the admissibility of the Reference, both as a whole and as regards a number of its constituent parts.

46. In accordance with settled case-law, the preliminary reference procedure constitutes an instrument of cooperation, intended to assist the administration of justice, by enabling a national court to obtain a ruling on the interpretation or validity of Union

law that is necessary for it to be able to resolve a particular dispute upon which it is called to adjudicate.[8] Moreover, references made pursuant to Article 267 TFEU are admissible only where the ruling to be delivered is capable of being taken account of by the national court, and is necessary for the effective resolution of a dispute.[9] While it is acknowledged that national courts have wide discretion in determining both the necessity for a reference, and the terms of any questions referred, the Court has consistently held that, since its function under the reference procedure is to assist in the administration of justice, it will not deliver advisory opinions on general or hypothetical questions.[10]

47. However, in the present case, the reference raises questions that are, in a number of respects, hypothetical. Moreover, there is no clear indication as to the existence of a particular dispute regarding the interpretation or validity of the specific provisions which form the basis of questions 2 to 7. Furthermore, it is not apparent from the Order for Reference, that a ruling on each of the questions referred is in fact necessary for the effective resolution of the proceedings before the national court.

48. In the first instance, the Commission considers that in the context of judicial review proceedings concerning *anticipated national measures implementing a Union directive*, challenges to a yet unimplemented directive are hypothetical in character, when they concern provisions which do not have direct effect, and the implementation of which is liable to depend on the exercise of Member State discretion. This is because the relevance of any ruling on such provisions will depend on the future choices that Member States will make in implementing the Directive and therefore, can only be known once discretion has been exercised. Thus, for example, the question on the entitlement for a Member State to prohibit online tobacco sales is, from the Claimants' perspective, purely hypothetical if the national legislator chooses not to prohibit such sales. It follows that questions concerning the interpretation of non-directly effective provisions which confer discretion on Member States, such as those which constitute the basis of questions 1(a), (b), (c)(iii), for example, are merely hypothetical until such time as the national implementing measures are adopted.

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[8] Case 244/80, *Foglia,* ECLI:EU:C:1981:302, paragraph 18, Case C‑225/02, *García Blanco,* ECLI:EU:C:2005:34, paragraphs 27 and 28; and Case C-212/04, *Konstantinos Adeneler and Others v Ellinikos Organismos Galaktos (ELOG)*, ECLI:EU:C:2006:443, paragraph 40.

[9] Case C-225/02, *García Blanco*, ECLI:EU:C:2005:34.

[10] Case 244/80, *Foglia,* ECLI:EU:C:1981:302, paragraph 18. See also Joined Cases C-261/08 and C-348/08, *María Julia Zurita García and Aurelio Choque Cabrera v Delegado del Gobierno en la Región de Murcia*, ECLI:EU:C:2009:648; and Case C-470/12, *Pohotovosť s.r.o. v Miroslav Vašuta* ECLI:EU:C:2014:101.

49. Questions 1(c)(iv), 4, 5 and 6 are equally hypothetical since they concern obligations and empowerments delegated to the Commission (as opposed to the Secretary of State). Moreover, in certain respects, they are even hypothetical as regards the Commission, since in some cases,[11] the conditions that would trigger obligations on the part of the Commission to adopt delegated or implementing acts have not yet arisen (and in theory may not arise as they depend on the occurrence of contingent events). In any event, since none of the measures provided for in these provisions has yet been adopted, the Secretary of State cannot be under any obligation to transpose such measures into national law.

50. In addition, certain questions on interpretation are also hypothetical in that they concern the interpretation of provisions that have not arisen in the context of a particular dispute as regards the application of the Directive's provisions to a specific set of circumstances. Thus, for example, any ruling in response to questions 1(a)(i) and 2(a), which call for generalised interpretations of Articles 13 and 24, would have to be delivered in the abstract, and therefore have the character of an advisory opinion.

51. The Commission is moreover concerned that the procedure by which the present reference has been made, is incompatible with the wording and spirit of Article 267 TFEU. Pursuant to that provision, the Court of Justice has jurisdiction to provide rulings on the interpretation or validity of Union law, where in the course of proceedings, such a question is raised before a court or tribunal and if it is considered that a decision "*is necessary to enable it to give judgment*".

52. However, the terms of the request for a preliminary ruling suggest that the numerous questions raised by the applicant tobacco manufacturers were forwarded to the Court of Justice without a full hearing of competing positions. Indeed, it is apparent from the request for a preliminary ruling that there was consensus that Union institutions are "*the persons best placed to defend the validity of the Directive*". The national court therefore considered it was not even necessary for the Respondent "*to produce submissions or evidence relating to the substance of the claim*".[12] In respect of questions 2 to 7, it is noted that while the reference sets out the arguments submitted by the Claimants, there is no information detailing the arguments submitted by the Respondent in response to each of the issues raised.

53. The Commission submits that such an approach is incompatible with Article 267 TFEU in several respects. First, the absence of such information means that it is not possible to identify any specific dispute arising in respect of the questions referred,

[11] See, for example, Articles 3(4) and 4(5) of the Directive.

[12] See the Order for Reference, paragraph 4, page 6.

when the existence of a dispute is required pursuant the well-established case-law of the Court.[13] The intervening Member States and Institutions, and this Court itself, are effectively invited to take positions on a single set of submissions rather than adjudicating on a substantive dispute between two parties.

54. More fundamentally still, the Commission is concerned that such a procedure reduces the role of the national court to that of a procedural intermediary which is at odds with the wording, spirit and character of the procedure established by Article 267 TFEU, which is founded on cooperation and dialogue between the national courts and the Court of Justice. Indeed, it is not apparent that the national court was in a position to conclude on the necessity of a ruling to resolve the issues raised, when it did not yet hear the parties' respective positions on the majority of questions referred.

55. Forwarding questions to the Court, without a substantive hearing of competing views and a genuine dispute at a national level, permits *United Kingdom based litigants* to take, what essentially amounts to direct actions for the annulment of Union acts. It further facilitates litigants engaging in trawling exercises, raising any number of grounds upon which to challenge Union legislation, regardless of their relevance or application to the circumstances of any particular case and without being subject to the time-limits imposed for the institution of annulment proceedings under Article 263 TFEU.

56. The Commission submits that the difference in treatment is exacerbated in circumstances, where claimants established in other Member States are not afforded the same possibility to participate as interveners in the national proceedings. In particular, it is noted that in the present proceedings, an association of tobacco growers based in Poland, KZPT, sought to intervene in the national proceedings giving rise to the present reference. Such an application was, however, refused, among others, on the ground that "*there was little or no evidence to connect KZPT to the UK*." The High Court considered that "*[e]ach of the organisations in this case was able to demonstrate, to a greater or lesser extent, a firmer relationship with the UK*".[14]

[13] Case 244/80, *Foglia,* ECLI:EU:C:1981:302.

[14] Order of Mr Justice Turner, High Court of Justice, Queen's Bench Division [2014] EWHC 3668 (Admin).

57. Certainly, the Commission acknowledges that the Court has, in Case C-491/01, *British American Tobacco (Investments) Ltd*,[15] previously accepted that a national court may refer questions relating to the validity of a yet unimplemented Directive. However, it is submitted that this case-law does not obviate the requirement for a genuine dispute and substantive proceedings at a national level, in which the national court has heard submissions from both parties and where the ruling to be delivered is both relevant and necessary for the effective resolution of the dispute at issue.

58. The Commission underlines that the combination of permitting references on non-transposed legislation, with the absence of substantive proceedings entailing a specific dispute at national level makes it possible for individuals or entities to challenge entire packages of Union legislation, no matter how hypothetical or remote the issues raised may be to their particular legal situation. Indeed, the situation is further exacerbated if, as in the present case, it could be considered sufficient for an Order for Reference to transmit Claimants' sweeping doubts about a great number of different provisions of Union law, against a great number of primary law rules and principles, on the basis that they are "reasonably arguable" and without it being necessary to provide an account of the reasons upon which such doubts are based. The Commission considers that the present proceedings seeks to extend the approach that was adopted in the BAT case, to an extent which amounts to a *circumvention (détournement)* of the preliminary reference procedure and is liable to establish a precedent that undermines the system of remedies provided for in the Union legal order.

59. Concerning the adequacy of information provided in the Order for Reference, the Commission wishes to highlight that in a number of instances, knowledge is erroneously assumed as regards the forms of order sought by the Claimants, the facts stated, and the contents of evidence referred to before the national court. Thus for example, paragraphs 16, 19-21, 25, 29, 34-36, 38-40, 43, 45, 49-50, 53 of the Order for Reference merely observe that the Claimants seek to rely on one or other expert report, study and witness statement in support of a particular claim, without providing any indication as to the content of such evidence and the basis for their authors' claims. Equally opaque is Question 7. Here the national court requests a ruling on the validity of Articles 8(3), 9(3), 10(1)(g), 13 and 14 in the light of the principle of subsidiarity, but fails to provide a single reason for which the Claimants, or indeed the Court, would consider such provisions incompatible with that principle. The Commission and interveners are thereby left in the position of

[15] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 74. See also Case C‑343/09, *Afton Chemical Limited/Secretary of State for Transport*, ECLI:EU:C:2010:419

having to speculate upon the possible grounds for which the Claimants may have considered those provisions invalid.

60. The same considerations apply to Question 6. Whereas, the national Court in a single sentence,[16] conveys the Claimants' doubts concerning the validity of Articles 6(1), 7(2), 7(3), 7(4), 7(10), 9(6) and 10(4), the Reference fails to set out any of the arguments that may have been advanced in support of that claim.

61. However, pursuant to Article 23 of the Statute of the Court of Justice, only the Request for a Preliminary Ruling is notified to the parties entitled to submit observations. Accordingly mere references to the arguments, studies, reports and witness statements relied upon in the main proceedings are not sufficient to safeguard the right of each party under the above provision to submit observations[17].

62. In the present case, it is evident that without a clearer picture of the arguments and evidence submitted and relied upon by the parties, the Commission, or indeed other Member States and Institutions, are not in a position to submit observations that engage in detail with the arguments, reports and witness statements invoked. For this reason too the questions referred by the High Court of Justice should therefore be held inadmissible.[18]

63. In light of the above considerations, the Commission has serious doubts as to the admissibility of the present reference as a whole. This would not, however, prevent the referring court from making a further request for a ruling, once it had an opportunity to consider competing views, to provide sufficient information regarding the arguments and evidence relied upon, and once it is assured that the questions to be raised are not hypothetical but necessary to resolve a specific and genuine dispute upon which it is called to adjudicate.

64. In the alternative, the Commission invites the Court to declare the inadmissibility of at least Questions 1(a), 1(b), 1(c)(iii) and (iv), 4, 5, 6 in their entirety and also Question 7, in as far as it refers to Articles 8(3), 9(3), 10(1)(g), 13 and 14 of the Directive.

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[16] See the Order for Reference, paragraph 55.

[17] See, for example, Case C-422/98, *Colonia Versicherung and others v Belgian State, ECLI:EU:C:1999:113*, paragraph 8 and more recently Case C-356/14, *Hunland-Trade Mezőgazdasági Termelő és Kereskedelmi kft v Fëldmûvelêsügyi Miniszter*, ECLI:EU:C:2014:2340, paragraphs 16 and 17.

[18] See in this regard the Opinion of Advocate General Wahls in Case C-497/12, *Gullotta and Farmacia di Gullotta Davide & C.* ECLI:EU:C:2015:168.

Question 1: Article 114 TFEU as a legal base

65. By the first part of its first question, the national court seeks guidance on the extent to which Article 24(2) of Directive 2014/40/EU permits Member States to adopt more stringent rules in relation to matters relating to the "standardisation" of tobacco products. In the light of the interpretation give, the court proceeds to ask whether the provision can properly be based on Article 114 TFEU.

Admissibility of Question 1(a)(i)

66. In addition and without prejudice to the general reservations on admissibility expressed in the first part of these submissions, the Commission has specific doubts relating to the admissibility of Question 1(a)(i) as an autonomous question on the interpretation of Directive 2014/40/EU.[19]

67. According to settled case-law of the Court, questions seeking the interpretation of a provision of Union law pursuant to Article 267 TFEU are admissible where the ruling to be delivered, is capable of being taken account of by the national court, and is necessary for the effective resolution of a dispute.[20] The Court has consistently held that, since its function under the reference procedure is to assist in the administration of justice, it will not deliver advisory opinions on general or hypothetical questions.[21]

68. However, in the context of the present proceedings, which concern solely the validity of a yet unimplemented Directive, there is no factual dispute between the parties that would require the interpretation and application of Article 24(2). It follows that any ruling on the scope and interpretation of that Article would have to be delivered in the abstract and therefore have the character of an advisory opinion.

69. The Commission therefore considers Question 1(a)(i) should be declared inadmissible as an autonomous question in its own right.

70. Of course, it is accepted that the competing interpretations of Article 24(2) may be relevant in the context of evaluating the validity of that provision. To that extent, the Commission proposes to consider the substance of Question 1(a)(i) as part of its overall observations on the validity of Article 24(2).

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[19] See in particular paragraph 50 above of these observations.

[20] Case C‑225/02 *García Blanco* [2005] ECR I‑523, paragraphs 27 and 28.

[21] Case 244/80, *Foglia,* ECLI:EU:C:1981:302, paragraph 18. See also Joined Cases C-261/08 and C-348/08, *María Julia Zurita García and Aurelio Choque Cabrera v Delegado del Gobierno en la Región de Murcia*, ECLI:EU:C:2009:648; Case C-470/12, *Pohotovosť s.r.o. v Miroslav Vašuta* ECLI:EU:C:2014:101.

Question 1(a)(ii), (b), (c)(i), (c)(ii), c(iii) and (c)(iv)

71. By the remainder of its first question, the national court inquires as to whether Article 114 TFEU, constitutes an adequate legal basis for the adoption of Directive 2014/40/EU. In particular, the Court inquires as to whether a number of specific provisions can adequately be based on Article 114 TFEU. Those provisions include:

(i) Article 24(2) of the Directive (permitting Member States to adopt further measures that are additional to those provided for under the Directive)
(ii) Article 24(3) of the Directive (permitting Member States to prohibit certain categories of tobacco or related product)
(iii) The provisions of Chapter II of Title II of the Directive, which relate to the packaging and labelling of tobacco products
(iv) Article 7 of the Directive, insofar as it prohibits menthol cigarettes and tobacco products with a characterising flavour
(v) Article 18 of the Directive, which allows Member States to prohibit cross-border distance sales of tobacco products; and
(vi) Article 3(4) and Article 4(5) which delegate powers to the Commission in relation to emission levels.

72. The Commission submits that the provisions of the Treaty upon which Directive 2014/40/EU was adopted, constitute both an appropriate and sufficient legal basis for the adoption of that Directive. Each of the aspects identified by the referring court shall be considered in turn.

(i) Article 24(2)

73. By the first part of the first question, the national court inquires whether, the extent to which Article 24(2) of Directive 2014/40/EU permits Member States to introduce further requirements applicable to tobacco products, renders that provision invalid on the grounds of incompatibility with Article 114 TFEU.

74. In the context of national proceedings, the Claimants had submitted that Article 114 TFEU is capable of serving as legal basis for measures which improve the functioning of the internal market. However, it alleged that insofar as the Directive permits Member States to introduce further measures, it does not facilitate the internal market for tobacco products and is therefore incompatible with Article 114 TFEU.

75. In this respect, the Commission observes that Directive 2014/40/EU does not seek to achieve full harmonisation of the packaging of tobacco products. As is apparent from its Article 1(b), the objective of the Directive is to approximate the laws,

regulations and administrative provisions of the Member States concerning, among others, "*certain aspects* of the labelling and packaging of tobacco products […]"[22]. The aspects concerned are those which are specifically and explicitly regulated in the provisions of Chapter II of the Directive, such as the health warnings (Articles 9 to 12), the use of misleading elements or features in product presentation (Article 13), the shape, the material and the opening mechanism (Article 14) of unit packets.

76. The fact that Directive 2014/40/EU states, in Article 24(2), that it does not affect Member States' right either to maintain or adopt further requirements as regards the packaging of tobacco products is the inevitable consequence of the fact that the Directive does not regulate all aspects of the packaging of tobacco products and constitutes an incremental, rather than an exhaustive, harmonisation measure. Since the Directive does not purport to harmonise exhaustively all aspects of tobacco production – and in particular the packaging of tobacco products - it follows that Member States retain certain competences in this field.

77. The only purpose of Article 24(2) is therefore to clarify that, in view of the limited scope of the harmonisation of national rules on labelling and packaging of tobacco products brought about by the Directive, Member States are not deprived of the power to regulate those aspects which are not specifically and explicitly addressed by the Directive. In other words, Article 24(2) makes clear that the silence of the Union legislature as regards certain aspects of the labelling and the packaging of tobacco products must be interpreted as leaving to the Member States, and not to manufacturers, the right to decide on those aspects.

78. This interpretation of Article 24(2) is confirmed by the wording of Recital (53) of the Directive according to which Member States "*should retain the power to impose further requirements in certain respects in order to protect public health […] in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules*"[23]. The same recital clarifies that the Union legislature's intention in adopting Article 24(2) was not to grant Member States the right to derogate from the provisions of the Directive. Measures adopted at national level as regards aspects of labelling and packaging not regulated by the Directive were not only required to be compatible with obligations under the Treaty and the WTO, but, in addition, could not "*affect the full application of the Directive*".

79. The Commission submits that the mere fact that the Directive clarifies the limits of its own scope cannot constitute grounds for its invalidity.

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[22] Emphasis added.

[23] Emphasis added.

80. Indeed, a similar provision was included in legislation preceding Directive 2014/40/EU, which was previously considered and upheld by the Court in Case C-491/01 *British American Tobacco*. Article 13(2) of Directive 2001/37/EC similarly clarified that that Directive did not affect the right of Member States to keep or introduce additional and more stringent rules.

81. The Commission underlines that while Article 114 TFEU provides for the approximation of national laws, it does not follow that the Union legislature is compelled to adopt measures that immediately provide exhaustive harmonisation. On the contrary, it is apparent from internal market provisions of the Treaty, and their evolution through successive Treaty amendments, that the drafters of the Treaties founding the Union envisaged the attainment of a single market as a gradual process achieved in stages. It is submitted, that in the context of Article 114 TFEU, it is perfectly legitimate for the Union legislature to approach harmonisation incrementally.

82. The legality of this approach has been confirmed by the Court's case-law. Thus, for example, in its judgment in Case 37/83 *Rewe*[24] the Court held that, in the exercise of the powers conferred upon Union institutions by (what is now) Article 114 TFEU, those institutions may proceed towards harmonization in stages and require only the progressive abolition of unilateral measures adopted by the Member States.

83. Indeed, it is established practice for the Union legislature to adopt measures which incrementally approximate Member States' laws, without seeking to immediately achieve exhaustive harmonisation. Thus, for example, in its judgment in Case C-491/01 *British American Tobacco*, the Court noted that legislation preceding Directive 2001/37/EC had only covered certain aspects (leaving it open for Member States to adopt measures in areas not covered by such legislation).[25] The Court further observed that increasing awareness of the health risks posed by tobacco products could reasonably be expected to result in a corresponding increase in regulation.[26] Directive 2001/37/EC could therefore be regarded as a further, incremental, step in regulating the manufacture and sale of tobacco products.

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[24] Case C-37/83*, Rewe-Zentral AG v Direktor der Landwirtschaftskammer Rheinland, ECLI:EU:C:1984:89*, paragraph 20.

[25] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 66.

[26] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 67.

84. It is apparent that, like Directive 2001/37/EC which preceded it, Directive 2014/40/EU forms part of a continuum of measures, ensuring the progressive approximation of rules governing the manufacture and marketing of tobacco and related products. This is also made clear from the terms of Article 28(2)(a) of the Directive, which imposes a reporting obligation on the Commission in view of the adoption of further harmonising measures in the future with regard in particular to the "*experience gained with respect to the design of package surfaces not governed by this Directive*".

85. The Commission submits that the mere fact that Directive 2014/40/EU does not provide for exhaustive harmonisation of the rules concerning the packaging of tobacco products, and that it does not therefore preclude Member States from taking measures which go further than those provided for in the Directive, does not mean that the harmonising rules which *it does adopt*, are not validly based on Article 114 TFEU. On the contrary, the Commission considers that for the purposes of determining the appropriateness of Article 114 TFEU, it is the rules *which are adopted* and not those, which are not adopted, that are of relevance. It is submitted that it is perfectly legitimate and established practice for the Union legislature to approach harmonisation incrementally.

86. As the Court has noted in its judgment upholding the validity of Directive 2001/37/EC, the very fact that that Directive enshrined in its Article 13(1), a provision guaranteeing the free movement of products which comply with its requirements, ensured the Directive's full effect in relation to its object of improving the conditions for the functioning of the internal market.[27] It is submitted that the same must apply equally in respect of Article 2014/40/EU, the equivalent provision of which is found in Article 24(1) of that Directive.

87. It becomes apparent that Article 24(2) of Directive 2014/40/EU simply reflects the principle of conferral, whereby Member States retain competence to maintain additional or further requirements in a field that has not, to date, been subject to exhaustive harmonisation. The Commission submits that without such a provision, there could be ambiguity and doubt as regards the specific scope for action of Member States as regards issues not regulated by the Directive.

88. Of course, while Article 24(2) of Directive 2014/40/EU permits the adoption of further measures in accordance with existing national competence, such existing competence is not unlimited. Article 24(2) of the Directive expressly stipulates that the exercise of national retained competence must be justified on grounds of public health and comply with the principle of proportionality. Moreover, it clarifies that

[27] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 74.

the measures may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In so doing, it reflects the well-established case-law of the Court of Justice concerning the exercise of national competences, as set out in a variety of different fields of action. Indeed, as the Court has held in Case C-135/08 *Rottman*[28]:

> "*the fact that a matter falls within the competence of the Member States does not alter the fact that, in situations covered by European Union law, the national rules concerned must have due regard to the latter.*"[29]

89. The Commission further notes that the Court has had the opportunity to rule on a situation similar to the present case, in Case C-366/04 *Georg Schwarz*.[30] Here, the Court accepted that the adoption of stricter measures by a Member State, constituted the exercise of retained competence, and fell outside the scope of the Directive at issue and consequently was to be analysed exclusively against the light of the relevant provisions of the Treaty.

90. The mere fact that Directive 2014/40/EU does not achieve exhaustive harmonisation, and that Article 24(2) of the Directive clarifies the continuing entitlement of Member States to exercise their retained competence does not mean that the Directive does not serve to enhance the functioning of the internal market and that Article 114 TFEU does not constitute a valid legal base for its provisions. The Commission submits that the measures adopted, including the obligation to permit the circulation of tobacco manufactured in compliance with the Directive, ensure that its objective of enhancing the internal market is fulfilled.

91. Finally, it follows from the above that the arguments advanced by the Claimants before the national court as regards the alleged breach of Article 114(5), (8) and (10) TFEU are also unfounded. Those provisions specify the discretion left to Member States in respect of matters that *have already been harmonised* at a Union level. However, given that the "*further requirements*" referred to in Article 24(2) of Directive 2014/40/EU, refers precisely to national measures that have not been harmonised by the Directive and fall outside its scope of application, Article 114(5), (8) and (10) is of no relevance to such measures.

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[28] Case C-135/08, *Rottman v. Freistaat Bayern*, ECLI:EU:C:2010:104.

[29] Case C-135/08, *Rottman v. Freistaat Bayern*, ECLI:EU:C:2010:104, paragraph 41.

[30] Case C-366/04, *Georg Schwarz*, ECLI:EU:C:2005:719.

(ii) Article 24(3)

92. By the second part of its first question, the national court inquires whether, in permitting Member States to prohibit particular categories of tobacco or related products, Article 24(3) of Directive 2014/40/EU is compatible with Article 114 TFEU.

93. Before the national court, the Claimants submitted that a provision authorising the prohibition of particular categories of tobacco or related products[31] cannot be regarded as facilitating the internal market for tobacco products and therefore cannot validly be based on Article 114 TFEU.

94. The Commission submits that, like Article 24(2), Article 24(3) of Directive 2014/40/EU serves to delimit the Directive's scope of application and to ensure consistency with and respect for the allocation of competences as provided for in the Union Treaties. In particular, whereas Directive 2014/40/EU harmonises the conditions under which tobacco products and related products are manufactured and marketed within the Union, Article 24(3) makes clear that such measures are not intended to encroach upon the competence reserved to Member States to prohibit a certain category of tobacco or related products on purely public health grounds, where despite the high level of health protection achieved by the Directive, such prohibition would be required having regard to the specific situation in the Member State concerned.

95. In this regard, it is recalled that pursuant to the terms of Article 168(5) TFEU, the Union is expressly precluded from adopting harmonisation measures relating to tobacco products on public health (as opposed to internal market) grounds. It follows that competence for the adoption of measures relating to tobacco whose direct objective is the protection of public health is retained by the Member States. A typical example of such a measure would be the imposition of a total ban of an entire category of product, such as a general ban on the placing on the market of all cigarettes based on purely public health grounds.

96. An alternative interpretation would mean that neither the Union nor its Member States could adopt such restrictive measures. By clarifying that Directive 2014/14/EU does not purport to interfere with the right reserved to Member States to prohibit a whole category of tobacco products or related products where, despite the level of health protection achieved by the Directive, their specific situation so

[31] As regards the notion of "related products" in Article 24(3), the Commission observes that this notion only includes e-cigarettes and herbal products, so that this provision does not allow Member States to prohibit specific components of tobacco products such as filters, papers, capsules.

requires, the Directive ensures that it respects the allocation of competences as provided for in the Treaties.

97. It may additionally be noted that Article 24(3) includes a number of procedural safeguards designed to prevent any unjustified use by the Member States of their competences in a way that would hamper the achievement of the internal market purpose of the Tobacco Products Directive. In fact, Article 24(3) provides for the national measures to be notified to the Commission, which must in turn approve or reject them after having verified whether those measures "are justified, necessary and proportionate to their aim" and "are a means of arbitrary or disguised restriction on trade between Member States". In the Commission's view, this mechanism ensures that the objective pursued by the Directive of enhancing the functioning of the internal market is fully achieved.

98. The Commission observes that Article 114(5), (8) and (10) TFEU do not provide any support for the Claimants' position. First of all these provisions are addressed to the Member States and not to the Union legislature and therefore they do not aim at limiting the power of the Union legislature in the adoption of harmonisation measures.

99. Secondly, paragraphs (5) and (8) of Article 114 TFEU do not purport to alter the substantive division of competences between the Union and its Member States as provided for in the Union Treaties. As such, those provisions only apply to the extent that the Union has harmonised a particular field – having had the necessary competence to do so. However, given that the Union legislature has no competence to prohibit an entire category of tobacco or related products in order to address a specific problem of public health in an individual Member State, that competence must necessarily remain with the Member States. It follows that Article 114(5) and (8) cannot apply and has no bearing on a provision such as Article 24(3) which serves merely to emphasise the fact that the Directive respects the competences reserved to Member States under the Treaties.

100. The same is true for Article 114(10) TFEU. This provision is also premised on the competence of the Union to adopt harmonisation measures that could provide the basis for the subsequent adoption of provisional measures by the Member States under the safeguard clause. However, as already observed, the competence of the Union under Article 114 does not extend to cover the situation described in Article 24(3), namely the ban of an entire category of tobacco or related products in order to address a specific problem of public health in an individual Member State.

101. Having regard to these considerations, it becomes apparent that it is a provision to the contrary - that is, a provision that would purport to preclude Member States from adopting measures prohibiting a whole category of tobacco or related products

on pure health grounds in a situation where the level of health protection afforded by the directive does not allow the specific concerns of that Member State to be addressed - which would render the Directive invalid, as it would be incompatible with the competences reserved to Member States under the Treaties.

102. The Commission concludes that the fact that the Directive clarifies the limits of its scope and that it reflects the guarantees of Member State competence in accordance with the principle of conferral, cannot constitute grounds for its invalidity. The fact that Directive 2014/40/EU does not preclude Member States from exercising their competence to prohibit a whole category of tobacco or related products on public health grounds in a situation where the level of health protection afforded by the Directive does not allow their specific concerns to be addressed, does not mean that the Directive does not serve to enhance the functioning of the internal market and that Article 114 TFEU does not constitute a valid legal base for its provisions. On the contrary, the Commission submits that the measures adopted, including the obligation to permit the circulation of tobacco products that are manufactured in compliance with the Directive, ensure that its objective of enhancing the internal market is fulfilled.

(iii) Chapter II of Title II

103. By the third part of the first question, the referring court essentially asks whether Article 114 TFEU constitutes an adequate legal basis for the Directive's provisions approximating the labelling and packaging of tobacco products.

104. It is apparent from the request for a preliminary ruling, that the Claimants dispute the internal market need for the introduction of the labelling and packaging measures adopted in Directive 2014/40/EU. In particular, they dispute the internal market justification for the restrictions that Article 13 imposes with respect to the information that may be placed on the labelling of unit packets and any outside packaging of tobacco products.

105. It is settled case-law that recourse to Article 114 TFEU is justified where the measures adopted on the basis of that provision are intended to improve the conditions for the establishment and functioning of the internal market and genuinely have that effect.[32] In particular, the Court has held the measures adopted must actually contribute to the elimination of obstacles to the free movement of

[32] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 60.

goods or to the freedom to provide services, or to the removal of distortions of competition.[33]

106. The Court has also held that the Union legislature may have recourse to, what is now, Article 114 TFEU, for the purposes of preventing the future emergence of obstacles to trade resulting from multifarious development of national laws. However, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them.[34]

107. In this regard, the Commission recalls that, in the context of examining the validity of Directive 2001/37/EC, the Court has accepted that trade between Member States in tobacco products, especially cigarettes, represents a relatively large part of that market in the Union[35] and that differences in their national laws relating to tobacco products, both actual and potential, justified the adoption of harmonising measures under Article 114 TFEU. Moreover, in that context, the Court expressly upheld the validity of provisions harmonising national rules on packaging and labelling.[36]

108. The Commission submits that notwithstanding the existence of previous Union instruments regulating labelling of tobacco products[37], differences between the Member States' laws, regulations and administrative provisions concerning, among others, the presentation and sale of tobacco products, continue to exist and act as a barrier to trade.[38] Such differences are highlighted expressly in the fourth and fifth

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[33] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd an Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 60.

[34] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 61 and cases cited.

[35] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 64. The Commission's Impact Assessment confirms that cross border trade of tobacco continues to be important and suggests that one third of tobacco products manufactured within the EU are sold across the borders (See Doc. SWD (2012) 452 final, of 19 December 2012, Commission Staff Working Document, Impact Assessment Accompanying the document "Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, Part 1, p. 12, fig 5).

[36] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraphs 61 to 99 (and paragraphs 65, 67, and 72).

[37] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 65, referring to Directive 89/622.

[38] See, by analogy, Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 65.

recitals of Directive 2014/40/EU as well as in the Explanatory Memorandum to the Proposal for the Directive. The latter document explains that the heterogeneous development of norms in Member States has led to, and is likely to continue to result in, fragmentation of the internal market.[39]

109. The extent of divergences existing in the legal orders of the Member States, as regards labelling and packaging, is also readily apparent from the Impact Assessment accompanying the Proposal for the Directive[40].

110. As regards labelling, for example, it is evident from the Impact Assessment that Member States' national rules vary as regards both the content and display of health warnings. Thus, for example, whereas certain Member States require only text warnings, others require images, or combinations of images and text.[41] The Impact Assessment also discloses differences as regards the use of specific images that may be used,[42] or the requirement and content of text health warnings[43]. The Impact Assessment notes that in at least one Member State (France) promotional elements on the package were already banned as part of the advertising ban and that certain Member States have indicated an intention to introduce standardised tobacco packaging.[44]

111. As regards packaging, it is apparent that here too significant variations emerge, with Member States applying different rules as regards the minimum[45] or

[39] Explanatory Memorandum, p. 2.

[40] Doc. SWD (2012) 452 final, cit.

[41] According to the Impact Assessment, eight Member States required combined picture and text health warnings to appear on cigarette packs. Whereas two Member States (Hungary and Ireland) had passed legislation introducing pictorial health warning as of 2013 and one Member State (Poland) was planning to pass similar legislation.

[42] The Impact Assessment points to variance between the Member States as regards the choice of pictorial image to be displayed on tobacco products. While two Member States (Belgium and Hungary) use a whole library of 42 warnings, a further eight Member States authorised the use of 14 images deemed most effective for their population. See Doc. SWD (2012) 452 final, Part 4, p.4.

[43] Thirteen Member States complemented health warnings with references to cessation services, of which four (Belgium, France, the Netherlands and Slovenia) on a mandatory basis.

[44] The Impact Assessment makes reference to developments in Belgium, France, Finland and the United Kingdom. Reference is also made to developments in Norway. See Doc. SWD (2012) 452 final, Part 4, p.4.

[45] According to the Impact Statement, fourteen Member States (Austria, Czech Republic, Estonia, Finland, France, Greece, Ireland, Luxembourg, Lithuania, Poland, Portugal, Denmark, Romania, and Spain). stipulate a minimum pack size of twenty cigarettes. Whereas in four Member States (Hungary, Germany, the Netherlands and Sweden) a pack must contain at least 19 Cigarettes. In Italy, cigarettes must be sold,

maximum[46] number of cigarettes that may be included in any cigarette package,[47] affecting the size of the package.

112. Furthermore, the adoption of additional rules on packaging and labelling is expressly provided for by the FCTC to which all the Member States are contracting parties. Article 11 of the FCTC expressly provides for the adoption of measures intended to ensure that tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions or that a particular tobacco product is less harmful than other tobacco products. Moreover, the Article 11 Guidelines propose the adoption of a wide variety of measures regulating the design of packaging and labelling of tobacco products. Such proposals cover, among other, specifications governing the size, language, location, rotation and content of health warnings, as well as the use and presentation of pictures or pictograms.

113. As the Court has recognised, the growing consciousness of the dangers to health posed by the consumption of tobacco products means that it is likely that obstacles to the free movement of those products will continue to arise by reason of the adoption by the Member States of new rules reflecting that development and intended more effectively to discourage consumption of those products by means of warnings and information appearing on their packaging or to reduce the harmful effects of tobacco products by introducing new rules governing their composition.[48]

114. In this context, the Claimants cannot validly assert that the Tobacco Products Directive unduly restricts their freedom to adapt the packaging of their products to national consumer preferences. Such freedom only exists as far as, and as long as, national rules are not adopted regulating the appearance of the packaging of these products. However, as already observed at paragraphs 108 to 113 above, rules on appearance and packaging had already been adopted or were likely to be introduced by the Member States at the time of the adoption of the Directive.

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either in packets of 10 or 20. In the UK, the minimum pack size is 10. See Doc. SWD (2012) 452 final, Part 4, p.4.

[46] Hungary has limited the maximum number of cigarettes that may be sold in a single packet to fifty.

[47] Certain Member States have specific rules prohibiting sale of tobacco products separately from their original packaging. Such prohibition arises, for example, in Slovenia. Lithuania bans the sale of single cigarettes, cigarillos and long cigarettes. Latvia bans the sale of single tobacco products and herbal smoking products, though not cigars and cigarillos.

[48] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 67.

115. It is submitted that the existence of the kinds of divergences between Member States as outlined in the Impact Assessment and summarised above, is of particular importance when read in conjunction with the sixth recital, in which it is observed that tobacco manufacturers increasingly concentrate the production of tobacco products for the entire Union, within a small number of plants within the Union. As the Union legislature noted, such a situation gives rise to significant cross-border trade of tobacco and related products justifying stronger legislative action at Union level.

116. The Commission further recalls that it is well established that differences in rules between Member States relating to the requirements to be met by products, including those relating to their packaging, are in themselves liable, in the absence of harmonisation at Union level, to constitute obstacles to the free movement of goods.[49]

117. Thus, for example, in Case C-366/04 *Georg Schwarz*,[50] the Court accepted that national measures which require different and potentially more burdensome packaging of certain categories of products, could constitute a barrier to free movement of goods and therefore an obstacle to the internal market, precisely because the difference in packaging requirements entails additional cost in adapting the products to the requirements of that market. The Commission submits that the such a logic applies *a fortiori* in a context where a number of different Member States operate (or are likely to operate) different packaging rules and where importers may be required to adapt their product to a number of different requirements set out in different Member States.

118. Similarly, in Case 261/81 *Walter Rau Lebensmittelwerke*[51] the Court acknowledged that the imposition of packaging requirements by a Member State was capable of rendering "*the marketing of […] products more difficult or more expensive either by barring them from certain channels of distribution or owing to the additional costs brought about by the necessity to package the products in question in special packs which comply with the requirements in force on the market of their destination.*" The Court therefore rejected the suggestion that individual packaging requirements imposed by a Member State could not constitute an obstacle to the marketing of the product.

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[49] See, in this regard, Joined Cases C-267/91 and C-268/91, *Keck and Mithouard* [1993] ECR I-6097, paragraph 15). See also Case 261/81, *Walter Rau Lebensmittelwerke* ECLI:EU:C:1982:382; Case C-366/04 *Georg Schwarz*, ECLI:EU:C:2005:719; Case C-457/05, *Schutzverband der Spirituosen-Industrie Ev* ECLI:EU:C:2007:576.

[50] Case C-366/04, *Georg Schwarz*, ECLI:EU:C:2005:719.

[51] Case 261/81 *Walter Rau Lebensmittelwerke,* ECLI:EU:C:1982:382, paragraphs 14 and 15.

119. The Commission considers that the Union legislature was perfectly entitled to adopt norms to ensure that the presentation of tobacco and related products are subject to harmonised laws applicable throughout the territory of the Member States and thereby promote the effective functioning of the internal market and avoid the distortion of competition within the Union.

120. Even if the provisions of Directive 2014/40/EU do not harmonise fully the appearance of the packaging of tobacco products, and thereby leave Member States with a certain degree of flexibility in exercising residual competences, and even if those provisions sometimes imply different requirements as regards different Member States[52], they nonetheless serve either to remove or prevent the emergence of some of the main obstacles to the free circulation of tobacco products in the internal market. As a result of these rules, manufacturers and importers are relieved from the obligation of having to adapt the main features of the packaging of these products - such as the size and the shape of the package or the pictures, the size and the layout of the health warnings - to the requirements of different national laws.

121. Furthermore, the Commission observes that, as the Court has recognised in Case C-491/01, *British American Tobacco*, the Union legislature can only properly exercise its function in safeguarding the general interests recognised by the Treaty, such as public health, if it has the freedom to amend the relevant Union legislation so as to take account of changes in circumstances or advancements in scientific knowledge and understanding. Therefore, even where a provision of Union law guarantees the removal of all obstacles to trade in the area it harmonises, that fact cannot make it impossible for the Union legislature to adapt that provision in step with other considerations, such as, in particular, new developments based on scientific facts[53]. The display of tar, nicotine and carbon monoxide levels and the size of health warnings were, according to the Impact Assessment[54], areas in which, despite the harmonisation achieved by Directive 2001/37, an update was necessary in order to take into account new evidence which has since become available.

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[52] This is the case, for example, with Article 8(1) of the Directive, according to which the health warnings must be written in the language or languages of the Member State where the product is placed on the market. The same requirement was already provided for in Article 5(6)(e) of Directive 2001/37 and is frequently imposed by the Union legislation harmonising the manufacture and the presentation of consumers products. See, for example, Article 15 of Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p.18). In other cases, the Directive leaves some flexibility to the Member States as regards, for example, the text of the general warning provided for in Article 9(1). Such flexibility must however be interpreted in the light of the judgment of the Court of 22 June 1993, Case C-11/92, *The Queen v Secretary of State for Health, ex parte Gallaher Ltd, Imperial Tobacco Ltd and Rothmans International Tobacco (UK) Ltd*, ECLI:EU:C:1993:262.

[53] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraphs 77 to 79.

[54] See Doc. SWD (2012) 452 final, Part 1, p.45.

122. The Court has also held, in the same case, that measures adopted on the basis of Article 114 TFEU may incorporate provisions not aimed directly at improving the conditions for the functioning of the internal market so long as their purpose is to ensure the effectiveness of other provisions concerning the internal market and imposed in pursuit of that objective[55]. As Recital (28) of the Directive makes clear, provisions regarding the dimension of health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including shape and opening mechanism, were necessary in order to ensure the integrity and visibility of health warnings.

123. The Claimants contend that the provisions on packaging and labelling of the Directive are in contradiction with the purpose of Article 114 TFEU as they have the potential to distort competition in the internal market by substantially impairing the ability of manufacturers to differentiate their products and by increasing illicit trade.

124. In this respect the Commission observes that the Directive still allows for some degree of differentiation as far as the packaging of tobacco products is concerned. Moreover there is no conclusive evidence that the new provisions on packaging and labelling of the Directive will lead to distorted competition.

125. In any case, it must be recalled that Article 114 TFEU provides for the adoption of measures aiming, on the one hand, at facilitating the internal market of the concerned products while, on the other hand, ensuring a high level of health protection. In the exercise of this competence the Union legislature is therefore called to strike a balance between competing interests. The fact that that degree of differentiation is now arguably more reduced than it was under Directive 2001/37/EC is but a reflection of the different balance between these competing interests that the Union legislature could – without exceeding its broad discretion – decide to strike in light of new developments.

126. Finally as regards the alleged impact of the contested provisions on illicit trade, the Commission observes that, as the Impact Assessment notes[56], concerns about increased illicit trade expressed by manufacturers and suppliers to the tobacco industries have never been fully substantiated. Moreover, the Union legislature has taken measures to tackle the risk of illicit trade by introducing a tracking and tracing system for the legal supply chain (Article 15 of the Directive) complemented by security features on unit packs (Article 16 of the Directive).

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[55] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 82.

[56] Doc. SWD (2012) 452 final, Part. 1, p. 96.

127. In view of the foregoing, the Commission concludes that Article 114 TFEU constitutes a perfectly appropriate and adequate basis for the provisions on labelling and packaging included in Chapter II of Title II of the Directive.

(iv) Article 7

128. By the fourth part of the first question, the referring court essentially asks whether Article 114 TFEU constitutes an adequate legal basis for Article 7, insofar as it prohibits menthol cigarettes and tobacco products with a characterising flavour.

129. The Commission notes that in regulating the ingredients of tobacco products, including those which give tobacco products a characterising flavour, the Directive builds on measures that had previously been adopted under Directive 2001/37/EC, which sought to harmonise the conditions pursuant to which tobacco and related products are manufactured and marketed within the Union.

130. In particular, Article 3 of Directive 2001/37/EC had previously established maximum tar, nicotine and carbon monoxide yields of cigarettes released for free circulation within the Union. Moreover, pursuant to Article 12 of that Directive, the Commission was invited to submit on the basis of information reported to it, a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, *inter alia*, their addictiveness. The present Directive constitutes a further step in the approximation of divergent national rules.

131. In this regard, the Commission recalls that the Court has expressly upheld the Union legislature's entitlement to adopt measures regulating the composition of tobacco products. Such measures were justified on the grounds that differences between the Member States' laws, regulations and administrative provisions concerning, among others, their composition, created both actual and potential obstacles to trade.[57] The Court's ruling followed well-established case-law according to which differences in Member States' national laws relating to the requirements to be met by products, including, as regards their composition, can constitute a barrier to free movement of goods.[58]

132. Moreover, it is manifest from the documents accompanying the Proposal for the Directive that substantial differences exist between the Member States as regards their approach to regulating the ingredients and composition of tobacco products. In

[57] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 65.

[58] See, in this regard, Joined Cases C-267/91 and C-268/91, *Keck and Mithouard* [1993] ECR I-6097, paragraph 15).

particular, the Impact Assessment revealed significant discrepancies both as regards the existence of rules regulating ingredients, and as regards the nature and substantive content of any rules that did exist.[59] Thus, for example, while certain Member States were observed to have adopted positive lists[60] setting out ingredients that may be permitted in tobacco products, others relied upon negative lists,[61] while a third group of States adopted a combination of positive and negative lists.[62] While certain Member States set out a detailed list of permitted ingredients, others were expressed in general terms,[63] or focussed on ingredients affecting specific aspects of tobacco consumption, such as, the perceived attractiveness of products.[64] Divergences also exist as regards the existence of and approach to regulation of capsules embedded in cigarette filters.[65]

133. The existence of divergent norms in Member States regulating the composition of tobacco products is also highlighted in the fifteenth recital of Directive 2014/40/EU. According to that recital, such divergences may be explained by the fact that certain Member States have adopted legislation or entered into binding agreements with the industry allowing or prohibiting certain ingredients. As a result, certain ingredients are regulated in some Member States, but not in others. The fifteenth recital further observes that Member States also take different approaches as regards additives in the filters of cigarettes as well as additives colouring the tobacco smoke. The lack of a harmonised approach to regulating the ingredients of tobacco products was therefore considered to affect the smooth

[59] The Impact Assessment disclosed that fourteen Member States regulate ingredients in their national law, whereas thirteen Member States have no specific rules in place, asides from the tar, nicotine and carbon monoxide ("TNCO") levels prescribed by Directive 2001/37.

[60] Belgium, France, Romania, and the United Kingdom. See Part 4 of the Impact Assessment, p.6.

[61] Lithuania introduced a negative list which restricts specific additives (for example vanilla root and clove).

[62] The Czech Republic, Germany, Hungary, Bulgaria (on an informal basis) and Slovakia. In Sweden there is no positive or negative list, but it is possible to regulate ingredients on an ad-hoc basis. See, Part 4 of the Impact Assessment, p.6.

[63] In particular, the lists of Germany, the Czech Republic and Hungary were reported to be very detailed, including several hundred ingredients. Finland and Spain was noted as possessing a very broadly drafted list of permitted substances.

[64] French law concerning ingredients focusses on the attractiveness of products. In particular it establishes maximum levels for ingredients that impart a sweet or fruity/acid taste to cigarettes.

[65] The Impact Assessment observes that Germany prohibits cigarettes with flavoured capsules embedded in the filter to be placed on the market and this prohibition had been upheld by a national court. Belgium prohibited three ingredients used in "menthol capsules" E418 "*gomme gellane*", E133 "*bleu brilliant FCF*" and Medium Chain Triglycerides (MCTs) . See Doc. SWD (2012) 452 final, Part 4, p.6.

functioning of the internal market and impact adversely on the free movement of goods across the Union.

134. It is apparent from the Order for Reference that the Claimants dispute the existence of an internal market justification for the prohibition of tobacco products with a characteristic flavour, such as fruit flavours, menthol or chocolate. In particular, it was argued before the referring court that no such justification could exist in relation to menthol cigarettes on the ground that such cigarettes are not prohibited by any of the Member States.

135. However, in this regard, the Commission emphasises that since the Union legislature is entitled to harmonise the composition of tobacco products, in general, it is not precluded from harmonising ingredients that give rise to particular flavours. The mere fact that a particular ingredient is not, at present, the subject of specific regulation, does not mean that the Union legislature, in adopting rules on ingredients that may be used in tobacco products, cannot adopt measures concerning the use of that ingredient. An alternative interpretation would lead to a situation where the Union legislature would be severely restricted in the selection of harmonised norms, since it would be limited to those specific ingredients that had previously been the subject of specific rules in one or other Member State.

136. Moreover, the interpretation advanced by the Claimants in the main proceedings would prevent the Union legislature, when selecting harmonised norms, to make choices that reflect the objective of ensuring a high level of health protection within the Union. However, the Court has previously accepted, that once the conditions for recourse to Article 114 TFEU are fulfilled, the Union legislature is entitled to take into account the objective of public health protection, in the choices it makes in the norms elaborated.[66]

137. Furthermore, the mere fact that tobacco products which contain ingredients producing a menthol flavour are not currently prohibited in the Member States, does not mean that such regulation is not liable to emerge, or indeed, would not have already emerged in the absence of agreement having been reached on the adoption of such a prohibition by Directive 2014/40/EU. As the Court has previously noted the growing awareness of the dangers to health posed by consuming tobacco products is likely to lead to the adoption of new rules governing the composition of tobacco products so as to reduce their harmful effect, thereby giving rise to new obstacles to the free movement of those products.[67]

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[66] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 62.

[67] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 67.

138. Specifically, as the sixteenth recital observes, the likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than one of tobacco, which could facilitate initiation of tobacco consumption or affect consumption patterns. The recital further states that the adoption of measures introducing unjustified differences of treatment between different types of flavoured cigarettes should be avoided. Thus, even if Member States have not yet prohibited tobacco products possessing ingredients which give rise to a menthol flavour, the Union legislature was perfectly entitled to consider that there exists a real likelihood that such prohibitions would arise in the light of increasing concern and awareness of the dangers associated with tobacco consumption. It should also be recalled that the Member States have been aware and positively supported the adoption of rules on ingredients adopted at a Union level which is also capable of explaining why additional parallel rules have not been adopted in the Member States.

139. In any event, further regulation concerning the composition and ingredients of tobacco products is expressly anticipated by virtue of commitments undertaken by the Union and the Member States within the framework of the FCTC. Article 9 of the Convention, entitled "*Regulation of the contents of tobacco products*", provides for the adoption of guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Pursuant to that Article, each Party is under a positive obligation to implement effective legislative, executive and administrative or other measures for such testing and measuring.

140. Moreover, the Article 9 and 10 Guidelines recognize that masking tobacco smoke harshness with flavours contributes to promoting and sustaining tobacco use and recommend the adoption of measures providing for the elimination of substances that seek to "*mitigate the harsh and irritating character of tobacco smoke"*. The Guidelines expressly recommend that Contracting Parties "*regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products*." Among these ingredients, the Guidelines expressly mention menthol, along with benzaldehyde, maltol and vanillin.

141. In adopting rules that harmonise the composition of tobacco products, Directive 2014/40/EU ensures that there is a uniform market and standard of tobacco products that circulate within the Union, thereby ensuring the smooth functioning of the internal market. In so doing, it is following a well-established practice, according to which the Union legislature adopts acts harmonising the substantive components of products that are manufactured and circulated throughout the Union.[68]

[68] See, for example, Union measures defining the ingredients of chocolate: Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended

142. The Commission concludes that Article 114 TFEU constitutes a perfectly appropriate and adequate basis for the approximation of Member States' laws on the ingredients and composition of tobacco, including as regards ingredients that give rise to a particular characterising flavour, thereby ensuring that they are subject to uniform conditions of manufacture, and thereby facilitating the effective functioning of the internal market of tobacco products.

(v) Article 18

143. By the fourth part of its first question, the referring Court asks whether Article 114 TFEU can constitute an appropriate legal basis for the Directive's provisions permitting Member States to prohibit cross-border distance sales of tobacco products.

144. The Claimants consider that the prohibition provided for in Article 18 of the Directive, by its very nature, cannot be considered to improve the internal market and is therefore invalid for lack of an adequate legal basis.

145. At the outset, the Commission underlines that Article 18 does not impose any obligation on Member States to prohibit cross-border distance sales of tobacco products. It only affords Member States the possibility to prohibit cross-border distance sales. As Recital (33) explains, such a possibility is provided having due regard to particular concerns and difficulties that such sales may entail in certain Member States, and with a view to securing full compliance with the Directive. Asides from this possibility, Article 18 simply requires retail outlets engaging in cross-border distance sales of electronic cigarettes and refill containers to register in both the Member State where the retail outlet is established and in the Member State where the actual or potential consumers are located. These common rules on the registration of retail outlets engaging in such sales ensure appropriate enforcement of the Directive, since the entity responsible for the compliance of the product sold at a distance will be known by both the authorities of the Member State from which it operates and the authorities of the Member State of consumption.

146. The Commission submits that such an approach is both justified and proportionate and may be regarded as facilitating the circulation of tobacco products.

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for human consumption. Recital (2) of Directive 2000/36/EC recites, for example, that approximation was warranted by the fact that differences between national laws on several kinds of cocoa and chocolate products could hinder the free movement of this product, and thereby have a direct effect on the establishment and functioning of the common market.

147. In the first instance, the Commission recalls that pursuant to the Directive's 33rd recital, a justification for the prohibition of cross-border distance sales is to prevent the circulation of tobacco products that do not comply with the requirements laid down in the Directive. Internet sales can facilitate circumvention by certain tobacco manufacturers, including unlawful ones, of applicable laws. By permitting Member States to adopt measures countering the illicit trade of tobacco products that breach the Directive, the Directive serves to facilitate the manufacture and sale of licit tobacco products.

148. Moreover, it is apparent from the Impact Assessment, that there exist fundamental divergences as between Member States as regards rules governing sales of tobacco products. In particular, considerable divergences exist as regards the means by which Member States approach the protection of consumers and the way in which they limit underage consumers' access to tobacco products.

149. In the first instance, while all the Member States set age limits as regards the purchase of tobacco, the age limit imposed varies among Member States.[69] Member States also use a variety of different means, including, regulation by ID control[70], locks[71] or other technical or electronic systems.[72] Other differences included different approaches to regulating internet sales of tobacco.

150. As regards internet sales, the Impact Assessment reports that nine Member States have adopted measures regulating or prohibiting the sale of tobacco online. While certain Member States (France and Lithuania) have introduced outright ban on online sales, other States (e.g. Austria, Bulgaria, Hungary, Latvia and Spain) grant licences or permission to sell tobacco through other sales channels. Different Member States apply a variety of restrictions, ranging from licensing of internet retailers (Cyprus, Denmark, Greece and Finland), imposing age limits (Czech Republic and Sweden) and advertising bans (e.g Germany, Malta, Portugal and the UK).[73]

151. The Commission recalls that in the context of examining the validity of Directive 2001/37/EC, the Court has recognised that, once the conditions for recourse to

[69] The Impact Assessment reports that the buying age is 18 in twenty two Member States and 16 years in five (Austria, Belgium, Italy, Luxembourg and the Netherlands): See Doc. SWD (2012) 452 final, Part 4, p.7.

[70] Germany, Austria and Italy. See Doc. SWD (2012) 452 final, Part 4, p.8.

[71] For example, Belgium. See Doc. SWD (2012) 452 final, Part 4, p.8.

[72] For example, Portugal. See Doc. SWD (2012) 452 final, Part 4, p.8.

[73] See Doc. SWD (2012) 452 final, Part 4, p.8.

Article 114 TFEU are fulfilled, the Union legislature cannot be prevented from relying on that legal basis on the ground that the public health protection is a decisive factor in the choices to be made.[74]

152. It is also settled case-law that Article 114 TFEU authorises the Union legislature to intervene in adopting measures the effect of which is to restrict (uniformly) the circumstances in which tobacco is sold and marketed, as long as these provisions facilitate the functioning of the internal market. Indeed, such an approach has been expressly upheld in the context of Union environmental legislation.[75] In Case C-91/79, for example, the Court accepted that the Union legislature was entitled to adopt rules restricting the use of detergents, even if they may be regarded as a burden upon the undertakings to which they apply.

153. The Commission further underlines that by creating a common regulatory framework governing the cross-border distance sales of tobacco products, the Directive enhances clarity of rules. Article 18 of the Directive therefore contributes to preventing the fragmentation of laws and serves to promote the trade of tobacco products manufactured in compliance with the Directive. As such, it is submitted that Article 114 TFEU constitutes a perfectly appropriate basis for that provision.

(vi) Articles 3(4) and 4(5)

154. By the fifth part of its first question, the referring Court asks whether Article 114 TFEU can constitute an appropriate basis for Articles 3(4) and 4(5) of the Directive empowering the Commission to adopt delegated acts in relation to emissions levels.

155. In the Commission's understanding, the Claimants, in essence, consider that Article 114 TFEU could not constitute a valid basis for the adoption of Articles 3(4) and 4(5) of the Directive because those provisions empower the Commission to bring about harmonisation with respect to emission levels and measurement methods without first assessing whether the conditions for adopting harmonising measures in the areas concerned are satisfied.[76]

156. According to the Order for Reference, the Claimants contend that since Articles 3(4) and 4(5) of the Directive oblige the Commission to adopt "*standards agreed*" by the Parties to the FCTC or the WHO, these provisions effectively delegate to

[74] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 75.

[75] See Case C-91/79, *Commission v Italy*, ECLI:EU:C:1980:85 and Case C-92/79; Case C-92/79, *Commission v Italy*, ECLI:EU:C:1980:86.

[76] Order for Reference, paragraph 30.

these bodies the task of determining new maximum emission levels and measurement methods, beyond those provided for in the Directive. Furthermore, one of the Claimants contends that such a delegation cannot validly be based on Article 114 TFEU because it does not entail a prior assessment as to whether harmonisation would improve the functioning of the internal market.[77]

157. The Commission observes, at the outset, that the Claimants' submissions under this part of Question 1 overlap to a certain extent with those advanced under Question 5, insofar as they each challenge Articles 3(4) and 4(5), on the basis that they are alleged, in essence, to constitute delegations to external bodies rather than to the Commission.[78] In order to avoid duplication, the Commission will limit itself to analysing arguments that relate to the alleged unlawful recourse to Article 114 TFEU. The remainder of the submissions will be considered as part of the Commission's observations on Question 5.

158. As regards the sufficiency of Article 114 TFEU as legal basis, the Commission recalls, first of all, that the Union legislature has already, in Articles 3(1) and 4(1) of the Directive, set specific maximum emissions levels and measurements standards for cigarettes, particularly in respect of tar, nicotine and carbon monoxide. Given that these provisions are based on Article 114 TFEU, it follows that the Union legislature has already considered and determined that such harmonisation serves the interests of the internal market. The delegations of powers contained in Articles 3(4) and 4(5) therefore concern an area which is already largely, albeit not completely, harmonised by the Directive on the basis of Article 114 TFEU.

159. The Commission next recalls that, according to settled case-law of this Court, Article 114 TFEU may be relied upon as a basis for the adoption of harmonisation measures in order to prevent the emergence of future obstacles to trade between Member States resulting from multifarious development of national laws. The Court has specified that recourse to Article 114 TFEU in such circumstances is justified provided that the emergence of those obstacles is likely and the measures in question are designed to prevent them.[79]

160. The Commission submits that in the present case those conditions are satisfied. In the first instance, the possibility for the Commission to act on the basis of Articles 3(4) and 4(5) of the Directive only arises where the parties to the FCTC, which

[77] Order for Reference, paragraph 30.

[78] Order for Reference, paragraphs 52 and 53.

[79] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 61

include the Union and all its Member States, agree on further standards regarding emissions. The mandate of the Commission is to integrate such standards into Union law.

161. Should standards on emission levels for tobacco products be agreed by the parties to either of those international instruments, it is reasonable to believe that they would be implemented at the national level by at least some Member States. In the Commission's view, this holds true regardless of whether the standards in question are agreed in the form of a legally binding obligation or, rather, of a recommendation. Even in this latter case, it is sufficiently likely that Member States, which as parties to the FCTC or members of the WHO would have contributed to the elaboration of those standards, will take them as a basis for national regulations[80]. The requirement for the adoption of delegated acts pursuant to Articles 3(4) and 4(5) only arise once this situation has arisen, i.e. in a context where a multifarious development of national laws is likely.

162. Given that developments within the framework of the FCTC are likely to result in the adoption of further specifications regarding emissions levels and measurement methods, the adoption of delegated acts provided for in Articles 3(4) and 4(5) would clearly serve to prevent the emergence of potential obstacles to trade, in that they will set uniform level for emissions applicable throughout the Union. The Commission thus considers that the mechanism permitting the Union legislature to take account of international developments sanctioned by the Member States is therefore perfectly consistent Article 114 TFEU as interpreted by the case-law of this Court.

163. The Commission therefore considers that the claims advanced by the Claimants in the main proceedings under Question 1(c)(iv) as regards Articles 3(4) and 4(5) of the Directive are without foundation.

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[80] It may be recalled that Articles 9 and 10 of the FCTC require the Parties to regulate content and emissions of tobacco products. Work is currently ongoing at an international level to validate testing and measuring methods for cigarette contents and emissions. This is a logical first step in order to set, at a later stage, limits for emissions other than those already regulated in the Directive. In this regard, the WHO Study Group on Tobacco Products Regulation has identified a priority list of 38 toxicants and Parties have been recommended to use the list to start monitoring the contents and emissions of cigarettes on their markets and eventually regulate contents and emissions, as required by Articles 9 and 10 of the FCTC (see the Progress Report submitted to the 6th Conference of the Parties (COP 6) to the FCTC on 13/14 October 2014: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_14Add1-en.pdf). The COP 6 invited WHO to finalize, within one year, the validation of the analytical chemical methods for testing and measuring cigarette contents and emissions and to assess, within two years, whether the standard operating procedures for nicotine, tobacco-specific N-nitrosamines (TSNAs) and B[a]P in cigarette contents and emissions are applicable or adaptable, as appropriate, to tobacco products other than cigarettes, including smokeless tobacco and waterpipe smoke. (see: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(12)-en.pdf).

(v) Conclusion

164. For the reasons outlined above, the Commission proposes that the first question be answered to the effect that the Directive is not invalid for lack of an appropriate legal basis.

Questions 2 and 3: Proportionality and fundamental rights

165. By its second and third questions, the national court inquires as to whether specific provisions of the Directive are compatible with the principle of proportionality and the protection of fundamental rights in the Union legal order.

166. In the first part of Question 2, the national court seeks confirmation on the interpretation of the scope of Article 13 governing rules relating to the presentation of tobacco products. If confirmed, the court then proceeds to ask whether the provision is compatible with the principle of proportionality and with Article 11 of the Charter.

167. Question 3(a) concerns the proportionality of Articles 7(1) and 7(7), insofar as they prohibit the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components. Question 3(b) concerns the proportionality of Articles 8(3), 9(3), 10(1)(g) and 14 insofar as they impose various labelling and packaging requirements. Question 3(c) concerns the proportionality of Article 10(1)(a) and (c), insofar as that Article requires health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging.

(i) On the admissibility of Question 2(a): Interpretation of Article 13

168. In addition and without prejudice to the general reservations on admissibility expressed in the first part of these submissions, the Commission has specific doubts relating to the admissibility of Question 2(a) as an autonomous question on the interpretation of Directive 2014/40/EU.[81]

169. As the Commission has noted in its observations on Question 1(a)(i)[82], references seeking the interpretation of a provision of Union law pursuant to Article 267 TFEU are admissible where the ruling to be delivered, is capable of being taken account of by the national court, and is necessary for the effective resolution of a

[81] See in particular paragraph 50 above of these observations.

[82] See paragraph 66 of these observations.

dispute.[83] The Court has consistently held that, since its function under the reference procedure is to assist in the administration of justice, it will not deliver advisory opinions on general or hypothetical questions.[84]

170. However, in the context of the present proceedings, which concern solely the validity of a yet unimplemented Directive, there is no factual dispute between the parties that would require the interpretation and application of Article 13. It follows that any ruling on the scope and interpretation of that Article would have to be delivered in the abstract and therefore have the character of an advisory opinion.

171. The Commission therefore considers Question 2(a) should be declared inadmissible as an autonomous question in its own right.

172. It is accepted that the competing interpretations of Article 13 may be relevant in the context of evaluating the validity of that provision. To that extent, the Commission proposes to consider the substance of Question 2(a) as part of its overall observations on the validity of Article 13.

(ii) Application of the principle of proportionality

173. Pursuant to the principle of proportionality, measures implemented through Union provisions must be appropriate for attaining the objectives pursued and cannot go beyond what is necessary to achieve those objectives.

174. The Commission recalls that the case-law of the Court contains a number of overarching interpretative principles applicable to the judicial review of acts adopted by the Union legislature.

175. In the first instance, the Court has consistently held that the Union legislature is conferred with broad discretion in a field, such as that in the present case, which involves political, economic and social choices on its part, and in which it is called on to undertake complex assessments[85]. The criterion to be applied in the assessment of the validity of a measure adopted in such a field, is not whether the measure adopted was the only or the best possible measure, but whether the

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[83] Case C‑225/02 *García Blanco* [2005] ECR I‑523, paragraphs 27 and 28.

[84] Case 244/80, *Foglia,* ECLI:EU:C:1981:302, paragraph 18. See also Joined Cases C-261/08 and C-348/08, *María Julia Zurita García and Aurelio Choque Cabrera v Delegado del Gobierno en la Región de Murcia*, ECLI:EU:C:2009:648; Case C-470/12, *Pohotovosť s.r.o. v Miroslav Vašuta* ECLI:EU:C:2014:101.

[85] See Case C-434/02, *Arnold André,* ECLI:EU:C:2004:800, paragraph 46, and Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 123.

measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue[86]. The Court has further held that in the context of such assessment "*the Community judicature cannot substitute its assessment of scientific and technical facts for that of the legislature on which the Treaty has placed the task.*"[87]

176. Secondly, the Commission recalls that the Court has held that the broad discretion conferred on the Union legislature "*applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts*". This discretion requires the Union institutions which adopted the act in question to be able to show that, in adopting the act, they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate.[88]

177. Thirdly, while the Union legislature may certainly be required to demonstrate that it has had due regard to relevant scientific research available, it is not limited to considering data in respect of which there exists unanimous consensus from amongst all members of the scientific community.[89] It follows that mere reference to the purported existence of scientific studies that are alleged to contradict the ones upon which the Union legislature relied in its deliberations does not mean that the measures adopted are not in conformity with the principle of proportionality.

178. Fourthly, the Court has recognised the entitlement of the Union legislature to act in accordance with the precautionary principle. Pursuant to that principle, *"*[w]*here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective."*[90].

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[86] See, to that effect, Case C‑189/01, *Jippes and Others*, ECLI:EU:C:2001:420, paragraphs 82 and 83; Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 123. See, also Case C-434/02, *Arnold André,* ECLI:EU:C:2004:800, paragraphs 45 and 46 (emphasis added).

[87] Case C-343/09 *Afton Chemicals*, ECLI:EU:C:2010:419, paragraph 28.

[88] See Case C-343/09, *Afton Chemicals*, ECLI:EU:C:2010:419, paragraphs 33 and 34.

[89] See, to that effect, Case Arnold André, C-434/02, ECLI:EU:C:2004:800, paragraph 49, and Case C–210/03, *Swedish Match*, ECLI:EU:C:2004:802, paragraph 51.

[90] Case C-343/09 *Afton Chemicals*, ECLI:EU:C:2010:419, paragraph 61. See also Case C-180/96 *UK v. Commission*, ECLI:EU:C:1998:192, paragraph 99.

179. Finally, the Commission recalls that according to the Impact Assessment, tobacco is not an ordinary commodity but the largest avoidable health threat in the European Union, responsible for almost 700,000 deaths in the Union each year. Around 50% of smokers die prematurely, on average 14 years earlier than non-smokers and a greater proportion of smokers' lives are characterised by serious disease. Annual public healthcare expenditure in the Union on treating six main disease categories related to smoking is estimated at around 25.3 billion euro and it has been estimated that society loses 8.3 billion euro per annum due to productivity losses, including early retirements, deaths and absenteeism, linked to smoking.[91]

180. The Commission submits that it is in the light of the interpretative principles laid down above and with due regard to the very serious health risks posed by tobacco consumption, that the proportionality of the measures introduced by the Union legislature fall to be considered.

(iii) Question 2(a) and (b): On the validity of Article 13

181. As is apparent from Recitals (25) and (27), Article 13 of Directive 2014/40/EU seeks to prohibit the use, on tobacco products packaging, of certain statements, elements and features that could be misleading to consumers.

182. Given that Article 13(1)(a) is concerned with elements, features or statements that create an erroneous impression as regards the characteristics, health effects, risks or emissions of tobacco products, it is manifestly concerned with false or misleading elements, features or statements as opposed to true and non-misleading ones.

183. As regards subparagraphs (b),(c),(d) and (e) of Article 13(1), their scope is not defined by reference to the truth of particular elements referred to in those subparagraphs, but on whether they are liable to convey a positive image of the products on which appear. In the light of the serious risks that the consumption of tobacco products poses to human health, the Union legislature considered the use of such elements in packaging of these products to be inherently misleading.

184. In this regard, the Commission underlines that it would be simplistic to suggest that specific true statements expressed in carefully circumscribed and narrow terms, necessarily correspond to the truth in any global or fundamental sense of the term. Statements which may be strictly true in relation to specific issues can nevertheless also be fundamentally misleading if they are not considered in context and with knowledge of the relevant facts. Moreover, it is recalled that as a rule, the

[91] See SWD (2012) 453 final, page 1.

motivation for which manufacturers place text or images on their products is not so much to inform consumers as to promote those products.

185. In this context, the Commission submits that the Union legislature was perfectly justified in considering claims of tobacco products' possessing "vitalising", "healing" or "rejuvenating" properties to be misleading, when their consumption is known to cause illness, disease and death. By the same token, references to the products' capacity to reduce the harmful components of smoke are liable to impact upon consumers' perception of actual risk. References to taste or smell may create associations with food, including healthy food, fruit, flowers or spices that are equally liable to affect consumers' perception of risk[92]. References to biodegradability or the absence of additives may convey the impression that the product is better, or at least less harmful, than others. More generally, there is evidence that the taste and sensory properties of cigarette smoke are used by consumers as indicators or risk. For example, harsh-tasting smoke is perceived as being more dangerous. [93]

186. On the basis of such considerations, the Union legislature considered that the elements, features and statements prohibited in paragraphs (b) to (e) of Article 13 were inherently misleading because, regardless of the truth of very specific claims made, their effect is nevertheless to disguise or downplay the extent of the harm to health that such products pose.[94] The Commission therefore submits that the prohibition provided for in Article 13 constitutes an appropriate measure to prevent tobacco manufacturers from making claims that misrepresent their product in a fundamental sense. Moreover, it is recalled that Article 7 of Directive 2001/37 previously banned product descriptors such as "light" and "mild" on the assumption that these descriptors could mislead consumers into believing that certain products were less harmful than others. In this context, Article 13 of Directive 2014/40/EU may be considered as building on that existing measure.

187. It is apparent from the Order for Reference that the Claimants' challenge to the proportionality of Article 13 of the Directive is essentially based on the fact that the

[92] The Commission notes in this context that Article 13(1)(c) only covers elements and features that directly refer to the taste of a product. It does not prohibit the use of elements or features (for example numbers) which indirectly allow consumers to identify products with a particular flavour when this flavour is not prohibited by the Directive (such as menthol till 20 May 2020).

[93] See in this respect Seema Mutti, David Hammond, Ron Borland, Michael K. Cummings, Richard J. O'Connor, & Geoffrey T. Fong, Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey, Addiction 2011; 106:1166-75, mentioned in fn. 146 of the Impact Assessment.

[94] See, by analogy, claims relating to properties of an alcoholic beverage: Case C-544/10, *Deutsches Weintor*, ECLI:EU:C:2012:526, paragraphs 51, 52 and 53.

prohibition restricts communication between tobacco manufacturers and consumers.[95] PMI, in particular, relies on witness statements purporting to demonstrate that consumers should be informed of *"reduced risk products"* and be in a position to distinguish those products from other tobacco products. PMI further maintains that the Union legislature did not appear to have taken into account its submissions regarding the introduction of such products.[96]

188. BAT relies on witness statements emphasising the importance of communicating information about flavour, taste and smell on tobacco product packaging. In its view, a less restrictive approach would have been to require products to carry a warning that conventional cigarettes are not less harmful than others. In BATs view, the Union legislator's failure to consider a less restrictive alternative undermines the Union legislator's contention that the prohibition is proportionate. [97]

189. Finally, the Claimants seek to rely on expert witnesses to refute assertions made by the Commission that the statements covered by Article 13 would (wrongly) cause consumers to believe that some conventional tobacco products were less harmful than others or that consumers would alter their smoking behaviour if these statements were banned.

190. As regards so-called “reduced risk” tobacco products, the Commission considers that marketing a tobacco product as "less harmful" is fundamentally misleading when that product remains capable of causing serious illness and death. Moreover, it is recalled that harm from the consumption of tobacco is not derived merely from the product in question, but the manner in which it is used, for example, the frequency of use and how the smoke is inhaled. In addition, it is necessary to consider the potential for “reduced risk” products to act as a source of initiation of smoking or to encourage dual use (as between so-called “reduced risk” and conventional tobacco products).

191. Furthermore, the Commission underlines that the fundamental danger posed by the features, elements or statements which seek to relate the purported risks of one particular type of tobacco product to other such products, is not so much that consumers will consider such products to be harmless. Rather the danger lies in their leading consumers to underestimate the extent of the risk that such products pose. In other words, drawing attention to the purported reduced risk of particular products is liable to induce consumers into believing that such products, while being harmful, are nonetheless less harmful than they actually are. The Commission

[95] Order for Reference, paragraph 33.

[96] Order for Reference, paragraphs 34 and 35.

[97] Order for Reference, paragraph 36.

maintains that the packaging could adversely impact consumers' perception and judgment of risk. In this context, the Commission reiterates that although PMI refers to its efforts to develop *"reduced risk products"*[98], the Order for Reference does not provide any evidence of actual reduced risk for public health (or the environment).

192. As regards the Claimants' submissions concerning the scientific basis for Article 13, it is certainly the case that since the prohibition set out in Article 13 did not exist prior to the Directive's adoption, its effect on smokers' behaviour is not, and could not, yet be known.[99] However, such concrete evidence on the actual results of a particular measure is not and, it is submitted, could not be a precondition to the right to legislate. Otherwise the Union legislature would never be able to introduce any novel measure in the Union legal order since, by definition, the full effects of a specific novel measure cannot be known prior to its adoption. Moreover, it is plainly apparent from the Impact Assessment, that the Union legislature had extensive recourse to scientific studies. Indeed, the conclusion of such studies supported the view that the types of statements covered by Article 13 have an impact on the perception of risk of consumers, which constitutes one of the main factors that influence consumer behaviour.[100] The conclusions reached in the studies referred to in the Impact Assessment have been confirmed in studies published subsequently[101].

193. Moreover, as mentioned at paragraph 177 above, the mere fact that the Claimants make references to different and competing scientific assessments has no bearing

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[98] Order for Reference, paragraphs 34 and 35.

[99] Certain studies do however exist investigating the impact of descriptors such as "light, "mild" and ultra" on consumer behaviour. See, for example, Cohen et al. "*Impact of the removal of light and mild descriptors from cigarette packages in Ontario, Canada: Switching to 'light replacement' brand variants*" (2014 Prev. Medicine).

[100] *"Since the adoption of* [Directive 2001/37]*, misleading descriptors such as "light, "mild" and "ultra" has been replaced by the use of colours which can be misleading and give the impression that some products are less harmful than others* […]. *Recent studies have demonstrated that packages have the potential to mislead smokers and potential consumers and present them with an erroneous comfort about the risk of smoking. For instance, FMC packets featuring the descriptors 'slim' to 'extra-slim' were rated significantly more appealing than packets without those descriptors.* […] *Some packages make different types of health claims by conveying the impression that a product has health benefits as it contains fruits, vitamins or is associated with energy. Other packages claim that FMC contain "no additives" or are "natural", which can lead to misperceptions that certain products are less harmful."* (SWD (2012) 452 final, Part 1, p. 30-31, with reference to the studies mentioned).

[101] Agaku IT, Omaduvie UT, Filippidis FT, Vardavas CI, "*Cigarette design and marketing features are associated with increased smoking susceptibility and perception of reduced harm among smokers in 27 EU countries*" (Tob Control. 2014 Oct 21).

on the proportionality of the contested measure. The proportionality of a measure is not based on the existence of unanimous consensus among members of the scientific community, but on whether the measure adopted was manifestly inappropriate with respect to the objectives pursued. In this regard, it is apparent that the approach adopted by the Union legislature was the product of careful and extensive evaluation of different options and is supported by available scientific literature.

194. In any event, and for good measure, the Commission recalls that the objective of the prohibition laid down in Article 13 is not merely to alter the smoking behaviour of *existing smokers*, but also to reduce the risk of initiation by non-smokers. Consequently, the question as to whether such measures may or may not alter the habits of *existing smokers* would not in any event affect the justification for the measure. The Commission therefore submits that measures laid down in Article 13 constitute both appropriate and effective means of ensuring that consumers' perception concerning the extent of harm posed by tobacco products are safeguarded from the promotion of the alleged positive qualities of such products.

195. The Commission further observes that the assertion by BAT [102] according to which the Union legislature had not considered alternative measures before adopting the approach laid down in Article 13 – is factually incorrect. In its Impact Assessment, the Commission identified four different policy options regarding the issue of packaging and labelling[103], and went on to analyse thoroughly the likely impact of each of those options[104]. However, the Union legislature considered that the restriction of the elements and features laid down in what became Article 13 of the Directive constituted the most appropriate and effective means of ensuring that consumers were not misled by the packaging and labelling of tobacco products.

196. The Commission rejects the suggestion advanced by BAT that an appropriate alternative measure would have been to permit manufacturers to use the descriptors or statements referred to in Article 13 on the condition that they also print a product specific health warning stating that all tobacco products are equally harmful.[105] In the Commission's view, printing conflicting and contradictory messages on packaging of tobacco products is not so much likely to protect consumers as

[102] Order for Reference, paragraph 36.

[103] Namely Option 0: No change; Option 1: Mandatory enlarged picture warnings; Option 2: Option 1 plus harmonise certain aspects of packets and prohibit promotional and misleading elements; and Option 3: Option 2 plus full plain packaging (See SWD (2012) 452 final, Part 1, pages 55-56).

[104] See SWD (2012) 452 final, Part 1, pages 87-97.

[105] As suggested in the Order for Reference, at paragraph 36.

confuse them. The Commission submits that such an approach would not have been as effective as the measures provided for in Article 13 of the Directive. Recalling that the Union legislature is afforded broad discretion in selecting the most appropriate means to obtain objectives identified, the Commission submits that it did not exceed the limits that discretion by finding that alternative measures could not be deemed as efficient as Article 13 of the Directive, since they would not have the same preventive effect[106].

197. The Commission accepts that Article 13 of the Directive limits the manner in which the Claimants may communicate with consumers, and is capable of limiting product differentiation or removing niche products. However, it is submitted that restricting the commercial use of claims which may be regarded as inherently misleading may be both necessary and appropriate to ensure a high level of human health protection in accordance with Article 35 of the Charter. Thus, for example, in its judgment in Case C-544/10, *Deutches Weintor,* the Court found that the Union legislature was fully entitled to take the view that specific claims (in that case, relating to alcoholic beverages), which highlighted one particular quality, were liable to encourage their consumption and ultimately increase the risks for consumers' health.[107] The Court concluded that the prohibition of such claims was warranted in the light of the requirement to ensure a high level of health protection for consumers.

198. Moreover, Article 13 of the Directive should be considered in a context where it builds on Article 7 of Directive 2001/37, which prohibited the use on the packaging of tobacco products of signs suggesting that a particular tobacco product is less harmful than others. The Court held that Article 7 of Directive 2001/37 does not infringe the principle of proportionality[108].

199. In light of the considerations laid down above, the Commission submits that Article 13 of the Directive is not manifestly inappropriate in relation to the objective pursued and therefore does not breach the principle of proportionality.

200. The Commission notes that the Order for Reference also raises the issue of the compatibility of Article 13 with the Charter. It observes, in this respect, that the Claimants contend that the prohibition of *"true and non-misleading statements on*

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[106] On the criterion of the "same preventive effect" see Case C-434/02, *Arnold André,* ECLI:EU:C:2004:800, paragraph 55.

[107] See, to that effect, Case C-544/10, *Deutsches Weintor*, ECLI:EU:C:2012:526, paragraphs 51, 52 and 53.

[108] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraphs 133 to 141.

tobacco product packaging […] *constitutes* […] *a disproportionate interference with Article 11 of the Charter*"[109]. The Commission rejects that contention.

201. In the Commission's view, as the Directive itself indicates, the Directive respects the fundamental rights and principles enshrined in the Charter and Article 13, in particular, does not entail a disproportionate limitation upon the freedom of expression and information.[110] The Commission reiterates that freedom of expression is not absolute and may be limited in accordance with Article 52(1) of the Charter. Pursuant to that provision, any limitation must be provided for by law and respect the essence of those rights and freedoms. In addition, it must comply with the principle of proportionality, be necessary and genuinely meet the objectives of general interest recognised by the Union.

202. The Commission observes that "*ensuring a high level of human health protection […] in the definition and implementation of all the Union's policies and activities"* as provided for in Article 35 of the Charter constitutes such an objective of general interest. The Commission next recalls that the kind of claims that are covered by the prohibition laid down in Article 13 are ones that would be liable to alter the consumers' perception of risk. Given that the objective of and underlying rational for Article 13 is to remove the risk that consumers perception of risk is misled by the labelling and packaging of tobacco products, it was perfectly reasonable and coherent for the Union legislature, to prohibit the display of elements, features or statements that are considered as inherently misleading to consumers.

203. The Commission further recalls that such an approach has been previously considered and upheld by the Court in Case C-544/10, *Deutches Weintor,* where the Court found that the total prohibition of particular claims relating to alcoholic beverages was "*warranted in the light of the requirement to ensure a high level of health protection for consumer […] and may be regarded as being necessary to ensure compliance with the requirements that stem from Article 35 of the Charter*.."[111] Moreover, as far as the need to preserve the essential content of the freedom of expression and information is concerned, the Commission notes that such a right does not extend to the provision of information that is susceptible to

[109] Order for Reference, paragraph 32.

[110] See Recital (59): *"The obligation to respect the fundamental rights and legal principles enshrined in the Charter* […] *is not changed by this Directive. Several fundamental rights are affected by this Directive. It is therefore necessary to ensure that the obligations imposed on manufacturers, importers and distributors of tobacco and related products not only guarantee a high level of health and consumer protection, but also protect all other fundamental rights and are proportionate with respect to the smooth functioning of the internal market."*

[111] See, to that effect, Case C-544/10, *Deutsches Weintor*, ECLI:EU:C:2012:526, paragraphs 51, 52 and 53.

mislead consumers as regards the fundamental nature of the products concerned and the risks they entail for consumers' health.

(iv) Question 3: Other provisions of the Directive

204. By its third question, the national court inquires as to whether a series of provisions of the Directive are compatible with the principle of proportionality and the protection of fundamental rights in the Union legal order. The provisions at issue include:

(a) Articles 7(1) and 7(7), insofar as they prohibit the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components.

(b) Articles 8(3), 9(3), 10(1)(g) and 14 insofar as they impose various pack requirements.

(c) Article 10(1)(a) and (c), insofar as that Article requires health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging.

205. Each provision will be considered in turn.

(a) Article 7(1) and 7(7)

206. According to the referring court, the Claimants in the national proceedings have challenged the proportionality of the prohibition of the use of menthol and the prohibition on the use of certain flavourings laid down in the first and seventh paragraphs of Article 7. BAT is referred to as having raised three principle arguments in support of its position, namely, that the prohibition: "*(a) is not necessary to achieve compliance with the FCTC, which does not include any binding obligation to ban menthol* […]; *(b) is not necessary and/or appropriate to achieve the public health objective, and (c) has a disproportionate impact*"[112].

207. At the outset, the Commission notes that the Order for Reference does not allow the interveners, or indeed the Court, to identify which flavourings – other than menthol – were intended to fall within the scope of this Question. Indeed, since paragraph 37 of the Order for Reference refers only to *"certain flavourings in components*", it would appear that the proportionality of Article 7(1) and 7(7) of the Tobacco

[112] Order for Reference, paragraph 37.

Products Directive is not challenged as regards *all* flavourings. Given that paragraphs 38 to 40 of the Order for Reference refer exclusively to menthol, it is not possible to determine which other flavours might be the subject of the complaint's application.

208. As regards the manufacturers' first argument, the Commission simply observes that the scope of action of the Union legislature is determined by the objectives and principles laid down in the Union law and not by the FCTC. If follows that the Union legislature, in adopting measures intended to improve the functioning of the internal market in accordance with Article 114 TFEU, cannot be regarded as being confined to minimum binding requirements laid down in the FCTC. As a consequence the claim according to which the FCTC contains no "*binding obligation to ban menthol"*[113] has no bearing whatsoever on the proportionality of the measure at issue.

209. It is, however, underlined that both the terms of the FCTC and the guidelines adopted in support of its implementation, actually reinforce the appropriateness of the measures adopted by the Union legislature. In this regard, the Commission notes that pursuant to Article 9 of the FCTC, which is binding both on the Union[114] and its Member States, each Party is obliged to adopt and implement effective measures for the regulation of the contents of tobacco products.

210. The Conference of the Parties has adopted partial guidelines for the implementation of this Article[115]. Their stated purpose is *"to assist the Parties in meeting their obligations under Articles 9 and 10"* of the FCTC. The guidelines on Article 9 state, inter alia, that from the perspective of public health, "*there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive*". Paragraph 3.1.2.2 of the Guidelines expressly recommends regulating contents "*by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products*". That recommendation clearly also applies to flavouring ingredients, as the section immediately preceding that recommendation, refers expressly to spices and herbs like cinnamon, ginger and mint. Menthol is mentioned among the examples of "*flavouring substances*" masking tobacco smoke harshness, which contributes to promoting and sustaining tobacco use[116].

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[113] Order for Reference, paragraph 37.

[114] Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213 of 15.6.204, p. 8.

[115] Adopted by the Conference of the parties at its fourth session in 2010, with amendments adopted at its fifth session in 2012, point 1.2.1.1.

[116] *Ibid.* point 3.1.2.2.

211. Therefore, even if the FCTC does not impose any specific obligation to prohibit menthol such prohibition is manifestly, in the view of the Conference of Parties to the FCTC, an appropriate means of implementing the FCTC and, in any event, consistent with the Convention.

212. The Commission submits that the review of the proportionality of the provisions at issue entails consideration of the objective they seek to pursue. In this regard the Directive's objective is to eliminate obstacles to the smooth functioning of the internal market in tobacco and related products while ensuring a high level of health protection in accordance with Article 114(3) TFEU.[117] The Commission has already outlined, in the context of its submissions on Question 1, that Article 7 of the Directive is a perfectly adequate and appropriate means to facilitate the functioning of the internal market as it aims at removing obstacles to the free circulation of tobacco products. As regards the subordinate public health objective, Recital (8) of the Directive recalls the particularly harmful effects of tobacco on human health and the need to give health protection "*high importance, in particular to reduce smoking prevalence among young people*". Moreover, Recital (16) underlines the "*concerns over tobacco products having a characterising flavour other than one of tobacco, which could facilitate initiation of tobacco consumption or affect consumption patterns*".

213. Given that the addition of ingredients producing characterising flavours can artificially increase the attractiveness and the palatability of tobacco products, it follows that the restriction of those ingredients is an apt and appropriate means to prevent tobacco products from acquiring more attractive and palatable characteristics.

214. The Commission reiterates that in the context of the judicial review of proportionality, the relevant criterion is not whether the measure adopted was the only or the best possible measure, but whether the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue. In this regard, the Commission submits that nothing contained in the Order for Reference would suggest that the approach to regulating ingredients adopted in Article 7 is manifestly inappropriate to achieve the objective of ensuring uniform rules that ensure a high level of public health in the Union.

215. On the contrary, Article 7 was the result of an extensive Impact Assessment process. As part of that process, the Commission carried out an exhaustive analysis of the available scientific literature and of the market impact, the result of which is

[117] See Article 1 of the Tobacco Products Directive.

summarised in the Impact Assessment. As regards the ingredients of tobacco products in particular, the Commission examined three possible approaches to regulating ingredients of tobacco products.[118] For each approach, the Commission analysed its respective economic, social and health impact. In addition, the Commission analysed the indirect impact of the preferred policy options on economic stakeholders along the production chain as well as on government and society.[119]

216. The Impact Assessment revealed that the adoption of the preferred option would result in substantial benefits both for the internal market (facilitated cross-border trade in cigarettes as a consequence of the removal of trade barriers stemming from actual and potential divergences between national laws[120]) and for a high level of health protection (namely a lower appeal of tobacco products as a result of the ban of those with a characterising flavour, the reduction of smoking uptake – in particular among young people – and, over time, reduced morbidity/mortality from smoking and a higher level of well-being[121]). The Commission, and the Union legislature, considered that these benefits outweighed the possible negative impacts identified (a quite moderate loss of cigarette sales, a limited impact on growers and suppliers, and a limited social impact[122]).

217. Moreover, as observed above, the approach is consistent with the Guidelines endorsed by the FCTC.

218. The Commission strenuously contests the view expressed by BAT according to which Article paragraphs 1 and 7 of Article 7 are not supported by objective findings as far as menthol is concerned.[123] The Commission's Impact Assessment entailed careful consideration of studies on the effect that flavourings can have on smoking uptake[124]. Indeed, the Commission's Impact Assessment specifically

[118]See SWD (2012) 452 final, Part 1, pages 97 to 104. The options entailed (a) a prohibition of toxic, addictive and attractive additives in tobacco products, (b) a prohibition of tobacco products with characterising flavours and products with increased toxicity or addictiveness and (c) a prohibition of additives not essential for manufacturing.

[119] See SWD (2012) 452 final, Part 1, pages 112 to 117.

[120] See SWD (2012) 452 final, Part 1, page 98.

[121] See SWD (2012) 452 final, Part 1, pages 101 and 102.

[122] See SWD (2012) 452 final, Part 1, pages 99 and 100.

[123] Order for Reference, paragraph 38.

[124] *"A significant number of scientific studies show that certain tobacco additives make* [factory manufactured cigarettes (FMC)] *more appealing. The WHO Study Group on Tobacco Product Regulation summarises the international public health knowledge about flavourings added to FMC and other tobacco*

considers the role of menthol cigarettes in this context[125], and referred to a series of studies and reports, in particular:

- a scientific study as finding, that "menthol FMC [Factory Manufactured Cigarettes] use was significantly more common among newer, younger smokers";

- a research report as finding "a greater risk of progression to regular smoking and nicotine dependence for those who start smoking menthol cigarettes compared to those starting with non-menthol cigarettes";

- the US Tobacco Products Scientific Advisory Committee ("TPSAC") as confirming "on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it was more likely than not that the availability of menthol FMC increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC."

219. Moreover, the U.S. Food and Drugs Administration (FDA) has since recently undertaken a comprehensive review of the available science concerning menthol cigarettes and concluded *inter alia* as follows: "*While there is little evidence to suggest that menthol cigarettes are more or less toxic or contribute to more disease risk to the user than non-menthol cigarettes, adequate data suggest that menthol use is likely associated with increased smoking initiation by youth and young adults. Further, the data indicate that menthol in cigarettes is likely associated with greater addiction. Menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking. These findings, combined with the evidence indicating that menthol's cooling and anaesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to non-menthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with non menthol cigarettes.*"[126]

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products and their attractiveness to young and older smokers. The Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concludes, in its Opinion of 2010, that the use of fruit and candy flavourings in high amounts seems to favour smoking initiation by young people. It is also suggested that some additives decrease the harshness and increase the smoothness of the smoke" (See SWD (2012) 452 final, Part 1, page 36, with references to the relevant studies).

[125] See SWD (2012) 452 final, Part 1, page 101.

[126] Preliminary scientific evaluation of the possible public health effects of menthol versus non-menthol cigarettes.http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf. Emphasis added.

220. In a recent European study based on Eurobarometer data, flavours (including menthol) were associated with the initiation of smoking and reduced perception of harm among females and younger smokers[127]. Indeed, the data revealed, on the one hand, that menthol cigarettes are particularly popular among young people[128] and, on the other hand, that the consumption of menthol cigarettes has significantly increased in certain Member States between 2006 to 2012.[129]

221. Furthermore, a report by the German Cancer Research Centre has found that innovations, such as capsules with menthol embedded in the cigarette filter, target young people[130]. The report finds, based on studies conducted in the US and Japan, that menthol cigarettes are widely used by young people and that adolescents who start smoking quite often choose menthol cigarettes. The report further underlines that the market share for cigarettes with menthol capsules have has experienced rapid growth both outside and inside Europe, e. g. in France, the Netherlands, Switzerland and Romania.[131] In its recommendations, the report warns that the new technologies increase the popularity of cigarettes especially among young people and new smokers – without making geographical or ethnic reservations. It recommends a European ban, both of cigarettes with menthol capsules and of menthol as a tobacco additive in general.[132]

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[127] Agaku IT, Omaduvie UT, Filippidis FT, Vardavas CI, "*Cigarette design and marketing features are associated with increased smoking susceptibility and perception of reduced harm among smokers in 27 EU countries*". (Tob Control. 2014 Oct 21).

[128] See the extracts from the Euromonitor country reports in Annex II to the present observations.

[129] The consumption of menthol cigarettes has significantly increased in certain Member States between 2006 to 2012, See Annex III.

[130] See, for example, *"The new products containing menthol capsules are designed to appeal mainly to young consumers, because the target group mentioned again and again in documents of the tobacco industry are 'adult smokers under 30'"*, in: German Cancer Research Centre (DKFZ) Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product (2012) Red Series Tobacco Prevention and Control, Volume 17, page 13, with further findings and references. (http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_17_Menthol_Capsules_in_Cigarette_Filters_en.pdf)

[131] German Cancer Research Centre (DKFZ) Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product (2012) Red Series Tobacco Prevention and Control, Volume 17, section 3, pages 19 to 23 with further references.

[132] German Cancer Research Centre (DKFZ) Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product (2012) Red Series Tobacco Prevention and Control, Volume 17, section 4, page 25-26 as well as page VII: "*Cigarettes with menthol capsules will, in all probability, help spread tobacco consumption further, especially among children and adolescents, and must therefore be banned.*"; and page V: "*Additives in tobacco products, particularly flavouring compounds, increase the attractiveness of these products. They promote smoking initiation by children and adolescents and make it more difficult for smokers to quit. The German Cancer Research Center (DKFZ) calls for a German and European ban on tobacco additives, such as menthol, sugar, fruit flavours and other substances which*

222. The Commission notes that the Claimants seek to invoke alternative scientific studies with different conclusions in an attempt to refute and undermine those relied upon by the Union legislature in the adoption of what became Article 7. As those studies and statements do not form part of the case-file notified to all interested parties, such parties are not in a position to make any specific observations either on their scientific merit or indeed their impartiality. However, it is submitted that engagement with such studies would not, in any event, be necessary, since, as mentioned above,[133] the proportionality of the measure is not dependent on unanimity among the scientific community. The Commission submits that the Union legislature had ample evidence at its disposal and that the option finally retained to restrict artificial ingredients aimed at enhancing the attractiveness and palatability of tobacco products constituted an appropriate means of furthering the objectives pursued by the Directive.

223. The Commission observes that a further argument advanced by the Claimants is that Article 7(7) is disproportionate because it forbids all flavourings in components and all technical features allowing modification of the smell or taste of tobacco products, including non-characterising flavourings and the additives which can legitimately be added to the tobacco itself under Article 7(1).

224. In this respect, the Commission notes that Article 7(7) seeks to capture innovative products particularly attractive to young people in respect of which Member States have taken different approaches. Moreover, as additives in components are in no way essential for manufacturing, there is no need to allow the use in components of additives which are essential for the manufacture as in Article 7(1) for additives used in tobacco itself.

225. Furthermore, the Commission notes that the exclusion of tobacco products other than cigarettes and roll-your-own tobacco from the scope of application of Articles 7(1) and 7(7), provided for in Article 7(12) of the Directive, does not amount to an unacceptable discrimination in favour of these products.

226. In this respect the Commission notes that the prevalence of regular pipe and cigar use among young people is significantly lower than the use of factory manufactured cigarettes or roll-your-own tobacco. Eurobarometer data from 2014 indicates that daily or weekly use of cigars is 1% in the age group 15-24 years (compared to 5%

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mask the unpleasant, harsh and irritating character of tobacco smoke. Such a ban is intended to protect consumers from the hazardous health effects of tobacco smoking. Informations on these issues are available in several DKFZ publications wherein an urgent need for regulation has been emphasized."

[133] See paragraph 177 of these observations.

in the age group 55+). There is no evidence that pipe (excluding waterpipe) and cigars could be seen as a starter product in the EU. A large majority (83%) of smokers or ex-smokers say that boxed cigarettes were the first tobacco product they used (pipes and cigars 1% each).[134] Moreover, the age limit for purchasing tobacco is a question of national competence and Member States are also responsible for enforcing this age limit. Despite this, the average starting age according to the latest Eurobarometer (2014) is 17.6. 72% of the smokers start up to the age of 18.

227. Regarding the issue of the impact on illicit trade, mentioned in passing in the Order for Reference[135], it follows from the Impact Assessment that the institutions analysed the risk that the new ingredients regulation might be circumvented.[136] It is also noteworthy that the Impact Assessment considered that a general ban on tobacco products with characterising flavours (instead of regulating individual additives) makes it more difficult to circumvent the ban by developing alternative chemical combinations with the similar properties (taste/aroma).[137] Moreover, the Union legislature has taken measures to tackle these risks of circumvention by introducing a tracking and tracing system for the legal supply chain (Article 15 of the Directive) complemented by security features on unit packs (Article 16 of the Directive).

228. As far as a *"disproportionate impact of the menthol ban on Polish tobacco growers"*[138] is claimed, the Commission points out that the Impact Assessment takes due account of the situation of tobacco growers.[139] It predicts, based on experiences and estimations from other jurisdictions, a reduction of consumption of about 2% (between 1,7 to 2,6%) by <u>all</u> measures of the Directive combined. The ingredients regulation in general (including its effects on the sales of menthol cigarettes) is predicted to lead to a rather limited decrease of about 0,5 to 0,8% of cigarette consumption over five years.[140] It is assumed that this 2% reduction in

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[134] Special Eurobarometer 429 (data from 2014), not yet published

[135] Order for Reference, paragraphs 39 and 40.

[136] See e.g. SWD (2012) 452 final, part 1, page 113 ("*The option addresses concerns of some stakeholders claiming that revision of the TPD would result in increased illicit trade (however without substantiation)"*) and first sentence on page 111 ("*The proposed measure would ensure that the intended increase in awareness is not circumvented by illegal* ***products which do not comply with the relevant requirements*** *(such as labelling and ingredients regulation*)."

[137] See SWD (2012) 452 final, Part 1, page 105.

[138] Order for Reference, paragraph 40.

[139] See SWD (2012) 452 final, Part 6, pages 8 and 9; and part 1, page 100.

[140] SWD (2012) 452 final, Part 1, pages 113 and 114 and part 6, page 2.

consumption will lead to a linear reduction in purchases of the tobacco industry.[141] As the Impact Assessment states, the projected reduction in turnover would be an "*acceptable burden*"[142] compared to the benefits for the internal market and for the protection of health. Finally, the effect of the Directive on the production of raw tobacco will further be "softened" by the benefit of an additional four-year transitional period under Article 7(14) of the Directive which allows giving consumer demand time to switch to other tobacco products until 2020.

229. In view of the foregoing, the Commission respectfully submits that Question 3(a) should be answered in the negative.

(b) Articles 8(3), 9(3), 10(1)(g) and 14

230. By this second part of Question 3, the referring court seeks guidance on the proportionality of a number of provisions concerning the *labelling and packaging* of tobacco products. Article 8(3) of the Directive provides in particular that health warnings shall be irremovably printed, indelible and fully visible. Article 9(3) lays down a number of provisions relating to location and size of general warnings and information messages. Article 10(1)(g) of the Directive regulates the dimensions of combined health warnings. Article 14 governs the appearance and content of unit packets.

231. According to the Order for Reference, BAT challenges the proportionality of the "*pack standardisation measures*" in Articles 8(3), 9(3), 10(1)(g) and 14 of the Directive. BAT points out, in particular, that: *"there is no public health justification at all for the requirement in Article 14 [of the Directive] that each pack contains a minimum of 20 cigarettes"*[143]. BAT contends that the objective of improving the visibility and legibility of health warnings could have been met by a much more targeted measure – such as a requirement that they be fully visible and not distorted by packet shapes[144] and that the *"pack standardisation measures"* would have a manifestly disproportionate impact, distort competition and increase the incentives to engage in illicit trade.

232. The Commission notes that the sole measure that is specifically identified in the Order for Reference is the requirement in Article 14 of the Directive that each unit

[141] See SWD (2012) 452 final, Part 6, page 8.

[142] See SWD (2012) 452 final, Part 6, page 8.

[143] Order for Reference, paragraphs 41 and 44..

[144] Order for Reference, paragraph 43.

packet contains at least 20 cigarettes[145]. Question 3(a) otherwise refers, in rather vague terms, to the *"pack standardisation measures"*.

233. In this respect, the Commission notes, first of all, that, far from providing for "*pack standardisation measures*", Articles 8(3), 9(3), 10(1)(g) and 14 only regulate certain aspects of the packaging of tobacco products. As Recital (28) makes clear, the objective is to ensure the integrity and full visibility of the health warnings prescribed by the Directive.

234. Moreover, the Commission recalls that, in *British American Tobacco (Investments) and Imperial Tobacco*, the Court held that *"the obligation* […] *to print on the unit packets of tobacco products warnings concerning the risks to health posed by those products are appropriate measures for attaining a high level of health protection when the barriers raised by national laws on labelling are removed.*". The Court added that, *"[a]ccordingly, by requiring* [in Directive 2001/37] *an increase in the percentage of the surface area on certain sides of the unit packet of tobacco products to be given over to those indications and warnings, in a proportion which leaves sufficient space for the manufacturers of those products to be able to affix other material, in particular concerning their trademarks, the Community legislature has not overstepped the bounds of the discretion which it enjoys in this area*"[146].

235. The Commission submits that the same conclusion also holds true for Articles 8(3), 9(3), 10(1)(g) and 14 of the Tobacco Products Directive.

236. First, in its Impact Assessment, the Commission identified four different policy options regarding the issue of packaging and labelling, and proceeded to carry out a comprehensive analysis of their likely impact[147]. It is submitted that the very fact that these options and their possible consequences were assessed in the Impact Assessment is in itself a strong indication that the principle of proportionality has not been breached.

237. Second, the Union legislature did not manifestly exceed the limits of its broad discretion by finding that a *"more targeted measure, such as a requirement that health warnings be fully visible and not distorted by packet shapes"*[148] could not be

[145] Order for Reference, paragraph 44.

[146] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraphs 131 and 132.

[147] See paragraph 195 above of these observations.

[148] As suggested in paragraph 43 of the Order for Reference.

deemed as effective as the measures foreseen in Articles 8(3), 9(3), 10(1)(g) and 14 of the Directive.

238. In this respect, the Commission notes that such a vague requirement would not have helped achieve the desired level of harmonisation of rules applicable to the packaging of tobacco products, as it would have opened the door to very different interpretations by national authorities as to what is "fully visible" and "not distorted" and thus would have had an adverse impact on the internal market.

239. Moreover, the Union legislature was entitled to rely on the scientific evidence referred to in the Impact Assessment suggesting that *"bigger pictorial pictures on both sides are more effective than text-only warnings on a range of outcomes, including being a deterrent for new smokers and a means to increase cessation among current smokers"*[149]. The Impact Assessment also indicates that *"*[i]*n general, prominent pictorial warnings placed on the front of the packages are seen to be the most effective in increasing perceptions of risk and promoting behavioural change. Enlarged picture warnings on both sides of the package are expected to result in greater noticeability and salience for consumers, stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking. There is evidence that the warnings are more visible if placed on the front panel in the upper part of the package"*[150]. Moreover, the Impact Assessment points out that *"*[s]*ome of the current packet shapes make it difficult to effectively display health warnings affecting negatively the visibility and legibility of the warning. This is particularly the case for very narrow (including "lip-stick" shaped) packets which distorts text and picture warnings"*[151].

240. To this it should be added that certain new forms of packaging and opening mechanisms increase the part of the packaging area which may be used by manufacturers and thereby reduce the share of the pack to be used for health warnings. This can result in the warning becoming less visible and prominent and therefore less capable of attracting the attention of consumers.[152]

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[149] See SWD (2012) 452 final, part 1, pages 31 and 32, where reference is also made to the fact that *"some of the current packet shapes make it difficult to effectively display health warnings affecting negatively the visibility and legibility of the warning",* and to a study of young adults according to which *"so-called 'super-slim' 'parfume type' FMC packages were associated with femininity, elegance, slimness and reduced harm*".

[150] See SWD (2012) 452 final, part 1, p. 89-90, with reference to the supporting studies.

[151] See SWD (2012) 452 final, part 1, p. 31, with reference to the supporting study.

[152] For example, in "shell and slide packs" and in "wallet packs" an additional surface becomes visible (by sliding pack upwards or unfolding as a wallet) and this surface does not carry a warning. For examples, see Annex I.

241. As far as the justification for the requirement that each pack contains a minimum of 20 cigarettes is concerned, the Commission refers to Recital (28) of the Directive. Pursuant to that Recital, *"Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned"*.[153] That requirement was therefore imposed primarily for internal market purposes, which is fully in line with the legal basis of the Directive[154]. At the same time, it pursued a high level of health protection, given that requiring a minimum number of cigarettes in each package clearly helps to ensure that the size of the package allows for a sufficient space for health warnings[155].

242. Regarding the alleged disproportionate impact on BAT of the *"pack standardisation measures"*[156], the Commission points out that the Impact Assessment analysed the economic impact of all the options it envisaged to pursue regarding labelling and packaging[157], and noted that the preferred option regarding labelling and packaging *"would further reduce compliance costs for tobacco manufacturers and* […] *would result in even larger economies of scale, including standardised package size"*[158].

243. Regarding the distortion of competition alleged by BAT, the Commission has already observed in paragraphs 124 and 125 above, that the Directive still allows for some degree of differentiation as far as the packaging of tobacco products is concerned. Moreover there is no conclusive evidence that the new provisions on packaging and labelling of the Directive will lead to distorted competition.

244. The fact that the degree of differentiation is now arguably less than it had been under Directive 2001/37 is but a reflection of the different balance between

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[153] The development of national rules in this respect is encouraged by Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (O.J. L 022, p. 31-34) recommending Member States to prohibit the sale of cigarettes individually or in packets of fewer than 19 cigarettes.

[154] See SWD (2012) 452 final, part 4, p. 4, which provides an outlook on the different national rules in place as regards the minimum number of cigarettes per package.

[155] See SWD (2012) 452 final, Impact Assessment, Part 1, page 93.

[156] See Order for Reference, paragraph 45.

[157] See SWD (2012) 452 final, Impact Assessment, Part 1, pages 87-95.

[158] See SWD (2012) 452 final, Impact Assessment, Part 1, page 91.

competing interests that the Union legislature could – without exceeding its broad discretion – decide to strike in light of new developments[159].

245. Finally, as regards the vague allegation that the *"pack standardisation measures"* will increase the incentives to engage in illicit trade[160], the Commission refers to its observations under paragraph 126 above.

246. In view of the foregoing, the Commission respectfully submits that Question 3(b) should be answered in the negative.

(c) Article 10(1)(a) and (c)

247. By the third part of Question 3, the national court inquires as to the proportionality of the provisions governing the minimum surface area that warnings should cover on the external surface of tobacco products packaging. Pursuant to Article 10(1)(c), the text and pictorial warnings required by Article 10(1)(a), must cover at least 65% of both the external front and back surface of the unit packaging.

248. According to the Order for Reference, BAT considers the figure of 65% to be *"arbitrary and/or unreasoned"*. In its view, larger health warnings are not necessary to comply with the FCTC and are not necessary and/or appropriate to achieve the public health objective. In addition, the Claimants submit that the health warnings have a manifestly disproportionate impact.

249. At the outset, the Commission notes that since the question is only concerned with the proportion of the surface area that health warnings may be required to occupy on tobacco products packaging, it should only be regarded as concerning Article 10(1)(c) of the Directive.

250. The Commission observes that the Court of Justice has already had an opportunity to consider the proportionality of measures requiring the display of health warnings on tobacco products. In particular, as part of its examination of the validity of Directive 2001/37 in Case C-491/01, the Court held that the obligation "*to print on the unit packets of tobacco products warnings concerning the risks posed by those products are appropriate measures for attaining a high level of health protection when the barriers raised by national laws on labelling are removed.*"[161] The Court

[159] See paragraphs 124 and 125 above.

[160] See Order for Reference, paragraph 45.

[161] Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 131.

proceeded to uphold the validity a provision which increased the percentage of the surface area on certain sides of the unit packet of tobacco products.

251. It is submitted that this reasoning applies equally to the provision at issue in these proceedings. In particular, the Commission considers that the requirement for health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging, is appropriate to the objective of ensuring the visibility of such warnings and alerting consumers to the very serious health risks that tobacco products pose.

252. As part of its challenge to Article 10(1)(c), BAT claims that the requirement laid down in Article 10(1)(c) cannot be regarded as necessary for the purposes of complying with the FCTC[162]. However, in the Commission's view such an argument has no bearing on the proportionality of the measure at issue. The scope of action of the Union legislature is determined by the objectives and principles laid down in the Union law, in the present case Article 114 TFEU, and not by the FCTC. Moreover, Article 10(1)(c) was never presented by the Union legislature as being necessary to comply with the FCTC. Recital (24) of the Directive merely indicates that *"the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas"*.

253. The Commission rejects the claim according to which the figure of 65 % referred to in Article 10(1), is either arbitrary or unreasoned[163]. First, that figure is consistent with Article 11 of the FCTC, which provides that health warnings describing the harmful effects of tobacco use and appropriate messages *"should be 50% or more of the principal display areas"*. The corresponding Guidelines indicate that, *"*[g]*iven the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible"*[164].

254. Second, the Commission underlines that the objective for the requirement to display a prominent health warning is not simply to inform smokers, in general, that tobacco products are harmful. Rather it is intended to discourage smoking by making it possible for individuals to see, in vivid and realistic detail, the potential consequences of smoking for their health and the specific health risks related to

[162] Order for Reference, paragraph 48(b).

[163] See Order for Reference, paragraph 48(a). The Commission notes that Question 3(c) deals with compliance with the principle of proportionality, and not with the obligation to state reasons.

[164] Guidelines for implementation of Article 11 of the WHO FCTC on "Packaging and labelling of Tobacco Products", adopted by the Conference of the Parties in 2008, point 12 (Emphasis added).

tobacco consumption. Therefore, the fact that the health risks of smoking may be common knowledge for decades does not detract from the appropriateness of large pictorial health warnings with respect to the objective pursued by the Union legislature.

255. Third, Recital (25) of the Directive explains that the Union legislature decided to adopt more stringent requirements than under Directive 2001/37 because evidence *"suggests that large combined health warnings comprised of a text warning and a corresponding colour photograph are more effective than warnings consisting only of text. As a consequence, combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the surface of unit packets. Minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness"*. Those assertions are illustrated by the Impact Assessment, which indicates that *"[s]cientific evidence […] suggests that bigger pictorial pictures on both sides are more effective than text-only warnings on a range of outcomes, including being a deterrent for new smokers and a means to increase cessation among current smokers. In particular, they increase smokers' and potential consumers' awareness of warnings, knowledge and credibility of health risks, depth of processing and also cessation behaviours such as forgoing FMC, quit intentions and actual quitting"*[165]. The Impact Assessment illustrates this by noting that *"*[t]*he prevalence of adult smoking in Canada has declined approximately 6% since the implementation of large pictorial warnings in 2001, which is at least partially attributable to the picture warnings*"[166].

256. Subsequent evaluations of the effectiveness of large pictorial health warnings - even if still limited in number (as many jurisdictions have only introduced such measures recently)[167] have since confirmed the accuracy of the conclusions reached in the Impact Assessment.

257. In particular, several studies monitoring and examining trends in countries following the introduction of pictorial health warnings and comparative studies involving countries with different degrees of labelling provisions have been carried out in the context of the International Tobacco Control Policy Evaluation Project (the ITC Project)[168] and evidence on the effectiveness of pictorial health warnings

[165] See SWD (2012) 452 final, Impact Assessment, Part 1, page 31, and the studies mentioned.

[166] See SWD (2012) 452 final, Impact Assessment, Part 1, page 115, and the study mentioned.

[167] For example, 75% on both sides in Canada since 2012 (50% on both sides since 2000), 75% and 90% in Australia since 2012 (30% and 90% since 2006) 30% and 90% since 2008 in Zealand, 80% of both sides in Uruguay (2010), 60% and 70% in Mauritius (2009), 30% and 100% in Mexico (2010), 100% on one side in Brazil (2002), 75% on both sides in Brunei (2012), 60% on the bottom of each side in Ecuador (2012).

[168] http://www.itcproject.org/about

is presented and summarized in a recent report.[169] The results indicate that countries with large graphic warnings show highest levels of warning label effectiveness across the measures assessed compared to countries using only small text warnings. Measures include for instance noticing labels, thinking about health risks, likelihood of quitting, giving up smoking a cigarette.

258. Moreover, a recent study in Canada has assessed the effect of graphic tobacco health warnings on smoking behaviour based on the nationally representative sample of individuals aged 15 years and older from the Canadian National Population Health Survey 1998-2008. It found that graphic warnings had a statistically significant effect on smoking prevalence and attempts to quit.[170] This is confirmed by other studies and reports carried out in Canada[171].

259. The Commission submits that nothing in the Claimants' submissions as summarized in the Order for Reference puts into question the appropriateness of the approach adopted by the Union legislature as a means of obtaining the objective pursued by the Directive, namely to ensure the adoption of harmonized norms that take into account the objective of ensuring a high level of public health in the Union. On the contrary, the Commission underlines once again that the Union legislature's decision was informed by extensive consideration of competing options as part of the Impact Assessment procedure and was grounded on the basis of solid scientific research.

260. As regards the extent of scientific evidence required, the Commission rejects the claim according to which the right to legislate would have been conditional on existence of specific evidence of a "demonstrable need" for the 65% percent figure in particular. First, as a general principle, the Union legislature could never innovate, if the entitlement to legislate was conditional on having specific data on its future effect. By definition, the full effects of a specific novel measure cannot be known prior to its adoption.

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[169] ITC Project (March 2012). Health Warnings on Tobacco Packages: ITC Cross-Country Comparison Report. University of Waterloo, Waterloo, Ontario, Canada. http://www.itcproject.org/files/ITC_Cross-Country_Report_-_Warning_Labels-Final.pdf .

[170] Azagba S, Sharaf MF. "*The Effect of Graphic Cigarette Warning Labels on Smoking Behavior: Evidence from the Canadian Experience*." Nicotine Tob Res 2013;15(3):708-17.

[171] Huang J, Chaloupka FJ, Fong GT. *"Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis*". (Tob Control. 2014 Mar;23 Suppl 1:i7-12.); Evaluation of Canadian Tobacco Product Health-Related Labels (Cigarettes and Little Cigars). Report of Harris/Decima prepared for Health Canada (2013) Contract Number: HT372-123681/001/CY Contract Award Date: February 8, 2013. Date of Delivery: August 28, 2013.

261. Secondly, the specificity of the evidence that the Claimants' argue ought to be required, namely, demonstrable evidence that a health warning must occupy a specific percentage of a packet's surface area for it to achieve its public health objective, is nearly impossible to produce in practice. By their nature, tobacco control policies are composed of a combination of a variety of different measures, which are typically mutually reinforcing. It is not at all apparent that it would even be possible to identify which measure contributed to the success and to which degree. Such an assessment is further complicated by the fact that certain measures require time to take full effect.

262. The figure of 75% initially proposed by the Commission had been advanced in the light of *"scientific evidence and international experience and developments as well as the impact on economic stakeholders"*[172]. However, nothing prevented the Union legislature, acting within the limits of its broad discretion, from striking a different balance between those same parameters. The fact that, in doing so, the Union legislature finally opted for the lower – and therefore less onerous for the industry – figure of 65 % is a strong indication that it did not breach the principle of proportionality. In view of the broad legislative discretion recognised in this respect, that conclusion would obviously hold even if it were accepted that that requirement would make it more difficult for operators such as BAT to communicate with consumers and seek to differentiate their products[173].

263. Finally, the Commission notes that already, according to Directive 2001/37, in Member States with three languages the warning on the back of the packaging covers around 65% of the surface area (including the mandatory border). According to the Tobacco Products Directive, the combined warning on front and back will cover 65% of the surface area, including the border, in all the Member States, irrespective of the number of official language. This represents an advantage for the manufacturers who will no longer be obliged to adapt the size of the pictorial health warnings according to the number of languages of the Member States where the product is placed on the market. At the same time, no Member State will be obliged to reduce the size of its current health warnings. For all the considerations set out above, and having regard the interpretative principles laid down above, the Commission submits the measure at issue is perfectly appropriate.

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[172] See SWD (2012) 452 final, Impact Assessment, Part 1, page 97. Experimental research from Canada indicates that sizes from 75% onwards produces statistically significant effects. See Createc, Effects of modified packaging through increasing the size of warnings on cigarette packages: Quantitative study of Canadian adult smokers. HC POR-07-47. Ottawa, ON: Health Canada, 2008. http://www.smoke-free.ca/warnings/WarningsResearch/modified%20pac kaging%20-%20report-adult.pdf.

[173] See Order for Reference, paragraph 50.

264. As regards the alleged discriminatory effect of the Directive in so far as, in Article 11, it allows Member States to exempt products other than cigarettes and roll-your-own tobacco from the obligation to carry the combined health warnings provided for in Article 10, the Commission refers to paragraphs 225 and 226 above.

265. Regarding the allegations pertaining to the disproportionate impact and the increase in incentives to engage in illicit trade, the Commission refers respectively to paragraph 126 above.

Question 4

266. By its fourth question, the national court seeks to ascertain whether the provisions made by the Directive for the adoption of delegated measures is in conformity with the Union Treaties. In particular, the national courts inquires whether provision for the adoption of delegated acts in Articles 3(2), 3(4), 4(5), 7(5), 7(11), 7(12), 9(5), 10(1)(f), 10(3), 11(6), 12(3), 15(12), 20(11) and 20(12) are compatible with Article 290 TFEU.

267. According to Order for Reference, the Claimants' challenge to such provisions is based on the claim they seek to confer on the Commission the power to regulate matters that constitute "essential elements" of the Directive and therefore are contrary to the requirements of Article 290 TFEU. Moreover, the Claimants submit that the objectives, content and scope of the empowerments are not sufficiently defined.[174] Finally, one of the Claimants further submits that the powers conferred by Article 7(5) and 7(11) are not in the nature of delegated acts but, instead, seek to implement the Directive and are therefore invalid for that reason too.[175]

(i) On the admissibility of Question 4

268. Although the Order for Reference expresses and conveys' the Claimants' doubts concerning the alleged delegation of "essential elements" to the Commission, it provides no indication or explanation as to the reasons upon which such doubts are based. Nor is there any indication or explanation as regards the grounds for which the Claimant's allege the objectives, contents and scope of the delegations to be insufficiently defined.

269. This absence of information is exacerbated by the fact that in Question 4 the national court raises questions concerning the validity of certain provisions (e.g. Articles 3(2), 3(4) or 4(5)) but leaves unchallenged - and seem implicitly approves – a number of other provisions having a comparable content (e.g. Article 4(3)). The

[174] Order for Reference, paragraph 51.

[175] Order for Reference, paragraph 54.

same applies to the allegedly insufficient definition of the "*objective, content and scope*" of the delegations disputed in Questions 4 and 5.

270. As a consequence, the Commission, the other interveners, as well as the Court itself, are left in the position of essentially having to speculate upon the possible grounds which may have lead the national court to entertain doubts concerning the validity of the provisions it has referred. It further results in the Commission having to set out in a vacuum, and therefore in somewhat general terms, why it considers that recourse to delegated acts in the provisions singled out by the national court in Question 4 comply fully with Articles 290 and 291 TFEU.

(ii) Preliminary observations on Articles 290 and 291 TFEU

271. Insofar as the Commission can make out, the Claimants' challenge to the 14 provisions referred to in Question 4, is based on three general and overarching claims.

272. First: it is alleged that the empowerments entail an unlawful delegation by the Union legislature of elements which are considered "essential" to the Tobacco Products Directive in breach of Articles 290 and 291 TFEU. Second: the Claimants submit that their objects, content and scope is insufficiently clear and precise. Third: it is alleged that empowerments provide for measures that are not in the nature of delegated acts, but should more properly have been achieved using implementing acts.

273. It is proposed to briefly set out the general legal principles in respect of each of these claims, before proceeding to apply them to each of the provisions raised by the referring court.

(a) *Distinguishing "essential" from "non-essential" elements*

274. In the first instance, the Commission recalls that the entitlement of the Union to provide for empowerments to the Commission has existed long before the entry into force of the Lisbon Treaty. In the context interpreting provisions establishing empowerments under the terms of the Common Agricultural Policy, the Court has consistently held that:

> *"It cannot be a requirement that all the details of the regulations concerning the common agricultural policy be drawn up by the Council according to the procedure laid down in Article 43. It is sufficient for the*

purpose of that provision that the basic elements of the matter to be dealt with have been adopted in accordance with that procedure […]"[176]

275. The Court has also had an opportunity to provide guidelines on the differentiation between "essential" and "non-essential" elements of a legislative act. The concept of essential elements has, in particular, been defined as "*rules which (...) are essential to the subject-matter envisaged*"[177] and "*which are intended to give concrete shape to the fundamental guidelines of Community policy*".[178] More recently, the Court has further specified that this concept covers "*provisions which, in order to be adopted, require political choices falling within the responsibilities of the European Union legislature*".[179]

276. In addition, the Court has made it clear that "[a]*scertaining which elements of a matter must be categorised as essential is not […[for the assessment of the European Union legislature alone, but must be based on objective factors amenable to judicial review*" and for that purpose "*it is necessary to take account of the characteristics and particularities of the domain concerned*".[180]

277. It follows from such case-law that the concept of "essential elements" must be regarded as those elements which embody the fundamental policy choices in a legislative text and which define the substance of the approach adopted by the Union legislature in a particular area. Moreover the identification of the elements which are "essential" to a given matter must be based on objective factors, having regard to the characteristics and particularities of the domain in which it is adopted.

278. It is manifest that not all the elements which are regulated at the legislative level are by that reason alone "essential". If that were the case, Article 290 TFEU would remain devoid of purpose. Moreover, the mere fact that a particular provision may, at one point, have been considered to constitute an essential element of a particular act, does not mean that it will automatically or necessarily remain such an element if the act in which it features is substantially amended. The Commission submits in

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[176] Case 230/78 *Eridania* ECLI:EU:C:1979:216, paragraph 7, referring back to Case 25/70 *Köster,* ECLI:EU:C:1970:115. See also Case 46/86 *Romkes* ECLI:EU:C:1987:287, paragraph 16.

[177] Joined Cases C‑63/90 and C‑67/90, *Portugal and Spain v Council* ECLI:EU:C:1992:381, paragraph 14 and Case C‑240/90, *Germany v Commission*, ECLI: EU:C:1992:408, paragraph 36.

[178] See Case C‑356/97 *Molkereigenossenschaft Wiedergeltingen* ECLI:EU:C:2000:364, paragraph 21. See also Case C‑240/90, *Germany v Commission*, ECLI: EU:C:1992:408, paragraphs 36 and 37.

[179] See Case C-355/10, *Frontex*, EU:C:2012:516, paragraphs 64 to 68 and cited case-law. This judgment was developed in connection with an Implementing act under the pre-Lisbon rules, however, applies *mutatis mutandis* to the case of delegated acts.

[180] Case C-355/10, *Frontex*, EU:C:2012:516, paragraph 76.

determining whether or not a particular element may be regarded as essential, regard should be had to the scope and contents of the particular act as a whole.

279. It should further be added that, when powers are delegated to the Commission pursuant to Article 290 TFEU, the Commission may still, depending on the circumstances, enjoy a certain amount of discretion regarding the non-essential elements it is empowered to regulate. The prohibition to delegate powers on essential elements should thus not be understood as restricting the scope of the delegation to purely mechanical operations not necessitating any discretion. Thus, the fact that the Commission is left with a certain room for discretion in supplementing an element of a legislative act is not indication of the "essential" nature of the element in question.

(b) Specification of the objectives, content and scope of delegations

280. Pursuant to Article 290(1) TFEU, "*the objectives, content, scope and duration of the delegation of power must be explicitly defined in the legislative act granting such a delegation.*" In this regard, the Court has held that "[t]*hat requirement implies that the purpose of granting a delegated power is to achieve the adoption of rules coming within the regulatory framework as defined by the basic legislative act*".[181]

281. The Commission considers that the obligation to define the "*scope*" and "*content*" of the delegation should be understood as the obligation to define the subject-matter and the parameters of the power conferred on the Commission, in order to make it possible for the co-legislators to exercise their political scrutiny and, in any event, to allow the Court to review the legality of the delegated act to be adopted. However, it does not follow that the legislature is at the same time bound to define the "*content*" of the future delegated act. Furthermore, nothing in Article 290 TFEU suggests that the "*scope*" of a delegated act must be narrow. As explained above, Article 290 TFEU only prohibits delegation of powers concerning "*essential elements*".

(c) Implementing v delegated acts

282. The Court's case-law in *Biocides*[182] and *EURES*[183] provides important guidance on the delineation of the concepts of delegated acts pursuant to Article 290 TFEU and implementing acts pursuant to Article 291 TFEU.

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[181] See Case C-427/12*, Commission v Parliament and Council (Biocides),* EU:C:2014:170, paragraph 38.

[182] Case C-427/12, *Commission v Parliament and Council (Biocides)*, EU:C:2014:170.

[183] Case C-65/13, *Parliament v Commission (EURES)*, EU:C:2014:2289.

283. First, in *Biocides* the Court held that delegated powers conferred pursuant to Article 290 TFEU refer to the adoption of "*rules which supplement or amend certain non-essential elements of* [the legislative] *act*" and come "*within the regulatory framework as defined by the basic legislative act*". By contrast, implementing powers conferred on the basis of Article 291 TFEU allow the Commission "*to provide further detail in relation to the content of a legislative act, in order to ensure that it is implemented under uniform conditions in all Member States*".[184] Regarding the delineation of implementing powers, the Court further clarified in *EURES* that the "*Commission must be deemed to provide further detail in relation to the legislative act within the meaning of* [Biocides] *if the provisions of the implementing measure adopted by it (i) comply with the essential general aims pursued by the legislative act and (ii) are necessary or appropriate for the implementation of that act without supplementing or amending it*.[185]

284. Second, the Court recognised that the Union legislature has discretion when assessing whether a given regulatory mechanism included in a legislative act requires a delegation of powers pursuant to Article 290 TFEU or, rather, a conferral of implementing powers under Article 291 TFEU. The Court then came to the conclusion that "*judicial review is limited to manifest errors of assessment as to whether the EU legislature could reasonably have taken the view, first, that, in order to be implemented, the legal framework which it laid down ... needs only the addition of further detail, without its non-essential elements having to be amended or supplemented and, secondly, that the provisions ... require uniform conditions for implementation*".[186]

285. The Commission will now analyse in turn each of the provisions covered by Questions 4 and 5. In the interests of brevity, delegated powers having similar content, structure or function will be considered together.

(iii) Articles 3(2), 3(4) and 4(5)

286. Articles 3 and 4 of Tobacco Products Directive establish a framework for the establishment of maximum emissions levels from cigarettes and for the measurement of such levels.

287. Article 3(1) of the Directive sets maximum emission levels from cigarettes for tar, nicotine and carbon monoxide (TNCO). Pursuant to Article 3(2) the Commission is

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[184] See Case C-427/12, *Commission v Parliament and Council (Biocides)*, EU:C:2014:170, paragraphs 38 and 39.

[185] See Case C-65/13, *Parliament v Commission (EURES)*, EU:C:2014:2289, paragraphs 43 and 46.

[186] See Case C-427/12, *Commission v Parliament and Council (Biocides)*, paragraph 40.

empowered to decrease such levels in order to be in a position to adapt to relevant developments at international level.

288. Article 3(4) of the Directive delegates to the Commission the power to set, first, maximum emission levels from cigarettes as regards substances other than TNCO and, second, maximum emission levels for products other than cigarettes. The power delegated to the Commission under Article 3(4) is conditional upon the existence of standards relating to those emissions, which have been agreed by the parties to the FCTC or by the WHO.

289. Article 4 lays down requirements on measurement methods for emissions. Article 4(1) provides that TNCO emissions must be measured on the basis of the relevant ISO standards. Article 4(3), the validity of which is not disputed in the present case, delegates to the Commission the power to adapt the methods of measurement for TNCO where this is necessary based on scientific or technical developments or internationally agreed standards. Article 4(5) empowers the Commission to integrate in the Directive the standards for measurement methods that are internationally agreed by the parties to the FCTC or by the WHO.

The delegation of powers provided for in Articles 3(2), 3(4) and 4(5) do not concern essential elements

290. The Commission submits that applying the criteria set out in paragraphs 274 to 279 above, it is apparent that none of the delegations of powers provided for in Articles 3(2), 3(4) and 4(5) concern the essential elements of the Directive.

291. As far as Article 3 is concerned, it is clear from the wording of paragraphs (2) and (4) that the fundamental political choice of the Union legislature was to ensure that maximum emission levels are set at a level that is consistent with the most recent available standards and duly reflects the generally acknowledged public health concerns at a certain point in time.

292. As part of this choice, the Union legislature took the decision to tie the evolution of the Union's regulatory approach to the scientific and technical developments at international level, in the context of the FCTC or of the WHO. The delegations of powers in Article 3(2) and 3(4) do not in any way alter the balance set by the legislature, but rather embody the flexibility needed in order to ensure that the fundamental political choice made by the legislature is duly followed.

293. The same considerations apply to Article 4(5).

294. Moreover, as Recital (8) of the Directive recalls, the Union legislature is, pursuant to Article 114(3) TFEU, under a positive obligation to ensure that the regulatory

choices it makes, takes a high level of health protection as its basis. In this regard, it is obliged to take into account any new developments based on scientific facts. The mechanisms put in place under Articles 3(2), 3(4) and 4(5) serve to ensure respect for that obligation.

295. Furthermore, the Directive itself, highlights the particular importance of developments at international level for the regulation of emissions and measurement methods. In this regard, the Commission observes that Recital (4) states that "*in the light of scientific, market and international developments […] discrepancies are expected to increase […]*". Recital (11) recalls that "*for measuring the tar, nicotine and carbon monoxide yields of cigarettes […]reference should be made to the relevant, internationally recognised ISO standards… For other emissions from tobacco products, there are no internationally agreed standards or tests for quantifying maximum levels. The ongoing efforts at international level to develop such standards or tests should be encouraged*". Finally, Recital (12) points out that: "*As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness*". Those statements provide a clear guidance to the Commission as regards the exercise of the corresponding delegated powers.

296. In the Commission's view, the elements set out above support the view that the delegations of powers contained in Articles 3(2), 3(4) and 4(5) relate to non-essential elements of the Directive and therefore comply fully with Article 290 TFEU.

<u>The delegation of powers are drafted in sufficiently clear and precise terms</u>

297. The Commission submits that objective, scope and content of the empowerments provided for in Articles 3(2), 3(4) and 4(5) are sufficiently clear and precise.

298. In this context the Commission makes the following observations. First: As regards each of those provisions, the terms of empowerment provided for are clearly set out and circumscribed. Second: the scope and content are also explicitly stated in Articles 3(2), 3(4) and 4(5). These terms become even clearer when read in light of the definitions of "*emission*", "*maximum emission level*", "*tobacco product*" and "*cigarette*" that are provided in Article 2, respectively at points (4), (10), (21) and (22).

299. Regarding specifically TNCO emissions, which are the more significant ones as far as cigarettes are concerned, the Commission's room for action is further circumscribed, since pursuant to Article 3(2) the applicable maximum levels set in Article 3(1) paragraph 1 of same article may only be decreased.[187]

300. The Commission accordingly submits that the Claimants' claims according to which the provisions at issue are not sufficiently explicit is entirely without foundation.

(iv) Article 7(5) and 7(11)

301. Article 7(5) forms part of a mechanism established under Article 7(1) to (5) concerning the prohibition of non-essential additives that result in tobacco products possessing characterising flavours. The Commission considers that the fundamental and essential political choice in this matter is enshrined in Article 7(1), which requires Member States to prohibit the sale of such products.

302. According to the definition in Article 2, point (25), a "characterising flavour" is a "*clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additive*s*, including, but not limited to fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product*". However, Article 7(1) does not specify the level of additives (or combination thereof) that may impart a characterising flavour. That task is instead entrusted to the Commission under Article 7(5). Pursuant to that provision, the Commission may, following action by a certain minimum number of Member States, set maximum content level for additives or combination of additives that have been found to impart a characterising flavour.

303. Article 7(5) thus empowers the Commission to lay down a general rule (the maximum content level) on the basis of the measures taken against individual products by the Member States. Such a general rule manifestly supplements the general framework already laid down in Article 7(1) to (4).

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[187] In this regard, and for the sake of completeness, the Commission would like to draw the attention to the fact that according to the definition in Article 2(22) of the Directive, "*maximum emission level*" means "*the maximum content or emission, including zero, of a substance in a tobacco product…*". In light of that definition, the question may arise as to whether Article 3(2) would also allow the Commission to set TNCO emission levels at zero, which would be tantamount to prohibiting the placing of the market of cigarettes, since TNCO emissions are practically unavoidable in case of tobacco combustion. However, this would run counter the very wording of Article 3(2) which does not encompass any such prohibition. In fact Article 3(2) only empowers the Commission to "*decrease*" TNCO maximum emissions level "*where this is necessary based on internationally agreed standards*". Moreover, it is evident that the Commission must exercise the powers conferred by Articles 3(4) and 4(5) in the light of the aim the Tobacco Products Directive and cannot incorporate into Union Law agreed standards which would put in danger the achievement of the objective of this Directive.

304. The same applies with respect to the mechanism established under Article 7(9) to (11) of the Directive. Here again, the fundamental political choice is expressed in Article 7(9), which lays down the prohibition on the placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a product in a significant or measurable way.

305. However, the prohibition in Article 7(9) refers to individual products. No maximum content level for additives is set in this regard. Under Article 7(11) the Commission may, based on action by a certain number of Member States, set maximum content level for additives that have been found to increase the toxic or addictive effect, or the CMR properties of a tobacco product. Consequently, Article 7(11) performs the same function as Article 7(5), namely to lay down a general rule (the maximum content level) on the basis of the measures taken against individual products by the Member States and in order to supplement the general framework already established in Article 7(9) and (10).

306. As regards the objectives, scope and content of the delegations in Article 7(5) and 7(11), the Commission submits that they are expressed in clear and explicit terms. Recitals (15) to (19) clearly explain the concerns that prompted the Union legislature to regulate the ingredients of tobacco products under Article 7, and thus state the objectives of the powers delegated to the Commission in that respect. Moreover, those powers are clearly and strictly delimited in Articles 7(5) and 7(11) themselves. It is further underlined that, in both cases, the Commission is only empowered to set maximum content levels when at least three Member States have acted and, in the case of Article 7(11), those maximum levels must be set on the basis of the lowest maximum level that has led to one of the national prohibitions pursuant to Article 7(9).

307. In the Commission's view, it follows from the above that the delegations of powers contained in Article 7(5) and 7(11) are fully in conformity with Article 290 TFEU.

308. The Commission submits that the same reasoning applies to the Claimants' additional contention that the delegated acts to be adopted under Article 7(5) and 7(11) would not in fact supplement the basic act in accordance with Article 290 TFEU, but rather implement it under Article 291 TFEU.[188]

309. In particular, it follows from case-law referred in paragraphs 282 to 284 that implementing powers under Article 291 TFEU are aimed at providing further detail to the content of a legislative act, without however supplementing it. However, it is clear that the powers conferred on the Commission under Articles 7(5) and 7(11),

[188] See of the Order for Reference, Schedule B, paragraph 54.

do not merely seek to apply the prohibitions laid down in a specific product or to "*provide further details in relation to the content*" of Article 7(1) or 7(9). Quite the opposite, the empowerments provided for in Article 7(5) and 7(11) entrust the Commission with laying down rules of general application, namely maximum content level for additives or combinations of additives, that are aimed at supplementing the prohibitions imposed under Article 7(1) as regards products with characterising flavours and Article 7(9) as regards products containing additives in quantities that increase the toxic or additive effect or the CMR properties of the product concerned.

310. From this point of view, Articles 7(5) and 7(11) are different from Articles 7(2) and 7(10), according to which the Commission, by implementing act, is allowed to decide if a specific product falls within the ban of products having a characterising flavours or containing additives in quantities that increase its toxic or additive effect or its CMR properties.

(v) Articles 7(12) and 11(6)

311. The delegations provided for in Articles 7(12) and 11(6) both empower the Commission to withdraw the exemptions granted to certain classes of tobacco products, respectively, from the prohibitions on additives laid down in Article 7(1) and 7(7), and from the labelling requirements provided for in Article 11(1).

312. More particularly, Article 7(12) of the Directive provides that tobacco products other than cigarettes and roll-your-own tobacco are exempted from both the prohibition on characterising flavours laid down in Article 7(1) and from the prohibition on flavoured components provided for in Article 7(7). At the same time, however, Article 7(12) empowers the Commission to withdraw, by means of a delegated act, any of those exemptions in respect of a particular product category if a Commission report establishes that there is a "*substantial change of circumstances*" as regards the product category in question.

313. Similarly, Article 11(6) empowers the Commission to withdraw the possibility, conferred on Member States by Article 11(1), to grant exemptions from the labelling requirements laid down in Articles 9(2) and 10 as regards tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco. In this case too, the Commission is only empowered to act in the event that it is established in a report that a "*substantial change of circumstances*" has occurred with respect to any of the product categories concerned.

314. As is apparent from Recitals (19) and (26) of the Directive, Articles 7(12) and 11(1) must be understood as conditional exemptions, granted "*as long as there is no substantial change of circumstances in terms of sales volumes or consumption*

patterns of young people". It is therefore clear from the text of the Directive that the legislature only envisaged the withdrawal of those exemptions in case of substantial change of circumstances.

315. It should further be recalled that the concept of "*substantial change of circumstances*" has a well-defined meaning under Article 2, point (28). It refers to an increase in sales volumes, or in consumption patterns among younger consumers, for a given product category according to certain fixed rates and in a certain proportion of Member States which is deemed to be representative.[189]

316. It follows that the Commission may only make use of the delegated powers provided for in Articles 7(12) and 11(6) after having established in a report that the conditions set out in Article 2, point (28), are satisfied in respect of a given product category.

317. The Commission therefore considers that the delegated acts to be adopted pursuant to Articles 7(12) and 11(6) do not encroach on a legislative competence, since the fundamental political choices regarding the conditions for maintaining or withdrawing the exemptions provided for in Articles 7(1), 7(7) and 11(1) have already been made by the legislature and are clearly reflected in the text of the Directive. The Commission is only bound to adjust, through delegated acts, the regulatory framework in accordance with a mechanism established by the legislature itself.

318. Finally, the Commission is of the view that having regard to the clear wording of Articles 7(12) and 11(6), read in conjunction with Article 2, point (28) and further illuminated by the corresponding Recitals (19) and (26), there is no doubt that the objectives, scope and content of the delegations at issue are clearly and explicitly defined in the legislative text, as required by Article 290 TFEU.

(vi) Articles 9(5), 10(3)(a), 12(3) and 20(12)

319. Articles 9(5), 10(3)(a), 12(3) and 20(12) seek to ensure that the Commission is able to adapt the wording of information and text warnings required by the Directive.[190]

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[189] According to Article 2, point (28), a "*substantial change of circumstances*" means "*an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level*."

[190] The Order for Reference (paragraph 51) also points to Article 10(1)(f) to the Directive. However, in the Commission's view, Article 10(1)(f) is actually irrelevant for the purpose of Questions 4 and 5. In fact, due

320. Thus, for example, Article 9(2) of the Directive provides that each unit packet and any outside packaging of tobacco products for smoking must carry the information message "*Tobacco smoke contains over 70 substances known to cause cancer*". Article 9(5) then empowers the Commission to adapt that wording to scientific and market developments, by means of delegated acts.

321. Articles 10(3)(a), 12(3) and 20(12) follow the same structure and apply to three categories of products: tobacco products for smoking, smokeless tobacco products and electronic cigarettes respectively.

322. Crucially, all these delegations authorise the Commission to "*adapt*", i.e. to adjust the information and text warnings required under various provisions of the Directive, so as to keep in step with scientific research and market developments. In other words, the Commission is empowered to revise or replace the formulation of the warnings set out in the Directive where new elements arise from scientific research or development of the market for the products or classes of products concerned. The powers of the Commission are further circumscribed by the definition of "health warning" in Article 2, point (32). That definition limits what may be included to warnings concerning the adverse effects on human health of a product or other undesired consequences of its consumption.

323. It is therefore clear in the Commission's view that none of the delegations at issue encroaches on the legislature's competence. It is underlined that the measures at issue merely supplement fundamental political choices that are already embedded in the text of the Directive. The Union legislature has made the choice to require information and text warnings to convey messages on the adverse health effects of tobacco and drawing attention to the fact that nicotine consumption is addictive and harmful. The delegations at issue merely enable the Commission to bring those elements in line with new factual developments, where and insofar as necessary.[191]

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to a clerical error in the text Article 10(1)(f) cross-refers to Article 10(3), which contains two delegations of powers in points (a) and (b), whilst in reality it should have made reference to Article 10(4), which in contrast provides for implementing powers as regards the layout, design and shape of combined health warnings. This clerical error is currently being rectified through a corrigendum.

[191] By way of example, the information message provided for in Article 9(2) states that "[t]*obacco smoke contains over 70 substances known to cause cancer*". It is quite clear that this information may require an update should further scientific evidence arise as regards e.g. the number of harmful substances. Obviously such update does not entail any complex political, social and economic assessment reserved to the legislature. However, in the absence of a delegation of powers such as that contained in Article 9(5), the update may only be possible through a full legislative procedure. In this instance the legislature took the view that this would be excessively cumbersome and opted instead for a delegation pursuant to Article 290 TFEU.

324. The Commission submits that the objectives, content and scope of the delegations at issue are clearly and explicitly set out in each of the relevant provisions as well as in their corresponding recitals.[192]

(vii) Article 10(3)(b)

325. Article 10(3)(b) empowers the Commission to "*establish and adapt*" the picture library in Annex II to the Directive. Pursuant to Article 10(1)(a), that library features the colour photographs which, together with the text warnings included in Annex I, are part of the "*combined health warning*" for tobacco products for smoking.

326. In the Commission's view, neither the establishment nor the adaptation of the picture library affects an essential element of the Directive. In fact, it follows from the very wording of Article 10(1)(a), read in light of Recital (25), that the picture library is merely the visual representation of the text warnings included in Annex I of the Directive. Therefore, the fundamental political choices by the Union legislature, namely to require health warnings consisting in a combination of text and images, as well as the message to be conveyed through those warnings, are already enshrined in the text of the Directive, namely, in Article 10(1)(a) and Annex I. Recital (25) is clear evidence of this, in that it states: "*...large combined health warnings comprised of a text warning and a corresponding colour photograph should become mandatory throughout the Union ...*".

327. The Commission maintains that it is manifest from the provisions at issue that the objective, content and scope of the delegation conferred on the Commission in Article 10(3) (b) are clear and explicit in accordance with Article 290 TFEU.

(viii) Article 15(12)

328. Pursuant to Article 15(12) of the Directive, the Commission is empowered to adopt delegated acts to define the key elements of the data storage contracts referred to in paragraph 8 of same article. The elements to be defined include duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts.

329. The Commission submits that the 'essential element' of the legislative act is contained in Article 15(8) and consists in requiring manufacturers and importers to conclude data storage contracts. Some further criteria are equally laid down in that paragraph. Any delegated act adopted in accordance with Article 15(12) will only

[192] See, in particular, Recitals (25) and (42).

supplement that provision, in accordance with Article 290 TFEU. The power to define these elements has no impact on the essential scope of application of the directive, its fundamental aims or the main obligations it imposes.

330. While Recital (31) explains why the Union legislature found it necessary to impose such data storage contracts, Article 15(12) itself enumerates explicitly and in detail the contractual elements that the Commission's delegated act shall address.

(ix) Article 20(11)

331. The delegation provided for in Article 20(11) of the Directive arises with respect to electronic cigarettes. The first subparagraph of Article 20(11) provides for a safeguard clause aimed at enabling the competent authorities of a Member States to withdraw from the market specific electronic cigarettes or refill containers or type of electronic cigarettes or refill containers that, while being in conformity with the requirements of the Directive, have been proved to be dangerous.

332. The second subparagraph of Article 20(11) empowers the Commission to extend the prohibition to all the Member States, where it finds that such prohibition has been imposed, on duly justified grounds, in at least three Member States.

333. In the Commission's view, the structure of this delegation is essentially the same as those found in Articles 7(5) and 7(11). Article 20(11) empowers the Commission to lay down a general rule (the prohibition on a certain product or type of products in all the Member States) on the basis of the measures taken against individual products by the Member States. Such a general rule will undoubtedly come into, and supplement, the general framework already laid down in Article 20, within the meaning of the Court's case-law in the *Biocides* case.

334. Regarding the objectives, scope and content of the delegations in Article 20(11), the Commission observes that Recital (46) makes clear that concerns of unforeseen risk to human health prompted the Union legislature to introduce the safeguard clause laid down in the first subparagraph of Article 20(11). It further states that the objective of the delegation conferred on the Commission is "*to ensure the smooth functioning of the internal market for products complying with* [the] *Directive but not presenting the same health risks*".

335. Moreover, Article 20(11) clearly and explicitly delimits the powers delegated to the Commission. Pursuant to that Article, the Commission is only empowered to take measures when at least three Member States have acted and it considers that measures taken at the national level are supported by "*duly justified grounds*". Moreover, it is apparent from the very wording of Article 20(11) that the delegated act to be adopted by the Commission must have the same scope as the national

measures that have prompted the Commission to act, i.e. it must concern the same product or type of products that have been prohibited at the national level.[193]

336. In the Commission's view, it follows from the above that the delegations of powers contained in Article 20(11) is fully in conformity with Article 290 TFEU.

Question 5

337. By its fifth question the national court once again seeks a ruling on the validity of Articles 3(4) and 4(5), but from a different perspective. According to the Order for Reference, the Claimants consider the delegations of powers provided for in those articles to be excessively vague because they compel the Commission to implement standards "*agreed by the parties to the FCTC or by the WHO*" without at the same time defining what is meant by "*agreed by*".[194]

338. In particular, it is alleged that the references to standards "*agreed by*" could be interpreted as extending to non-binding guidelines or even "*statements of intent*" by only some of the parties to the FCTC or by the WHO. Furthermore, the Claimants contend that Articles 3(4) and 4(5) are invalid insofar as they delegate powers to external bodies that are not subject to the procedural safeguards of Union law.[195]

339. The Commission contests the claim that the concept of *"standards agreed by the parties to the FCTC or by the WHO*" is impermissibly vague. In this regard, is recalled that, similarly to other international instruments, the FCTC has its own decision-making mechanisms. The Conference of the Parties ("COP") is the governing body of the FCTC and is comprised of all Parties to the Convention. It may adopt various types of measures by majority vote or by consensus. For the purposes of Articles 3(4) and 4(5) of the Directive, the most relevant FCTC documents are probably the Guidelines for the implementation of Article 9 and 10 of the FCTC, which concern respectively the regulation of the contents of tobacco products and the regulation of tobacco product disclosures. Whilst non-binding in nature, those Guidelines are adopted through a formalized procedure and contain precise recommendations as well as genuine international standards.

340. In particular, the Guidelines are prepared in working groups in which the Union is involved, as any other Party to the FCTC. They are adopted by the COP where all the Parties to the FCTC are represented. For present purposes, it should be noted

[193] It follows that under no circumstances could the Commission adopt e.g. a general marketing prohibition concerning all electronic cigarettes or all refill containers on the basis of the delegation of powers contained in Article 20(11) of the Directive.

[194] Order for Reference, paragraphs 52 and 53.

[195] Order for Reference, paragraph 52.

that the Union even acts as a "Key Facilitator" within the working group tasked with the development of Guidelines for the implementation of Articles 9 and 10.[196] Likewise, the Union provides input into the COP decisions and can freely contribute its views on adoption of the Guidelines.

341. The Commission underlines that while the term "*agreed by*" in Articles 3(4) and 4(5) is intended to encompass standards adopted as part of FCTC Guidelines, it can in no circumstances be stretched, as the Claimants suggest, so far as to include unilateral "statements of intent" of only some of the Parties to the FCTC or the WHO. The words "*agreed by*" clearly refer to internal decision-making procedures of the FCTC and the WHO and cannot cover the positions taken by individual Parties to those organisations.

342. In this context, the Commissions submits that the Claimants' contentions about the allegedly vague meaning of the words "*agreed by*" in Articles 3(4) and 4(5) are entirely without merit and that the provisions comply with the principle of legal certainty.

343. Second, the Claimants contend that Articles 3(4) and 4(5) "*delegate powers to external bodies that are not subject to the procedural safeguard of EU law*", or in other terms, the delegation "*is not, in reality, to the Commission*".[197]

344. Such a contention is contested by the Commission. The delegations of powers contained in those Articles are explicitly addressed to the Commission as an institution of the Union. Nothing in Articles 3(4) and 4(5) indicates that any kind of power is conferred on entities external to the Union institutional framework.[198]

345. In this regard, it must also be observed that the use of delegated powers under Article 290 TFEU affords all the procedural and constitutional guarantees required under Union law and, at the same time, allows the Union institutions to keep political control over the decision-making procedure. In fact, any powers delegated to the Commission under Article 290 TFEU must by definition be exercised in accordance with the fundamental rights and principles of EU law, including the principle of proportionality, and with the objectives pursued by the Directive. It is recalled that this fact has been underlined by the Court in its judgment in Joined

[196] Work on these issues is ongoing within the FCTC and WHO framework – for details see footnote 80.

[197] See respectively paragraphs 52 and 53 of Schedule B of the Order for Reference.

[198] As was the case e.g. in Case 9/56, *Meroni*, EU:C:1958:7. On this matter, see also Case C-270/12, *United Kingdom v Parliament and Council* (Short selling), EU:C:2014:18.

Cases C-402/05 P and C-415/05 P, *Yassin Abdullah Kadi and Al Barakaat International Foundation*. [199]

346. Therefore, Articles 3(4) and 4(5) could never be interpreted as imposing upon the Commission the obligation to adopt standards that, while being agreed at international level, are incompatible with those fundamental rights and principles or with the objectives and scheme of the Directive. Furthermore, a delegated act adopted pursuant to Article 3(4) and 4(5) of the Directive is subject to the political scrutiny and possible veto of the co-legislators[200], besides being open to judicial review by the Court of Justice.

347. The Commission therefore submits that the fifth question should be answered in the negative.

Question 6

348. By its sixth question, the national court requests a ruling on the compatibility of Articles 6(1), 7(2)-7(4), 7(10), 9(6) and 10(4) with Article 291 TFEU.[201] According to the Order for Reference, the Claimants submit that the Directive unlawfully empowers the Commission to adopt implementing acts because it fails to lay down the required legal framework for those acts. It is further submitted that the uniform conditions of implementation are neither needed nor justified.

(i) On the Admissibility of Question 6

349. At the outset, the Commission observes that the Order for Reference contains no indication as to the basis upon which it is considered that the legal framework governing the adoption of the implementing acts in those provisions is insufficient. Indeed, the Reference does not even provide an explanation as to what legal framework the national court or the Claimants consider would have been required. Furthermore, the Order for Reference contains no explanation or reason in support of the sweeping allegation that there exist no justification or need for uniform conditions of implementation in respect of any of the empowerments provided for in Articles 6(1), 7(2)-7(4), 7(10), 9(6) and 10(4).

350. In the absence of minimum reasoning, the Commission, and indeed, the other interveners are left to speculate as to the grounds for which the national court had

[199] Joined Cases C-402/05 P and C-415/05 P, *Yassin Abdullah Kadi and Al Barakaat International Foundation v Council of the European Union and Commission*, ECLI:EU:C:2008:461.

[200] See Article 27 of the Directive.

[201] Order for Reference, paragraph 55.

doubts concerning the validity of Articles 6(1), 7(2)-7(4), 7(10), 9(6) and 10(4) of the Directive.

351. However, the Court has consistently held that, in the context of the procedure laid down in Article 267 TFEU, the national court is required to communicate the reasons for which a ruling on the interpretation or validity of Union law is considered necessary. Such information has been considered to be necessary, not merely so as to enable the Court to give useful answers but also to ensure that governments of the Member States and other interested parties have the opportunity to submit observations in accordance with Article 23 of the Statute of the Court of Justice.

352. Moreover, pursuant to that case-law, it is for the Court to ensure that that opportunity is safeguarded, given that, under that provision, only the orders for reference are notified to the interested parties, accompanied by a translation in the official language of each Member State, but excluding any case-file that may be sent to the Court by the national court.[202]

353. On the basis of the considerations set out above, in particular, the lack of minimum information concerning the reasoning underlying the doubts on validity, the Commission submits that Question 6 should be declared inadmissible.

354. If, however, the Court would nevertheless consider Question 6 to be admissible, the Commission, in the alternative, considers the unsubstantiated claims in any event, to be entirely without foundation. Each provision will be considered in turn.

(ii) Article 6(1)

355. Article 6(1) of the Directive provides that in addition to the obligation to report on ingredients and emissions in accordance with Article 5, enhanced reporting obligations shall apply to certain additives contained in cigarettes and roll-your-own tobacco products that are included in a priority list.

356. The Article then requires the Commission to adopt implementing acts establishing and subsequently updating such a priority list of additives. The Article proceeds to set out the criteria determining the inclusion of additives to the list, namely, additives:

> *(a) for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the properties set out in points (a) to (d) of paragraph 2 of the same Article; and*

[202] Order of 23 March 2012 in Case C-348/11 *Thomson Sales Europe*, paragraph 49 and case-law cited.

(b) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to paragraphs 1 and 3 of Article 5 of the Directive.

357. Points (a) to (d) of Article 6(2) of the Directive refer to the properties of additives which:
   - contribute to the toxicity or the addictiveness of the products concerned (the effect of which is to increase the toxicity or addictiveness in the products concerned to a significant or measurable degree).
   - results in a characterising flavour
   - facilitates inhalation or nicotine uptake
   - lead to the formation of substances that have CMR properties (the effect of which is to increase the CMR properties in the products concerned to a significant or measurable degree).

358. The Commission submits that it is apparent from Article 6(1) that, contrary to what is alleged, that provision establishes a specific legal framework governing the identification of additives meeting specified objective criteria. It thus empowers the Commission to supply, within well-defined parameters, the details necessary to give effect to general rules that are already laid down in the basic act.

359. In the Commission's view, it follows that the claim regarding the absence of a required legal framework is entirely unfounded.

360. The Commission equally rejects the claim according to which the empowerment contained in Article 6(1) is in breach of Article 290 TFEU because uniform conditions of implementation are neither justified nor required.

361. In this regard, the Commission submits that the Union legislature was fully entitled to consider that additives that were particularly harmful or which facilitated the uptake or consumption of tobacco products should be subject to enhanced reporting obligations. This entailed the creation of a specific procedure enabling the relevant additives to be identified and included in a priority list. Given that the identification of such substances and the compilation of such a list constitute an extended and ongoing endeavour, the Union legislature considered it necessary to establish an autonomous mechanism for the continuing compilation and updating of the priority list.

362. The Commission underlines that once the Union legislature imposed reporting requirements in relation to tobacco products, such requirements could only be imposed in a manner that applies equally and uniformly to all manufacturers and importers of tobacco products in all the Member States. Any alternative approach

would result in a serious and manifest breach of Article 114 TFEU upon which the Directive is founded. Indeed, it would subvert the very purpose for which the Directive was adopted, namely, to reduce actual and potential differences in rules between the Member States' laws and thereby facilitate the functioning of the internal market.

363. The Commission further reiterates that the Order for Reference does not contain a single discernable argument in support of the claim regarding the alleged lack of a need or justification for the adoption of an implementing act in Article 6(1).

364. The Commission therefore submits that Article 6(1) complies fully with the requirements of Article 291 TFEU and that the unsubstantiated claims to the contrary are entirely without foundation.

(iii) Articles 7(2) - (4) and 7(10)

365. The Commission rejects equally the contention according to which paragraphs (2), (3), (4) and (10) of Article 7 do not constitute a sufficient legal framework for the adoption of implementing acts. Each of the provisions sets out, in clear and precise terms, the manner in which the Commission is authorised or may be required to supply the detail necessary to give effect to the provisions and objectives laid down in the basic act.

366. As regards Article 7(2) and 7(10), it is underlined that that the delegation conferred on the Commission in each of those provisions is carefully delimited to the identification of whether the characteristics of given tobacco product correspond to pre-determined criteria that would result in it falling, respectively, within the scope of Article 7(1) or Article 7(9).

367. Similarly, the Commission's role in Article 7(3) is circumscribed by the express requirement to lay down rules governing the procedure for the determination of whether a tobacco product has a characterising flavour and would therefore fall within the prohibition laid down in the first paragraph of that Article. Article 7(4) also clearly specifies the Commission's parameters for action. Pursuant to that provision, the Commission is entrusted with laying down procedures for the establishment and operation of an independent advisory panel.

368. The Commission therefore submits that contrary to what is alleged, each of these provisions lay down a legal framework governing the adoption of implementing measures. In the absence of any intimation as to the grounds for which the referring court has doubts concerning the adequacy of the legal framework, the Commission simply affirms that the Claimants' allegation is, in any event, without foundation.

369. The Commission further rejects the claim according to which the empowerment contained in paragraphs (2), (3), (4) and (10) of Article 7 are in breach of Article 290 TFEU because uniform conditions of implementation are neither justified nor required.

370. As mentioned above, Articles 7(2) and 7(10) of the Directive provide a means for the determination as to whether or not particular tobacco products correspond to criteria laid down in the basic act. As the identification process constitutes an ongoing endeavour, the Union legislature considered it necessary to establish an autonomous mechanism for the continuing analysis of tobacco products. In this context, it is submitted that recourse to implementing measures was both required and justified.

371. The Commission further underlines that once the Union legislature provide for the ongoing assessment and analysis of tobacco products, such assessment could only be imposed in a manner that applied equally and uniformly to all tobacco products in all the Member States. Any alternative approach would result in a serious and manifest breach of Article 114 TFEU upon which the Directive is founded and would subvert its fundamental purpose to reduce the differences in rules between the Member States' laws and facilitate the functioning of the internal market.

372. As regards Articles 7(3) and 7(4), it is manifest that the establishment, respectively, of rules of procedure and an independent advisory panel are intended to facilitate and support the functions entrusted to the Commission by virtue of Article 7(2). Given that recourse to the adoption of implementing acts is justified in Article 7(2), it follows that it must also be justified in the cases of Articles 7(3) and 7(4).

373. The Commission therefore submits that the challenge to the validity of Articles 7(2) to 7(4) and 7(10), unsubstantiated in the Order for Reference, is also unfounded.

(iv) Articles 9(6) and 10(4)

374. The Commission submits that the reasoning developed in respect of the empowerments provided for under Articles 6 and 7, apply equally to Articles 9(6) and Article 10(4).

375. In particular, the Commission maintains that the provisions at issue provide an appropriate and sufficient legal framework for the adoption of implementing acts. Each of the provisions sets out, in clear and precise terms, the manner in which the Commission is authorised or may be required to supply the detail necessary to give effect to the provisions and objectives laid down in the basic act.

376. Both Articles 9(6) and 10(4) are concerned with the design and display of the external packaging of tobacco products and the precise position of health warnings.

377. Pursuant to Article 9(6) of the Directive, the Commission is empowered to adopt an implementing act determining the precise position of the general warning, as well as the information message, on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches. Article 10(4) requires the Commission to adopt implementing acts defining the technical specifications for the layout, design and shape of the combined health warnings, taking into account the different packet shapes.

378. The Commission observes that, in respect of each provision, the role of the Commission is carefully circumscribed, not merely by the wording of the provisions themselves, but also by the very detailed requirements laid down in the other provisions forming part of Articles 9 and 10. In respect of Article 9, for example, the Union legislature has specified the text of the general warning (Article 9(1)) as well as the text of an information message, the font of the lettering and the percentage of the surface area they are required to cover. In addition Article 9(3) of the Directive stipulates that the general warning and information message for roll-your-own tobacco products shall appear on the surfaces that ensure the full visibility of those health warnings.

379. Similarly, the provisions under Article 10 set out, in detail, the requirements for health warnings. In particular, they specify the requirement for both text and images on the outside packaging of tobacco products for smoking. Article 10(1) specifies the surface area to be covered by combined health warnings, and the location where such warnings must appear. It further specifies the maximum height and width of the warnings. It becomes apparent that the legal parameters within which the Commission is empowered to operate are carefully drawn.

380. It follows that contrary to what is alleged, there is a clear and sufficient legal framework governing the adoption of implementing measures provided for by both Articles 9(6) and 10(4). Certainly, the Commission is afforded a degree of flexibility in providing the relevant detail as regards the precise position of warnings on roll-your-own tobacco products (Article 9(6)) or in the definition of technical specifications regarding the layout, design and shape of the combined warning in tobacco products (Article10(4)). However, such flexibility is necessary, given the fact that the measures to be adopted concern products that are presented in distinctive or irregular shaped packaging, entailing a case by case application. The empowerment thus caters for situations where uniform conditions are required for implementing the normative framework established under Articles 9(6) and 10(4) with regard to individual products with distinctive characteristics. In the absence of any intimation as to the grounds for which the referring court has doubts

concerning the adequacy of the legal framework, the Commission submits that the Claimants' allegation is without foundation.

381. The Commission further rejects the claim according to which the empowerment contained in Articles 9(6) and 10(4) would be in breach of Article 290 TFEU because uniform conditions of implementation are neither justified nor required.

382. Once the Union legislature provided for the establishment of a mechanism for adopting specific measures relating to the affixing of health warnings on distinctively or irregularly shaped products, such measures could only be imposed in a manner that applied equally and uniformly to all tobacco products in all the Member States. As stated previously, an alternative approach would increase the divergences as between Member States' laws, resulting in a serious and manifest breach of Article 114 TFEU upon which the Directive is founded.

(v) Conclusion

383. The Commission submits that each of the empowerments referred to in the context of this question, lay down clear parameters in accordance with which the Commission is authorised or obliged to act. In each case, the Union legislature has circumscribed the content, scope and objective of implementing measures to be adopted. Given that these empowerments provide for the adoption of further more specific norms, it follows that such measures must impose uniform conditions in the Member States so as to ensure consistency with and promotion of the Directive's internal market objectives.

Question 7: Subsidiarity

384. By its seventh question, the national court inquires as to whether Articles 7, 8(3), 9(3), 10(1)(g), 13 and 14 entail a breach of the principle of subsidiarity.[203]

(i) Admissibility

385. At the outset, the Commission observes that while the Order for Reference set out the Claimants' position as regards the prohibition of products having a characterising flavour (Article 7), it contains no indication whatsoever as to the basis upon the Claimants, or indeed, the Court, would consider each of the remaining provisions, namely, Articles 8(3), 9(3), 10(1)(g), 13 and 14 would be incompatible with that principle. The Commission and other interveners are thereby, once again, left in the position of having to speculate upon the possible grounds for which the Claimants may have considered those provisions invalid.

386. However, the Court has consistently held that, in the context of the procedure laid down in Article 267 TFEU, the national court is required to communicate the reasons for which a ruling on the interpretation or validity of Union law is considered necessary.[204] Such information has been considered to be necessary, not merely so as to enable the Court to give useful answers but also to ensure that governments of the Member States and other interested parties have the opportunity to submit observations in accordance with Article 23 of the Statute of the Court of Justice.

387. Moreover, pursuant to that case-law, it is for the Court to ensure that that opportunity is safeguarded, given that, under that provision, only the orders for reference are notified to the interested parties, accompanied by a translation in the official language of each Member State, but excluding any case-file that may be sent to the Court by the national court.[205]

388. On the basis of the considerations set out above, in particular, the lack of minimum information concerning the reasoning underlying the doubts on validity, the Commission submits that Question 7 should be declared inadmissible, insofar as it relates to Articles 8(3), 9(3), 10(1)(g), 13 and 14.

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[203] Order for Reference, paragraph 55.

[204] See to this effect, Case C-370/12 *Pringle,* ECLI:EU:C:2012:756, paragraphs 84 and 85.

[205] Order of 23 March 2012 in Case C-348/11 *Thomson Sales Europe*, ECLI:EU:C:2012:169, paragraph 49 and case-law cited.

389. If, however, the Court would nevertheless consider Question 7 to be admissible, the Commission, in the alternative, considers the claims in any event, to be entirely without foundation.

(ii) On the principle of subsidiarity

390. According to the Order for Reference, the Claimants submit that the Union legislature has failed to show that any alleged internal market benefit of Article 7 would be sufficient to justify depriving Member States of the freedom to act in relation to the public health issues relating to menthol. BAT contends that the Union legislature's objectives could have been sufficiently achieved at a Member State level. It is further alleged that the Union legislature failed adequately to assess the available scientific and industry evidence and consequently treats menthol more harshly than the evidence can justify[206].

391. In this regard, the Commission recalls that, according to the principle of subsidiarity referred to in the third paragraph of Article 5 TEU, in areas which do not fall within its exclusive competence, the Union is to take action only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved at Union level.

392. The internal market being an area of concurrent competence according to Article 4(2)(a) TFEU, the principle of subsidiarity applies where the Union legislature uses Article 114 TFEU as a legal basis[207].

393. As regards judicial review of the requirements imposed by the respect of the principle of subsidiarity, the Commission recalls that the Union legislature has been recognised as possessing broad discretion in the application of this principle which requires complex political, economic and social assessments. Only if a measure manifestly disregards the limits imposed on the Union by the principle of subsidiarity should the lawfulness of such a measure be affected. Beyond those cases of manifest disregard, respect for the principle of subsidiarity should be safeguarded by the Union legislature itself and by national parliaments through the mechanism provided for in Protocol No 2 to the Treaty on the Functioning of the European Union.

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[206] See the Order for Reference, paragraphs 57 and 60.

[207] This was already recognised by the Court case-law in respect of Article 95 EC. See for example Case British American Tobacco (Investments) and Imperial Tobacco, paragraph 179.

394. In the present case, it is worth recalling that the Court has already ruled that the objective of eliminating the barriers between Member States on the manufacture, presentation and sale of tobacco products called for action at Union level[208]. The Commission sees no reason to reach a different conclusion regarding the Tobacco Products Directive.

395. In the Recitals to the Tobacco Products Directive, the Union legislature explained that *"there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco and related products which present obstacles to the smooth functioning of the internal market".*[209].

396. Recital (4) of the Directive in particular states that *"[i]n the light of scientific, market and international developments these discrepancies are expected to increase. This also applies to […] ingredients [and to] certain aspects of labelling and packaging […]"*[210]. More specifically, *"[t]he size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the entire Union in only a small number of production plants within the Union and the resulting significant cross-border trade of tobacco and related products calls for stronger legislative action at Union rather than national level to achieve the smooth functioning of the internal market."*[211]

397. Regarding specifically labelling and packaging, the Impact Assessment notes *"[I]n the area of packaging and labelling, the disparities are expected to grow in coming years as Member States continue to take further measures, e.g. to adopt pictorial health warnings, introduce cessation information and/or further standardise tobacco packaging in line with the guidelines for implementing Articles 11 and 13 of the FCTC"*[212]. Action at Union level in relation to tobacco products having a characterising flavour (such as menthol), which could facilitate tobacco initiation or affect consumption patterns, was considered particularly necessary given the likelihood of diverging regulations[213]. To leave Member States the task of regulating trade in those products would therefore perpetuate the uncoordinated

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[208] See Case C-491/01, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, ECLI:EU:C:2002:741, paragraph 182.

[209] Recital (4) of the Tobacco Products Directive. Emphasis added.

[210] Recital (4) of the Tobacco Products Directive. Emphasis added.

[211] Recital (6) of the Tobacco Products Directive.

[212] See Doc. SWD (2012) 452 final, Part 1, page 42.

[213] Recital (16) of the Tobacco Products Directive.

development of national rules and, consequently, obstacles to trade between Member States and distortions of competition so far as tobacco products are concerned[214].

398. As far as the assessment of scientific evidence is concerned, the Commission notes that the effect of characterising flavours (such as menthol) on tobacco initiation and consumption patterns is underpinned by studies, quoted in the Impact Assessment, which *"have demonstrated an influence of flavourings on smoking initiation"*, in particular as far as menthol is concerned[215]. It is also worth noting that the Impact Assessment was drafted following extensive consultation of the public and stakeholders, including the flavouring industry[216]. It contains an extensive description of the tobacco market, with specific references to tobacco products with a characterising flavour, including menthol cigarettes[217], as well as a detailed analysis of the economic and social impact of the regulatory options proposed by the Commission.

399. Action was deemed necessary at Union level because differences between national regulations and administrative provisions on tobacco related products existed and were expected to increase following scientific, market and international developments. The Union legislature's choices regarding tobacco products with characterising flavour as well as the labelling and packaging of tobacco products is therefore supported by objective findings and represents a legitimate use of its discretion.

400. The Commission further refers to the observations it has submitted in the context of Question 1, in which it has considered in detail, the nature of both actual and potential divergences between Member States concerning its rules on the manufacture, presentation and sale of tobacco products.

401. The Commission submits that it follows from the considerations laid down above that action at a Union level was fully justified in the light of the internal market objective of the Directive.

402. It follows that in the Commission's view Articles 7, 8(3), 9(3), 10(1)(g), 13 and 14 comply fully with the principle of subsidiarity.

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[214] See, to that effect, Joined Cases C–154/04 and C–155/04, *Alliance for Natural Health e.a.,* ECLI:EU:C:2005:449, paragraph 106.

[215] See Doc. SWD (2012) 452 final, Part 1, pages 101 and 102.

[216] See Doc. SWD (2012) 452 final, Part. 2.

[217] See Doc. SWD (2012) 452 final, Part 3, pages 3 and 15.

D. CONCLUSION

403. For the reasons set out above, the Commission considers that the questions referred to the Court of Justice for a preliminary ruling by The High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), should be answered as follows:

Examination of the questions referred has disclosed nothing capable of affecting the validity of 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.

Jonathan TOMKIN Chiara CATTABRIGA Marc VAN HOOF

Agents for the Commission

EUROPEAN COMMISSION

LEGAL SERVICE

Brussels, 5 June 2015
sj.j (2015) 2656313

To the Registrar
Court of Justice of the
European Union - Registry
L-2925 LUXEMBOURG

Case: **C-547/14 Philip Morris Brands and others v. The Secretary of State for Health - Corrigendum**

Dear Sirs,

The Commission refers to the observations it submitted in the present case on 19 March 2015 and would wish to bring the following typographical error to the Court's attention.

In the context of submissions on Question 6 (page 89 onwards), the reference in paragraphs 360, 369 and 381 to "Article 290 TFEU" should in fact be to "Article 291 TFEU". This error has been corrected in the French language version of the observations.

Yours faithfully,

Jonathan TOMKIN Chiara CATTABRIGA Marc VAN HOOF

Agents of the Commission