Reports of Cases

OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 23 December 2015[1]

Case C-547/14

Philip Morris Brands SARL and Others(Request for a preliminary ruling

from the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), United Kingdom)

(Approximation of laws — Directive 2014/40/EU — Manufacture, presentation and sale of tobacco and related products — Choice of Article 114 TFEU as the legal basis — Principle of proportionality — Principle of subsidiarity — EU fundamental rights — Freedom of expression — Article 11 of the Charter of Fundamental Rights — Articles 290 TFEU and 291 TFEU — Delegation of regulatory and implementing powers to the European Commission)

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I – **Introduction**

1. In April 2014, following tough negotiations and an extremely animated legislative procedure, the Union legislature adopted, in Directive 2014/40/EU,[2] revised rules concerning the manufacture, presentation and sale of tobacco and related products in the European internal market.

2. Like its predecessors,[3] that directive is also the subject of fierce legal disputes. It is currently occupying the Court in three parallel cases, of which the present case — referred by a UK court at the instigation of the Philip Morris International (PMI) and British American Tobacco (BAT) groups — contains the most extensive challenges to the lawfulness of that internal market harmonisation measure and, in a kind of general onslaught, calls into question a particularly large number of its provisions.

3. However, the suitability of Article 114 TFEU (formerly Article 95 EC and Article 100a of the EEC Treaty) as a legal basis no longer plays the central role it did in earlier years, even though certain points of detail continue to be disputed. Interest is now focused on other legal questions, particularly in relation to the principles of proportionality and legal certainty, the principle of subsidiarity and EU fundamental rights. In addition, the possibilities for delegation of regulatory and implementing powers to the European Commission under Articles 290 TFEU and 291 TFEU are at issue.

4. A very basic problem ultimately underlies these legal questions, which involve huge economic interests and affect the lives of millions of Union citizens every day: what latitude does the Union legislature still have in ensuring that products may be placed on the market under uniform conditions throughout the European Union without losing sight of the fundamental objective of a high level of health protection, which has been enshrined prominently in primary law (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights of the European Union)?

5. In addition to the present case, two further cases on the lawfulness of Directive 2014/40 are also currently pending, each dedicated to very specific aspects of the rules enacted by the Union legislature. One of those cases[4] relates to the new rules on electronic cigarettes contained in Article 20 of the Directive; it stems from a request for a preliminary ruling made by the same court (but not the same judge) which referred the present case to the Court of Justice. The other[5] stems from an action for annulment brought by the Republic of Poland specifically challenging the prohibition on menthol cigarettes imposed by the Union legislature. I am also delivering my Opinions in those two cases today.

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

3 — See, in this regard, in particular judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741); *Arnold André* (C-434/02, EU:C:2004:800); *Swedish Match* (C-210/03, EU:C:2004:802); *Germany* v *Parliament and Council* (C-380/03, EU:C:2006:772); and *Commission* v *Denmark* (C-468/14, EU:C:2015:504).

4 — Case C-477/14 *Pillbox 38*.

5 — Case C-358/14 *Poland* v *Parliament and Council*.

II – **The main proceedings and the reference for a preliminary ruling**

6. PMI and BAT are engaged in the manufacture and marketing of tobacco products. Before the referring court, the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), Philip Morris Brands SARL and Philip Morris Limited, on the one hand, and British American Tobacco UK Limited, on the other, have each brought actions against the Secretary of State for Health[6] seeking to prevent the implementation of Directive 2014/40 in the United Kingdom. Those two actions have been joined by the national court.

7. In the main proceedings the following other undertakings were granted leave to intervene in support of the applicants: Imperial Tobacco Limited, JT International SA and Gallaher Limited,[7] Tann UK Limited and Tannpapier GmbH,[8] Deutsche Benkert GmbH & Co. KG and Benkert UK Limited,[9] V. Mane Fils,[10] and Joh. Wilh. Von Eicken GmbH.[11] Some of these undertakings manufacture tobacco products themselves, whilst others operate as suppliers to the tobacco industry, for example for tipping paper or flavourings.

8. In the main proceedings the Secretary of State maintains that the Directive is valid, but at the same time takes the view that the EU institutions that were involved in the legislative process are best placed to defend the Directive and that in any event the Court of Justice has exclusive jurisdiction to assess its validity. In his view, the present case is appropriate for making a reference of a preliminary ruling.

9. Against this background, the referring court decided that the Secretary of State was not required to produce submissions or evidence, but that it would ask the Court forthwith about the validity of the Directive. By order of 7 November 2014, received on 1 December 2014, it referred the following questions to the Court for a preliminary ruling pursuant to Article 267 TFEU:

'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 the Directive], 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?

6 — The United Kingdom Minister for Health.
7 — Together 'JTI'.
8 — Together 'Tann'.
9 — Together 'Benkert'.
10 — 'Mane'.
11 — 'Von Eicken'.

(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 the Directive], which relate to packaging and labelling;

(ii) Article 7 [of the Directive], insofar as it prohibits menthol cigarettes and tobacco products with a characterising flavour;

(iii) Article 18 [of the Directive], which allows Member States to prohibit cross-border distance sales of tobacco products; and,

(iv) Articles 3(4) and 4(5) [of the Directive], which delegate powers to the Commission in relation to emission levels?

Proportionality and fundamental rights

2. In relation to Article 13 [of the Directive]:

(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 [the Directive] 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 [the Directive] invalid because they infringe Article 290 TFEU:

(a) Articles 3(2) and (4) concerning maximum emission levels;

(b) Article 4(5) relating to measurement methods for emissions;

(c) Articles 7(5), (11) and (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 the Directive] 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 [the Directive] 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 [the Directive] and in particular Articles 7, 8(3), 9(3), 10(l)(g), 13 and 14 invalid for failure to comply with the principle of subsidiarity?'

10. Apart from setting out the wording of these questions referred for a preliminary ruling, the order for reference simply summarises the legal arguments against the Directive made by the applicants in the main proceedings and their interveners. As the referring court regards those claims as 'reasonably arguable', it considers it 'necessary and appropriate' to obtain a preliminary ruling from the Court.

11. In the written part of the preliminary ruling proceedings, observations were submitted by the applicants in the main proceedings and their interveners, the United Kingdom, French, Polish, Portuguese and Norwegian Governments, Ireland, the European Parliament, the Council of the European Union and the European Commission.[12] The same parties were represented at the hearing on 1 October 2015, whilst Italy and Hungary also participated in that hearing.

III – **Admissibility of the request for a preliminary ruling**

12. Before I examine the substance of the extensive list of questions asked by the national court, it is necessary to consider the admissibility of its request for a preliminary ruling. First, the question arises whether the validity of specific provisions of a directive may be challenged in isolation. Second, it must be examined whether the circumstances under which the Court was seised in the present case are compatible with the spirit and the operation of the preliminary ruling procedure under Article 267 TFEU.

A – *The restriction of the questions relating to validity to specific articles of the Directive*

13. To a large extent the referring court does not ask the Court about the validity of Directive 2014/40 as a whole, but only the validity of specific rules of that directive.

12 — The participating Member States and some of the participating undertakings confined their respective written pleadings to certain aspects of the request for a preliminary ruling. The written observations submitted by Poland concern only the prohibition on menthol cigarettes, as in the parallel proceedings pending in *Poland* v *Parliament and Council* (C-358/14).

14. According to settled case-law, the partial annulment of an EU act is possible only if the elements the annulment of which is sought may be severed from the remainder of the act ('the requirement of severability'). [13] There is no such severability where the partial annulment of the contested act would have the effect of altering its substance. [14] This case-law can be readily applied to the review of the validity of an EU measure in preliminary ruling proceedings. [15]

15. The contested provisions of the Directive lay down many different requirements governing the manufacture, presentation and sale of tobacco and related products. No evidence has been put forward before this Court to indicate that there is such a close interrelationship between those provisions that they should all stand and fall together. Therefore, even if in this case the Court were to declare specific contested provisions of the Directive to be invalid, the other provisions contained in the Directive would still have their *raison d'être* and their scope would not be altered. This applies in particular, but not only, to the rules in which the Commission is authorised to adopt delegated acts or implementing acts.

16. Accordingly, each of the provisions of the Directive at issue must be considered to be a severable part of Directive 2014/40 and their possible annulment would not affect the substance of that directive.

B – *The circumstances in which the Court was seised*

17. However, consideration must also be given to whether the circumstances in which the Court was seised in this case could affect the admissibility of the request for a preliminary ruling.

1. The time when reference was made to the Court

18. It is immaterial, first of all, that the request for a preliminary ruling was made at a time when the period for the implementation of the Directive had not yet expired and no national implementing measures had yet entered into force. [16] The principle of effective legal protection, which is also enshrined in Article 47 of the Charter of Fundamental Rights and finds expression in the second subparagraph of Article 19(1) TEU, specifically requires that individuals are able to obtain the judicial review of EU measures which are of concern to them, without having first to break the law. [17] Against this background, the possibility which exists in United Kingdom law, and has been used many times, of judicial review in combination with a possible reference to the Court for a preliminary ruling during the phase in which EU directives are implemented in national law should be welcomed in principle.

13 — Judgments in *Jamet* v *Commission* (37/71, EU:C:1972:57, paragraph 11); *Commission* v *Verhuizingen Coppens* (C-441/11 P, EU:C:2012:778, paragraph 38); *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraph 16); and *Commission* v *Council* (C-425/13, EU:C:2015:483, paragraph 94).

14 — Judgments in *France* v *Parliament and Council* (C-244/03, EU:C:2005:299, paragraph 13); *Commission* v *Verhuizingen Coppens* (C-441/11 P, EU:C:2012:778, paragraph 38); *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraph 16); and *Commission* v *Council* (C-425/13, EU:C:2015:483, paragraph 94); see, in the same vein, judgment in *France and Others* v *Commission* (C-68/94 and C-30/95, EU:C:1998:148, paragraphs 257 to 259).

15 — See also the Opinion of Advocate General Trstenjak in *AJD Tuna* (C-221/09, EU:C:2010:500, point 112 with footnote 69). See, further, judgments in *Eurotunnel and Others* (C-408/95, EU:C:1997:532); *Intertanko and Others* (C-308/06, EU:C:2008:312); *Volker und Markus Schecke and Eifert* (C-92/09 and C-93/09, EU:C:2010:662); *Association Belge des Consommateurs Test-Achats and Others* (C-236/09, EU:C:2011:100); and *AJD Tuna* (C-221/09, EU:C:2011:153), in each of which the Court took a view on the validity of specific provisions of EU measures following requests for a preliminary ruling from national courts, although it did not comment expressly on the abovementioned issue of admissibility.

16 — Judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 33) and *Intertanko and Others* (C-308/06, EU:C:2008:312, paragraphs 33 to 35).

17 — See to that effect, with regard to the fourth paragraph of Article 263 TFEU, judgments in *Telefónica* v *Commission* (C-274/12 P, EU:C:2013:852, paragraph 27) and *T & L Sugars and Sidul Açúcares* v *Commission* (C-456/13 P, EU:C:2015:284, paragraph 29).

19. Contrary to the view taken by the Parliament, the Council, the Commission and France, a merely artificial legal dispute also cannot be considered to exist in the present case.[18] It is true that in the main proceedings the defendant, the Secretary of State, has thus far made virtually no substantiated defence submissions. However, it is solely for the national court or tribunal to decide at what stage in the main proceedings to make a request for a preliminary ruling to the Court of Justice;[19] this can happen even *before* an inter partes hearing in the main proceedings.[20]

20. Specifically in a situation like the present case, the Court has ruled, moreover, that a disagreement — and thus a genuine legal dispute — between the parties must be taken to exist wherever the authorities of the Member State concerned have declared their intention to implement the contested directive.[21] Such an intention can be inferred in this case from the fact that the Secretary of State expressly declared in the main proceedings that he considered the Directive in its entirety to be valid. Under these circumstances, the question referred is certainly not based on a *manifestly* artificial legal dispute.

2. The possible absence of doubts on the part of the referring court itself as to the validity of the Directive

21. On the other hand, much greater weight must be given to the objection raised by the Parliament, the Council, the Commission and France that the referring court itself has not expressed doubts as to the validity of the Directive but, in its request for a preliminary ruling, merely presents to the Court the criticisms made by the applicants in the main proceedings and their interveners.

22. In fact, in essence, the order for reference simply summarises the legal arguments against the Directive made in the main proceedings so as to inform the Court about them.

23. It should be noted in this regard that the national court cannot simply forward an individual's complaints to the Court, but must *adopt as its own* the questions it refers to the Court for a preliminary ruling.[22] It is settled case-law that preliminary ruling proceedings under Article 267 TFEU do not constitute a means of redress available to the parties to a case pending before a national court themselves, but a procedure for cooperation and dialogue between the national court and the Court of Justice.[23]

24. Accordingly, it is for the national court itself to decide whether a question raised before it on the validity of an EU measure is necessary to enable it to give judgment in the main proceedings.[24] The fact that the validity of an EU act is contested before a national court is not in itself sufficient to warrant referral of a question to the Court for a preliminary ruling.[25] In principle, national courts are required to assist with the enforcement of EU law, including Directive 2014/40.[26]

18 — See the leading judgment in this regard in *Foglia* v *Novello* (104/79, EU:C:1980:73).

19 — Judgments in *Irish Creamery Milk Suppliers Association and Others* (36/80 and 71/80, EU:C:1981:62, paragraph 5); *AGM-COS.MET* (C-470/03, EU:C:2007:213, paragraph 45 in conjunction with paragraph 42); and *Coleman* (C-303/06, EU:C:2008:415, paragraph 29).

20 — Judgment in *Corsica Ferries* (C-18/93, EU:C:1994:195, paragraph 12 and case-law cited).

21 — Judgment in *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 15); see, in the same vein, judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 36).

22 — See, to that effect, order in *Adiamix* (C-368/12, EU:C:2013:257, paragraphs 22 and 32); see also judgment in *IATA and ELFAA* (C-344/04, EU:C:2006:10, paragraphs 30 and 31).

23 — Judgments in *SAT Fluggesellschaft* (C-364/92, EU:C:1994:7, paragraph 9); *Cartesio* (C-210/06, EU:C:2008:723, paragraphs 90 and 91); and *Consiglio Nazionale dei Geologi* (C-136/12, EU:C:2013:489, paragraph 28).

24 — Judgments in *SMW Winzersekt* (C-306/93, EU:C:1994:407, paragraph 15); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 34); *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 13 and 14); *Association Kokopelli* (C-59/11, EU:C:2012:447, paragraph 28); and order in *Adiamix* (C-368/12, EU:C:2013:257, paragraph 16).

25 — Judgment in *IATA and ELFAA* (C-344/04, EU:C:2006:10, paragraph 28) and order in *Adiamix* (C-368/12, EU:C:2013:257, paragraph 17).

26 — See in this regard Opinion 1/09 (EU:C:2011:123, paragraph 68).

25. In addition, the spirit of cooperation which must prevail in the operation of the preliminary reference procedure means that the national court is to set out in its order for reference the reasons why it considers such a reference to be necessary[27] (see also Article 94(c) of the Rules of Procedure of the Court of Justice).

26. Measured against these conditions, the order for reference with which the Court is confronted in this case is certainly far from exemplary. It is true that the referring court has communicated to the Court very lengthy statements on why it granted leave for certain undertakings to intervene in the main proceedings and not for others. On the other hand, the request for a preliminary ruling is extremely laconic with regard to the relevance of the questions referred to the decision to be taken by the national court.

27. Nevertheless, the national court has indicated that it regards the claims made in the main proceedings as 'reasonably arguable' and therefore considers it 'necessary and appropriate' to obtain a preliminary ruling from the Court.

28. Those statements indeed represent the absolute minimum of the information which must be provided by a national court in order to meet the conditions governing admissibility in the preliminary ruling procedure. In combination with the arguments made by the applicants in the main proceedings and their interveners, as reproduced in the order for reference, however, they form a sufficient basis — with certain exceptions still to be discussed[28] — for the Court and for those entitled to take part in the proceedings under Article 23 of the Statute of the Court of Justice to take a view on the legal problems raised in this case.

29. In view of the importance of the principle of effective legal protection (Article 47 of the Charter of Fundamental Rights) in the EU legal order,[29] the admissibility of requests for a preliminary ruling to review the validity of EU measures should not be subject to excessively strict conditions, particularly in cases like the present one in which, in the absence of the possibility of bringing a direct action, preliminary ruling proceedings are the only way for the undertakings concerned to obtain a judicial review at Union level and to present their case before the Court.[30]

30. All in all, this request for a preliminary ruling should not therefore be regarded as inadmissible in its entirety despite the defects attached to the order for reference in this regard.

3. Certain other defects in the request for a preliminary ruling

31. Lastly, a number of parties raise various detailed complaints by which they call into question, in whole or in part, the admissibility of the request for a preliminary ruling. Those complaints can essentially be classified under two headings: first, it is alleged that the description of the facts in the main proceedings is not sufficiently clear and, second, it is argued that the questions referred to the Court are not relevant to the resolution of the dispute in the main proceedings.

27 — Judgment in *IATA and ELFAA* (C-344/04, EU:C:2006:10, paragraph 31) and order in *Adiamix* (C-368/12, EU:C:2013:257, paragraphs 21, 22, 27 and 32).

28 — See below, points 35 to 51 of this Opinion.

29 — See judgments in *Les Verts* v *Parliament* (294/83, EU:C:1986:166, paragraph 23); *Inuit Tapiriit Kanatami and Others* v *Parliament and Council* (C-583/11 P, EU:C:2013:625, paragraphs 90 and 91); and *Schrems* (C-362/14, EU:C:2015:650, paragraph 60).

30 — With regard to the importance of the preliminary ruling procedure in such cases, see judgments in *Unión de Pequeños Agricultores* v *Council* (C-50/00 P, EU:C:2002:462, paragraphs 38 to 40); *Inuit Tapiriit Kanatami and Others* v *Parliament and Council* (C-583/11 P, EU:C:2013:625, paragraphs 92 to 96); *Telefónica* v *Commission* (C-274/12 P, EU:C:2013:852, paragraphs 27 to 29); and *T & L Sugars and Sidul Açúcares* v *Commission* (C-456/13 P, EU:C:2015:284, paragraphs 29 to 31).

a) The description of the facts

32. With regard, first, to the information on the facts in the main proceedings which must be contained in a request for a preliminary ruling as a minimum in order to be answered by the Court, it is clear that the order for reference in the present case — unlike in Case C-477/14 — contains only an extremely brief summary of the arguments of the applicants in the main proceedings and their interveners. Furthermore, the national court refers almost continually to statements by persons designated as witnesses or experts by the applicants in the main proceedings or their interveners, without communicating or even summarising their content. In addition, such statements — even if their content were known — cannot automatically be presumed to be correct, since no adversarial proceedings have taken place yet in the national court, as has been stressed by several parties before the Court.

33. As the Parliament, the Council, the Commission and France rightly observe, such a practice by the national court makes it more difficult both for the Court and for others that are entitled to take part in the preliminary ruling proceedings under Article 23 of the Statute to make meaningful statements in regard to the answers to the questions referred.

34. Despite these defects in the presentation of the factual circumstances on which the questions are based, I consider that the request for a preliminary ruling is nevertheless sufficiently comprehensible in respect of its subject-matter and its purpose to enable the Court and those entitled to take part in the preliminary ruling proceedings to make a reasonable statement. After careful consideration, I do not therefore consider that the *entire* request for a preliminary ruling should be declared inadmissible on account of the abovementioned — very serious — shortcomings in the description.

b) The relevance of individual questions to the national court's decision

35. With regard, second, to the relevance of individual questions to the national court's decision, the Parliament, the Council and the Commission take objection to two groups of questions: on the one hand, question 1(a), (b) and (c)(iii) and, on the other, question 1(c)(iv) and questions 4 to 6. In addition, the Parliament and the Commission also have doubts as to the admissibility of question 7, on grounds of insufficient relevance to the national court's decision, in so far as it refers to provisions other than Article 7 of the Directive.

36. The starting point for considering this issue should be that questions referred concerning EU law enjoy a presumption of relevance. The Court may refuse to give a ruling on a question referred by a national court only where it is quite obvious that the interpretation, or the determination of validity, of a rule of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it.[31]

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

37. Parts (a), (b) and (c)(iii) of question 1 relate to the latitude which the Directive, in Article 18 and Article 24(2) and (3) thereof, gives the Member States to adopt more stringent national measures than those prescribed by the Union legislature.

31 — Judgment in *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 25); see also judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 34 and 35); *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 13 and 14); and *Association Kokopelli* (C-59/11, EU:C:2012:447, paragraphs 28 and 29); with regard to the presumption of relevance, see also judgment in *Beck and Bergdorf* (C-355/97, EU:C:1999:391, paragraph 22).

38. As far as Article 24(2) of the Directive is concerned, the parties have debated intensively before the Court whether under that provision Member States are *permitted* to prescribe plain packaging for tobacco products in their respective national laws. However, the adoption of such rules on packaging for tobacco products is not at issue in the main proceedings at present, or at least the referring court has not made statements in this regard anywhere in its order for reference.

39. In addition, neither the referring court nor any of the parties has stated, with regard to the issue of national prohibitions on certain tobacco or related products addressed in Article 24(3) of the Directive, whether and in what form the United Kingdom intends to avail itself of that special rule.

40. The same holds for Article 18 of the Directive, which permits the Member States to impose a prohibition on cross-border distance sales. In this regard too, it is not clear whether at present it is planned to have recourse to that rule in the United Kingdom.

41. It should be emphasised that the Member States are certainly not *obliged*, on the basis of the abovementioned provisions of the Directive, to introduce any rules into their national law and there is nothing to indicate, according to the information available in the reference for a preliminary ruling, that the enactment of specific rules could be expected with virtual certainty.

42. Under these circumstances, I take the view that it would go beyond the scope of the cooperation between the Court of Justice and the national court defined by Article 267 TFEU if the Court answered parts (a), (b) and (c)(iii) of question 1. The request for a preliminary ruling clearly lacks relevance to the national court's decision in this regard, with the result that the Court would run the risk of purely stating an opinion on a hypothetical question. [32]

43. There is, of course, nothing to prevent national courts questioning the Court again in due course on the interpretation and validity of Article 18 and Article 24(2) and (3) of the Directive when they are required to deal with those provisions in the context of a specific legal dispute.

ii) Question 1(c)(iv) and questions 4 to 6

44. Question 1(c)(iv) and questions 4 to 6 all refer to provisions of the Directive which lay down various powers at Union level to adopt delegated acts and implementing acts, namely Article 3(2) and (4), Article 4(5), Article 6(1), Article 7(2) to (5) and (10) to (12), Article 9(5) and (6), Article 10(1)(f), (3) and (4), Article 11(6), Article 12(3), Article 15(12) and Article 20(11) and (12) of the Directive.

45. All the abovementioned provisions of the Directive are addressed solely to the Commission. On the other hand, none of those provisions impose any obligations on Member States in respect of the organisation of their national laws, regulations and administrative provisions.

46. However, because the proceedings before the national court concern solely the United Kingdom's intention and duty to implement the Directive, any legal problems connected with the Commission's powers under those provisions of the Directive bear no relation to the actual facts of the main action or its purpose. They therefore manifestly have insufficient relevance to the national court's decision.

47. Once the Commission has exercised the abovementioned powers by adopting delegated acts or implementing acts, the remedies against them provided by the system of legal protection established by the Treaties are available to all those affected.

32 — It is a different situation in *Pillbox 38* (C-477/14), in which the combined provisions of Article 20(6) and Article 18 of the Directive are being challenged from an entirely different angle. In that case it is argued that it is disproportionate for the Directive — and thus for the Union legislature itself — to lay down the same rules on distance sales for electronic cigarettes as for conventional tobacco products; see my Opinion delivered today in that case, points 134 to 148.

iii) Question 7

48. By question 7, the invalidity of the Directive as a whole and specific provisions thereof — namely Article 7, Article 8(3), Article 9(3), Article 10(1)(g), Article 13 and Article 14 — is alleged in the light of the principle of subsidiarity.

49. As the Parliament and the Commission rightly state, however, the order for reference contains, only in relation to the prohibition on menthol cigarettes laid down in Article 7 of the Directive, a few extremely superficial statements on why the compatibility of the Directive with the principle of subsidiarity is being questioned. On the other hand, the order for reference does not even begin to explain why, in addition, the Directive as a whole and the other provisions of the Directive expressly mentioned in question 7 might raise problems in the light of the principle of subsidiarity.

50. This approach is in flagrant contradiction with the spirit of cooperation between the national court and the Court of Justice in preliminary ruling proceedings. It is also incompatible with the requirements of Article 94(c) of the Rules of Procedure, under which the referring court must state the reasons which prompted it to inquire about the validity of provisions of EU law. It is unacceptable that the Court and those entitled to take part in the preliminary ruling proceedings under Article 23 of the Statute have to speculate why the validity of certain rules of EU law should be examined.

51. For this reason — and in order to ensure that the Court does not state its opinion on a purely hypothetical problem — question 7 can be considered to be admissible only in so far as it refers to Article 7 of the Directive. In other respects question 7 must be considered to be inadmissible.

C – *Interim conclusion*

52. All in all, question 1(a), (b) and (c)(iii) and (iv) and questions 4 to 6 must therefore be declared inadmissible. Question 7 is inadmissible in so far as it refers to provisions other than Article 7 of the Directive. As to the remainder, the request for a preliminary ruling is admissible.

IV – **Substantive assessment of the questions referred**

53. The request for a preliminary ruling contains, based on the arguments made by the applicants in the main proceedings and their interveners, a general attack on Directive 2014/40 by which all the main provisions of that EU measure are placed under examination from a variety of angles. In addition to the suitability of Article 114 TFEU as a legal basis for specific provisions of the Directive, it covers problems in relation to proportionality and subsidiarity and also the powers conferred on the Commission to adopt implementing acts and delegated acts. For questions which I consider to be inadmissible in whole or in part (see immediately above [33]), I will comment on the legal problems raised only in the alternative.

A – *Article 114 TFEU as the legal basis for the Directive*

54. Question 1 queries from a number of different angles whether it was possible to have recourse to Article 114 TFEU as the legal basis for Directive 2014/40. I will examine the specific issues raised by the referring court in a slightly altered order.

33 — Points 35 to 51 of this Opinion.

55. By way of introduction, it should be noted that a legislative act adopted on the basis of Article 114 TFEU must, first, comprise measures for the approximation of the provisions laid down by law, regulation or administrative action in the Member States and, second, have as its object the establishment and functioning of the internal market.[34] Furthermore, the object of such internal market harmonisation measures under Article 114 TFEU must genuinely be to improve the conditions for the establishment and functioning of the internal market.[35]

56. Provided that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, the Union legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.[36]

57. Consequently, in this instance recourse to Article 114 TFEU as the legal basis for Directive 2014/40 cannot be called into question solely because, in addition to improving the functioning of the internal market for tobacco and related products, the Directive also pursues a high level of health protection. That objective is precisely consistent with the task conferred on the Union legislature in primary law, as can be expressly seen from Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights.

1. The prohibition on tobacco products with characterising flavours (question 1(c)(ii))

58. Question 1(c)(ii) relates to the Union-wide prohibition on tobacco products with characterising flavours laid down in Article 7(1) and (7) of the Directive. The specific bone of contention for the applicants in the main proceedings and some of their interveners is the prohibition on *menthol cigarettes* imposed by that provision. They claim that it was not possible for the Union legislature to impose such a prohibition on the basis of Article 114 TFEU.

59. In the light of the very brief statements in the order for reference and the extremely superficial submissions on this subject made by the undertakings taking part in the preliminary ruling proceedings, I will also be relatively succinct on this point and refer to my opinion in Case C-358/14,[37] where the same problem was discussed in much greater detail.

60. In essence, the complaints raised against Article 7 of the Directive are that the prohibition on menthol cigarettes is neither capable of eliminating differences between the Member States' laws, regulations and administrative provisions (see immediately below, section (a) nor could it improve the conditions for the functioning of the internal market (see below, section (b)).

34 — Judgment in *United Kingdom* v *Council and Parliament* (C-270/12, EU:C:2014:18, paragraph 100).

35 — Judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 60); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 32); and *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535, paragraph 26).

36 — Judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 88); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 62); and *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 30).

37 — See my Opinion delivered today in *Poland* v *Parliament and Council* (C-358/14, points 37 to 83 and 105 to 108).

a) The elimination of differences between the Member States' laws, regulations and administrative provisions

61. According to settled case-law, the Union legislature may have recourse to Article 114 TFEU in particular where there are differences between national rules which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market [38] or to cause significant distortions of competition. [39]

62. A number of undertakings taking part in the preliminary ruling proceedings and Poland claim that at the time when the Directive was adopted there were absolutely no divergences between Member States' laws, regulations and administrative provisions *on menthol cigarettes*.

63. That claim is not pertinent as it is clearly based on the misassumption that the Union legislature would have had the power under Article 114 TFEU to adopt rules on the use of menthol as a characterising flavour in tobacco products only if there had been differences between Member States' rules specifically with regard to menthol cigarettes.

64. Such 'salami slicing', which takes account separately of each market segment regulated in an internal market harmonisation measure and indeed even individual product components, must be rejected. Instead, the relevant factor is whether the Directive as a whole may be based on Article 114 TFEU.

65. In addition, menthol cigarettes do not have special status [40] distinguishing them from other cigarettes with characterising flavours and calling for an exception to the Union-wide prohibition on marketing this class of tobacco products imposed by the Directive. [41]

66. The sole crucial factor for recourse to Article 114 TFEU is whether at the time when the Directive was adopted it was necessary to eliminate differences between the Member States' laws, regulations and administrative provisions in respect of the use of characterising flavours in tobacco products — whether menthol or other flavours — which could act as obstacles to trade in the European internal market.

i) The removal of existing obstacles to trade

67. As the EU institutions taking part in the preliminary ruling proceedings and some of the participating Member States have explained, a number of Member States had already regulated the use of characterising flavours at the time, whilst others had not. Where national rules existed, there were appreciable substantive differences and they did not necessarily concern the same flavours. [42] This patchwork quilt of national rules resulted in considerable obstacles to trade in the internal market for tobacco products, which is characterised by a lively cross-border trade. [43]

38 — Judgments in *Germany* v *Parliament and Council* (C-380/03, EU:C:2006:772, paragraph 37); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 32); and *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535, paragraph 26).

39 — Judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraphs 84 and 106); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 32); and *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535, paragraph 26).

40 — See, for further details in this regard, my Opinion in *Poland* v *Parliament and Council* (C-358/14, points 48 to 57).

41 — See, in the same vein, the Report of the WTO Appellate Body of 4 April 2012 (WT/DS406/AB/R, 'United States — Measures affecting the production and sale of clove cigarettes', available on the WTO website at www.wto.org), in which clove-flavoured cigarettes and menthol-flavoured cigarettes are considered to be comparable (see in particular the conclusions in paragraph 298 of that report).

42 — For example, Germany prohibited the use of all flavoured capsules in cigarettes, while Belgium banned only the use of menthol capsules. France imposed limits on the use of additives giving a sweet or sour flavour. Lithuania prohibited certain flavours completely, such as all flavours producing a vanilla or clove taste. An overview of the subject is contained in the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular part 1, p. 34, and part 4, p. 6.

43 — Recital 6 in the preamble to the Directive; see also, in the same vein, judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 64); *Arnold André* (C-434/02, EU:C:2004:800, paragraph 39); and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 38).

68. Even if there had been no notable obstacles to trade specifically with regard to menthol cigarettes, this would have been immaterial as far as recourse to Article 114 TFEU is concerned, since the application of Article 114 TFEU does not require that the answer to specific divergences between national laws, regulations and administrative provisions must be contained in each detailed provision of an internal market harmonisation measure adopted on that legal basis. Rather, consideration must be given to the provisions in their entirety. [44]

69. Furthermore, in this case the Union legislature was also permitted to take into account that the prohibition of cigarettes with characterising flavours would have made a much smaller contribution to achieving a high level of health protection if menthol cigarettes had still continued to be available in the internal market as an alternative for current or potential consumers of flavoured tobacco products. [45]

70. Aside from this, at the time when the Directive was adopted, there was already, in at least two Member States — Belgium and Germany — even a prohibition of certain menthol capsules in cigarettes, with the result that it was not permitted in any case to place this specific variant of menthol cigarettes on the market there. [46] On the other hand, as far as can be seen, there were no such prohibitions in other Member States at the time. The claim made by several of the participating undertakings and Poland that there were no divergences between national rules specifically in respect of menthol cigarettes is therefore not only generally irrelevant in relation to the functioning of Article 114 TFEU, but also factually inaccurate in the case at issue.

ii) The risk of a future different development of national laws, regulations and administrative provisions

71. Furthermore, several of the undertakings taking part in the preliminary ruling proceedings and Poland deny that in future obstacles to trade will emerge in the European internal market as a result of national prohibitions on menthol cigarettes.

72. I will consider this issue below only in the alternative. It follows from my earlier statements in any case that there were already notable obstacles to trade at the time when the Directive was adopted in view of the divergences which existed at that time between the Member States' laws, regulations and administrative provisions on tobacco products with characterising flavours. This actually makes the question of the emergence of *future* obstacles to trade obsolete.

73. Be that as it may, it is settled case-law that recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, provided the emergence of such obstacles is likely and the harmonisation measure adopted is designed to prevent them. [47]

74. That is precisely the case here, in particular if account is taken of the work of the World Health Organisation (WHO) as an international context.

44 — In the words of the Court, recourse to Article 114 TFEU as a legal basis does not presuppose the existence of an actual link with free movement between the Member States in every situation covered by the measure founded on that basis. What matters is that the overall measure based on Article 114 TFEU must actually be intended to improve the conditions for the establishment and functioning of the internal market (see judgment in *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 80).

45 — See also recital 16 in the preamble to the Directive, from which it can be inferred that the Union legislature has a particular concern for characterising flavours that are capable of affecting consumption patterns.

46 — See the evidence in the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular part 1, p. 34.

47 — Judgments in *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 29); *Germany* v *Parliament and Council* (C-380/03, EU:C:2006:772, paragraphs 38 and 41); and *Ireland* v *Parliament and Council* (C-301/06, EU:C:2009:68, paragraph 64).

75. The EU institutions taking part in the preliminary ruling proceedings and some of the participating Member States have argued convincingly that under the WHO Framework Convention on Tobacco Control [48] the Union and its Member States were called upon to limit or prohibit the use in tobacco products of ingredients which may improve their taste, including the use of menthol. Although this is not apparent from the wording of the Framework Convention itself, it is clear from the Guidelines for Implementation of Articles 9 and 10 which were adopted by the Conference of Parties a few years ago. [49]

76. Whilst those guidelines are not as such legally binding, they do constitute internationally applicable recommendations for implementation of the WHO Framework Convention by its Parties. [50] They therefore also serve as a guide for the EU Member States which concluded that Framework Convention.

77. In these circumstances, the Union legislature could legitimately assume that rules on the use of menthol and other characterising flavours in tobacco products would soon be adopted at national level if uniform provisions were not introduced at Union level.

78. The reason for the fact, highlighted by some of the parties, that in reality hardly any national rules in this regard had been enacted in the EU Member States for a considerable period of time appears to be that the Commission [51] had prepared for and initiated the legislative procedure for the adoption of the contested directive within the EU at more or less the same time as the WHO Guidelines appeared. [52]

79. Furthermore, the Union legislature could reasonably assume that any national rules to implement the WHO Framework Convention would differ from one Member State to the next and thus lead to the creation of new obstacles to trade in the internal market unless a harmonisation measure was adopted at Union level. Those Guidelines do not stipulate any specific measures for the Parties to the Convention, but accord them extremely broad latitude; in particular, the Guidelines allow them to choose between prohibitions and mere restrictions on the use of flavouring ingredients in tobacco products and only contain examples of such ingredients.

80. Accordingly, the doubts expressed by a number of participating undertakings and by Poland as to the existence of present or future differences between Member States' laws, regulations and administrative provisions are all unfounded.

b) Improving the conditions for the functioning of the internal market

81. The applicants in the main proceedings and several of their interveners dispute, moreover, that the prohibition on menthol cigarettes can help to improve the conditions for the functioning of the internal market.

48 — Approved by Council Decision 2004/513/EC of 2 June 2004 (OJ 2004 L 213, p. 8).

49 — See, in this regard, the 'Partial Guidelines for Implementation of Articles 9 and 10', adopted by the Conference of Parties to the WHO Framework Convention on Tobacco Control at its fourth session in Punta del Este (2010), FCTC/COP/4(10), and amended at its fifth session in Seoul (2012), FCTC/COP/5(6); also 'the Guidelines' or 'the WHO Guidelines'. Section 3.1.2.2 of the Guidelines, which refers expressly to menthol as a flavouring ingredient, states that 'Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products'.

50 — Ibid., section 1.1.

51 — The Commission's 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 (COM(2012) 788 final) was presented on 19 December 2012. The internal preparations and Commission hearings therefore took place at an earlier date.

52 — See, in the same vein, my Opinion in *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:190, point 34, last sentence).

82. Undoubtedly, the prohibition on tobacco products with characterising flavours is not capable of improving the functioning of the internal market for *those* products. However, it is recognised in case-law that Article 114 TFEU confers on the Union legislature the power to prohibit the placing on the market of a certain product in the entire European internal market if this helps to improve trading conditions for a class of *other* products. [53]

83. This can be illustrated using the example of the tobacco products at issue in this case. The prohibition under EU law of certain delivery forms of tobacco serves to create uniform trade conditions for all tobacco products throughout the European Union. Thus, the Union-wide prohibition on tobacco products that are mixed with a characterising flavour is, as it were, the price for the free circulation in the European internal market of 'normal' tobacco products which comply with the conditions laid down by the Directive, whilst at the same time ensuring a high level of health protection. [54] In other words, tobacco products may in principle still be placed on the market in the European Union, but only without characterising flavours.

84. A number of undertakings taking part in the preliminary ruling proceedings object that smuggling will increase and the black market in menthol cigarettes will flourish. However, this is no more than a mere assertion, with little by way of substantiation.

85. Furthermore, it is also irrelevant whether smuggling and black market trade can be effectively prevented by the measures laid down in the Directive. [55] Instead, the crucial factor is that it will become more difficult for consumers to continue to obtain supplies of menthol cigarettes and other flavoured cigarettes after a prohibition on the placing on the market of tobacco products with characterising flavours has taken effect. This alone justifies the view that such a prohibition cannot fail to help to ensure a high level of health protection. The fact that prohibitions may possibly be circumvented in isolated cases does not in general militate against their appropriateness for attaining the objective pursued.

c) Interim conclusion

86. All in all, it can therefore be stated that it was correct to have recourse to Article 114 TFEU as the legal basis for the prohibition on tobacco products with characterising flavours, in particular menthol cigarettes.

2. Labelling and packaging of tobacco products (question 1(c)(i))

87. Question 1(c)(i) relates to Chapter II of Title II of the Directive. The referring court is seeking clarification whether Article 114 TFEU provides an adequate legal basis for the requirements under EU law on the 'labelling and packaging' of tobacco products contained in that part of the Directive (that is to say, in Articles 8 to 16). This is denied by the applicants in the main proceedings and some of their interveners. They dispute that notable obstacles to trade exist in this area and claim that any differences that exist in the packaging and presentation of tobacco products in the various national markets are primarily due to the manufacturers' marketing strategy and different consumer preferences in the individual Member States.

53 — Judgments in *Arnold André* (C-434/02, EU:C:2004:800, paragraphs 34 and 35) and *Swedish Match* (C-210/03, EU:C:2004:802, paragraphs 33 and 34). The judgment recently delivered in *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535) also concerned a situation where Article 95 EC (now Article 114 TFEU) served as the legal basis for the prohibition on the marketing of products in the European internal market.

54 — See also Article 24(1) of the Directive.

55 — See, in the same vein, judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 129). A similar idea is also put forward in my Opinions in *CHEZ Razpredelenie Bulgaria* (C-83/14, EU:C:2015:170, point 123) and *Belov* (C-394/11, EU:C:2012:585, points 107 and 108).

88. It should be noted in this regard that many aspects of the labelling and packaging of tobacco products were already regulated by EU law in Directive 2001/37/EC,[56] the predecessor to the contested Directive 2014/40.

89. If an internal market harmonisation measure already exists on a certain subject, which was at the time legitimately based on Article 114 TFEU, the Union legislature must in principle be permitted, in exercising its discretion, to have recourse to the same legal basis again in order to review the rules laid down at the time on the basis of a new political assessment and in the light of the latest scientific knowledge and to adapt them to a new situation.[57]

90. In this regard, the Union legislature has the option, on the one hand, of replacing earlier rules with entirely different, new rules which, after reviewing the circumstances, it considers are better able to contribute to the functioning of the internal market. On the other hand, it may also — as in this case — retain the earlier rules in principle and merely develop them so as to contribute to a high level of health protection in accordance with the task laid down in Article 114(3) TFEU, going beyond what could be achieved under the earlier rules.[58] In this connection, new rules can also be adopted to increase the effectiveness of existing rules and to make it more difficult to circumvent them.[59]

91. Against this background, there can be no doubt that Article 114 TFEU constitutes the correct legal basis for the new rules to develop EU legislation on the labelling and packaging of tobacco products contained in Chapter II of Title II of the Directive.

92. An additional factor in this case is that under the predecessor rules certainly not all obstacles to trade in tobacco products in the European internal market were eliminated.[60] As the EU institutions taking part in the preliminary ruling proceedings and Ireland and France rightly state, at the time when Directive 2014/40 was adopted there were still serious divergences between the Member States' rules on the labelling and packaging of tobacco products.[61]

93. Thus, in some Member States combined health warnings (consisting of text and a photograph) were required and in others — in accordance with the minimum requirements applying at the time under Article 5 of Directive 2001/37 — only textual warnings. Furthermore, there were differences in the requirements under national law relating to the size of cigarette packets, their minimum content and the advertisements and product information permitted on packaging.

94. It is obvious, and recognised in settled case-law, that the rules on the labelling and packaging of products laid down in the law of the Member States can act as obstacles to trade.[62] Thus, in the present case there was also scope from this perspective for adopting internal market harmonisation measures under Article 114 TFEU in order to eliminate such existing obstacles to trade.

56 — 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); see in particular Articles 5 to 7.

57 — Judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 77 to 80) and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 34).

58 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, in particular paragraph 79).

59 — Judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 100) and *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 82).

60 — See, in the same vein, judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 65 and 66).

61 — See recitals 22, 23 and 28 in the preamble to the directive. Details can be found in the documents submitted by the Commission on 19 December 2012, namely the explanatory memorandum for the Commission's proposal for a directive, COM(2012) 788 final, pp. 6-8, and the Impact Assessment by the Commission staff, Doc. SWD(2012) 452 final, part 1, p. 29 et seq.

62 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 64, second sentence); see also judgments in *Rau Lebensmittelwerke* (261/81, EU:C:1982:382, paragraph 15); *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905, paragraph 15); and *Schwarz* (C-366/04, EU:C:2005:719, paragraph 29).

95. It cannot be objected that some of the undertakings taking part in the proceedings do not consider the divergences existing between the national rules on labelling and presentation of tobacco products to be obstacles to trade because, by their own account, they design their product packaging differently according to the Member State and consumer habits anyway.

96. Whilst the subjective view of the undertakings concerned may be relevant to some degree in assessing the existence of obstacles to trade, it cannot be the only decisive factor, especially where — as in this case — there is suspicion that some undertakings are downplaying the existence of obstacles to trade in order to avoid Union-wide uniform regulation with more stringent health protection requirements. [63]

97. Rather, an objective examination must always be made. In this connection, the Union legislature was able, first, to take into account that the manufacture of tobacco products for the internal market was increasingly being concentrated in a small number of production plants within the European Union, which naturally results in significant cross-border trade and a greater need for Union-wide uniform rules. [64] Second, the international context, in particular the requirements stemming from Article 11 of the WHO Framework Convention, made it likely that the individual Member States would enact new, and presumably divergent, rules governing the labelling and packaging of tobacco products if the Union legislature had not taken action. [65]

98. It is not possible, moreover, to deny that the contested provisions of the Directive are capable of removing obstacles to trade by claiming that in future national specificities in product packaging for tobacco products will continue to exist — from the language of warnings to any tax stamps. Article 114 TFEU does not operate on the basis of the all-or-nothing principle. Instead, Article 114 TFEU also permits partial harmonisation of the Member States' laws, regulations and administrative provisions, which can likewise contribute to the removal of obstacles to trade, in particular where it results in a cost saving for the undertakings concerned. The Union legislature could reasonably proceed from that basis in view of the standardisation of the size and minimum content of product packaging, the nature of the warnings to be carried on it and the permitted product information.

99. As regards the increase in smuggling and the flourishing of the black market predicted by some parties, I consider that argument to be just as unconvincing in the present context as previously in connection with the prohibition on characterising flavours. [66]

100. Lastly, in so far as some of the undertakings taking part in the preliminary ruling proceedings complain that the standardisation of product packaging will cause a loss of product diversity and competitive opportunities between manufacturers of tobacco products, this is in reality not a complaint of lack of competence, but a complaint regarding proportionality, which I will rebut below in connection with question 3. [67]

101. In summary, the objections to recourse to Article 114 TFEU as the legal basis for the rules contained in Chapter II of Title II of the Directive must be rejected, in much the same way as the Court has already done with regard to the predecessor rules. [68]

63 — See, in this regard, the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, part 1, p. 33.

64 — Recital 6 in the preamble to the Directive; see also, in the same vein, judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 64); *Arnold André* (C-434/02, EU:C:2004:800, paragraph 39); and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 38).

65 — See, in the same vein, above, points 74 to 77 of this Opinion, and additionally below, point 201 of this Opinion.

66 — See above, points 84 and 85 of this Opinion.

67 — See below, point 193 and points 204 and 205 of this Opinion.

68 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 63 to 91).

3. The free movement of tobacco products (question 1(a) and (b))

102. Question 1(a) and (b) examines the provisions contained in Article 24 of the Directive regarding the 'free movement' of tobacco products. Based on the complaints raised by the applicants in the main proceedings and some of their interveners, the referring court is seeking to ascertain whether Article 114 TFEU constitutes a suitable legal basis for those provisions of the Directive, in particular paragraphs 2 and 3.

103. I will begin by stating that in assessing this question any notes from the legal services of different EU institutions, to which certain undertakings taking part in the proceedings make reference, cannot be relevant. They are produced in purely internal processes, do not necessarily reflect the opinion of the institution in question and, as such, cannot be invoked against that institution before the Court. It is in the nature of things that the EU's political institutions make internal preparations for their decision-making and, in doing so, also discuss matters controversially. It is not possible to make any inferences from this fact alone as to the lawfulness of the contested provisions of the Directive.

104. Article 24 of the Directive has the following structure: Paragraph 1 of that provision postulates the principle of the free movement of tobacco products and related products which comply with the Directive; the Member States may not, for considerations relating to aspects regulated by the Directive, prohibit or restrict the placing on the market of such products. This applies, however, only 'subject to paragraphs 2 and 3'. Article 24(2) of the Directive permits the Member States, under certain circumstances, to lay down further requirements — that is to say, going further than the provisions of the Directive — in relation to the standardisation of the packaging of tobacco products. Under Article 24(3) of the Directive, the Member States may also, under the conditions mentioned therein, prohibit a certain category of tobacco or related products for purposes of health protection.

a) The Member States' right to establish further requirements in relation to the standardisation of the packaging of tobacco products (question 1(a))

105. First of all, question 1(a) casts doubt on the legal basis for Article 24(2) of the Directive. Under that provision, the Directive does 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. …'

106. The applicants in the main proceedings and their interveners take the view that that provision cannot be based on Article 114 TFEU because it does not lead to the removal of obstacles to trade, but to the creation of such obstacles. In support of their view, the participating undertakings essentially claim that Article 24(2) of the Directive enables the Member States to undermine the free movement of goods in respect of tobacco products by introducing more stringent rules on packaging than those laid down at Union level.

107. In this regard, the participating undertakings, like the United Kingdom, Ireland and Norway, adopt a particularly *broad interpretation* of Article 24(2) of the Directive. They presume that under that provision the Member States are to be permitted to impose more stringent requirements on the packaging of tobacco products *in any respect*, regardless of whether or not that aspect of the packaging has been the subject of harmonisation by EU law.

108. In fact, on such a broad interpretation, Article 24(2) of the Directive could be contrary to the objective of Article 114 TFEU, which is based on improving the functioning of the internal market. On such an interpretation, the Directive would harmonise the requirements for the packaging of tobacco products, but at the same time give Member States the right to continue to derogate from that harmonisation without respecting the conditions and procedures specifically laid down for that purpose under Article 114(4) to (10) TFEU. As BAT aptly puts it, the harmonisation given with one hand would therefore be taken away by the other.

109. However, it would be premature to conclude out of hand, without more in-depth consideration of the subject, that Article 24 of the Directive is incompatible with Article 114 TFEU and could not therefore be adopted on that legal basis. The broad interpretation of Article 24(2) of the Directive adopted by the participating undertakings, the United Kingdom, Ireland and Norway is not the only conceivable approach. In addition, according to established case-law, if secondary EU legislation permits more than one interpretation, its wording must be understood in such a way that it is consistent with primary law and its validity cannot be called into question. [69]

110. It seems to be perfectly possible to interpret Article 24(2) of the Directive in conformity with primary law, in particular ensuring that it is compatible with the legal basis of Article 114 TFEU. It is possible — in accordance with the view taken by the EU institutions taking part in the preliminary ruling proceedings, as well as France and Portugal — to adopt a *narrow interpretation* of Article 24(2) of the Directive and to interpret that provision of the Directive as permitting the Member States to adopt 'further rules' only in so far as the Union legislature itself has not carried out any harmonisation.

111. Such a narrow interpretation of Article 24(2) is also most consistent with the purpose and scheme of Directive 2014/40. Contrary to the view apparently taken by the applicants in the main proceedings and some of their interveners, the Directive does not give rise to full harmonisation, but only partial harmonisation or — in the words of Article 1(b) — it seeks 'to approximate the laws, regulations and administrative provisions of the Member States concerning certain aspects of the labelling and packaging of tobacco products'. This is also suggested by recital 53 in the preamble to the Directive, which states that 'in light of the different degrees of harmonisation achieved', the directive merely 'provides a first set of basic common rules' 'in relation to presentation and the packaging'.

112. It is true that the Directive includes an entire chapter with provisions on the labelling and packaging of tobacco products, ranging from the shape and the minimum content of unit packets to the requirement of (combined) health warnings and the prohibition of certain misleading statements on product packaging. Contrary to the view taken by a number of the undertakings taking part in the proceedings, there is nevertheless still scope for a wide variety of additional national rules on the labelling and packaging of tobacco products. In particular, it can be inferred from Article 28(2)(a) of the Directive that certain package surfaces are not governed by the Directive and the Commission monitors, among other things, developments at national level.

113. Thus, the Member States remain free, in particular, to lay down their own requirements as to colours of all parts of the packaging which are not reserved for warnings, extending as far as the standardisation of packaging. [70] Colouring is regulated — indirectly — in the Directive at most in so far as Article 13 prohibits tobacco products being given a misleading or deceptively positive presentation.

69 — Judgments in *Commission* v *Council* (218/82, EU:C:1983:369, paragraph 15); *Ordre des barreaux francophones et germanophone and Others* (C-305/05, EU:C:2007:383, paragraph 28); *Review in Commission* v *Strack* (C-579/12 RX-II, EU:C:2013:570, paragraph 40); and *Parliament* v *Council* (C-540/13, EU:C:2015:224, paragraph 39).

70 — See again recital 53 in the preamble to the Directive.

114. Against this background, the objection raised by some of the undertakings taking part in the preliminary ruling proceedings that a provision based on Article 114 TFEU, like Article 24 of the Directive, could not permit the Member States to adopt *any* more stringent national rules on the labelling and packaging of tobacco products because such matters in their entirety 'fall within the scope of the Directive' is unconvincing. That objection, which is probably fuelled by the fear of some of the undertakings concerned that national rules will be adopted to introduce plain packaging, ignores the fact that even today many aspects of the labelling and packaging of tobacco products are still to be regulated in EU law, not least colouring.

115. If one were to follow the participating undertakings' argument, the partial harmonisation of the Member States' laws, regulations and administrative provisions pursued by Directive 2014/40 would be reinterpreted as full harmonisation. This would be contrary to the broad discretion which the Union legislature enjoys under Article 114 TFEU in selecting the most appropriate method of approximation. [71] The Union legislature is not required, when having recourse to Article 114 TFEU, to decide 'all or nothing' between full harmonisation and no harmonisation at all but may also — as in this case — opt for partial harmonisation.

116. The same conclusion follows, moreover, from the judgments relied on by the applicants in the main proceedings. [72] It is true that in its first judgment on tobacco advertising the Court held a directive based on internal market competences, including on Article 100a of the EC Treaty (now Article 114 TFEU), to be unlawful because it did not contain any provisions on the free movement of products complying with the directive. However, if that passage of the judgment is read in context, it becomes apparent that the Court certainly did not intend to slam the door on the adoption of directives for the *partial harmonisation* of certain matters. Instead, it expressly recognised that internal market harmonisation measures could contain clauses allowing Member States to adopt stricter measures for the protection of the general interest. [73]

117. Only if the Union legislature were not seeking any free movement for products covered by and complying with a directive is it prevented from having recourse to Article 114 TFEU. [74] In addition, the Union legislature may not permit the Member States to prevent, *on grounds relating to the matters harmonised by the Directive*, the import, sale or consumption of tobacco products which comply with the Directive. [75]

118. That is not the case here, however. First of all, Article 24(1) of the Directive expressly recognises the principle of the free movement of tobacco products which comply with the Directive. Second, Article 24(2) of the Directive, interpreted in the light of recital 53, permits the Member States to introduce 'further requirements … in relation to the standardisation of the packaging' only in so far as there is *no* harmonisation by EU law.

119. Certainly, this kind of partial harmonisation means that products cannot automatically be exported from one Member State to another, even if their labelling and packaging complies with the requirements of the Directive in every respect, as each Member State may impose further requirements for non-harmonised aspects of product packaging. Nevertheless, such partial

71 — Judgments in *REWE-Zentrale* (37/83, EU:C:1984:89, paragraph 20); *United Kingdom* v *Parliament and Council* (C-66/04, EU:C:2005:743, paragraph 45); *United Kingdom* v *Parliament and Council* (C-217/04, EU:C:2006:279, paragraph 43); and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 35).

72 — Judgment in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 104); see also judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 74), and *Germany* v *Parliament and Council* (C-380/03, EU:C:2006:772, paragraph 73); similarly, judgments in *Gallaher and Others* (C-11/92, EU:C:1993:262, paragraph 16) and *Philip Morris Belgium and Others* (C-222/91, EU:C:1993:260, paragraph 13).

73 — See, in this regard, judgment in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraphs 103 and 104); see, in the same vein, judgment in *Lapin* (C-358/11, EU:C:2013:142, paragraph 32).

74 — See, to that effect, judgment in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraphs 104 and 105).

75 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 74).

harmonisation also undeniably offers advantages for the functioning of the internal market, since whilst it does not eliminate all obstacles to trade, it does eliminate some. In the present case, this means, for example, that manufacturers of tobacco products throughout the internal market are able to use cigarette packets which have a uniform basic design and are required to adapt that design to the specificities of their respective national laws, regulations and administrative provisions only in certain details (colours, for example), but no longer in every respect.

120. It is true that those provisions of Article 24(1) and (2) of the Directive and the relevant explanations in recital 53 therefore have primarily a clarificatory function. They explain the operation of the partial harmonisation pursued by the Directive. As is impressively illustrated by the fierce dispute between the parties over the lawfulness of possible national rules on the standardisation of packaging, such clarification can make good sense.

b) The Member States' right to prohibit certain categories of products (question 1(b))

121. In addition, question 1(b) queries Article 24(3) of the Directive, and in particular its first sentence. Under that provision of the Directive, a Member State may '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'.

122. As the referring court points out in its request for a preliminary ruling, the first sentence of Article 24(3) is being challenged in the main proceedings with essentially the same arguments as Article 24(2) of the Directive. It is thus alleged once again that the contested provision of the Directive does not lead to the removal of obstacles to trade, but to the creation of such obstacles.

123. Contrary to the view taken by the Parliament, the Council and the Commission, this claim cannot be rebutted by a reference to the Union's lack of competence to adopt public health harmonisation measures (Article 168(5) TFEU) and to the continued responsibilities of the Member States for the definition of their health policy (Article 168(7) TFEU). Directive 2014/40 is not a public health measure, but an internal market harmonisation measure for which the Union is competent under Article 114 TFEU.[76] Otherwise the prohibition on tobacco products with characterising flavours, which is fiercely disputed in the present case, could not have been included in the Directive.[77]

124. As I have already stated above,[78] moreover, as a matter of principle Article 114 TFEU could not serve as a legal basis for a provision under which the Member States were permitted to derogate unilaterally from the Directive's harmonising effect. This also applies to any measures taken on grounds of public health policy which individual Member States might adopt 'in order to take into account possible future market developments', as is stated in recital 54 in the preamble to the Directive. For such cases Article 114(8) TFEU, which, as a rule of primary law, ranks higher than the Directive, makes express provision for action at Union level rather than at national level. If a 'specific problem on public health' arises in a field which has already been harmonised in EU law, the Member State concerned must contact the Commission, 'which shall immediately examine whether to propose appropriate measures to the Council'. It is not possible to depart from this rule in secondary legislation. At most, the Member States may be authorised in a directive to adopt *provisional measures* for health protection which derogate from the measures contained in it (Article 114(10) TFEU).

76 — See, to that effect, judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 88); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 62); and *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 30).

77 — See above, points 58 to 86 of this Opinion.

78 — See above, points 108, 116 and 117 of this Opinion.

125. Accordingly, contrary to the view taken by the EU institutions taking part in the proceedings, Article 24(3) of the Directive may not be interpreted so broadly that it effectively gives the Member States *carte blanche* permanently to ban, on public health grounds, the placing on the market of certain products covered by the Directive, thereby unilaterally invalidating the free movement of those products. The argument put forward by the Parliament and the Commission that, on the basis of Article 24(3) of the Directive, individual Member States are permitted for example to prohibit completely the placing on the market of cigarettes cannot therefore be accepted. Such unilateral national prohibitions are possible only in respect of products which have *not* been the subject of harmonisation in Directive 2014/40. [79]

126. All this does not mean, however, that Article 24(3) of the Directive would be unlawful and would thus have to be annulled. As with the validity of Article 24(2) of the Directive, the validity of Article 24(3) can also be affirmed if a strict interpretation is given to that clause in the light of the legal basis used for its adoption, that is to say, in accordance with Article 114 TFEU. [80]

127. First of all, under Article 24(3) of the Directive unilateral national prohibitions of products which are covered by the Directive are permitted only in so far as the public health objective pursued at national level is not met adequately by the harmonisation measures in the Directive. This is indicated by the wording of the first sentence of Article 24(3) of the Directive, according to which any prohibitions on products imposed by the Member States must be 'justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive'.

128. Second, the first sentence of Article 24(3) of the Directive permits only prohibitions on products for public health reasons at national level 'on grounds relating to the specific situation in that Member State'. It is consistent with the principle of subsidiarity (Article 5(1) and (3) TEU) to leave it primarily for the Member States to resolve such problems. [81] If cross-border problems arise in this connection, the Union legislature has taken precautions in the other sentences of Article 24(3) of the Directive and, following the model in Article 114(5) and (6) TFEU, introduced an authorisation procedure to be conducted by the Commission.

129. Subject to that proviso, Article 24(3) of the Directive may be regarded as a measure covered by the legal basis of Article 114 TFEU.

130. The applicants in the main proceedings object that there is an inconsistency between Article 24(3) of the Directive and the prohibition on menthol cigarettes in Article 7 of the Directive. [82] They essentially claim that a prohibition on characterising flavours, as laid down in Article 7 of the Directive, is not necessary if the Member States are in any case given the possibility unilaterally to prohibit certain categories of tobacco products. In addition, they argue, it is not coherent to justify the prohibition on characterising flavours in Article 7 of the Directive by the prevention of possible future divergences in national rules, but at the same time to encourage further such divergences in Article 24(3) of the Directive.

131. This claim is also unconvincing. First, as has already been mentioned, [83] Article 7 of the Directive deals with a *cross-border problem* which affects the entire European internal market whereas, according to its wording, the scope of Article 24(3) of the Directive is confined to *specific situations in individual Member States*. Second, the Union legislature is free, in the exercise of its broad discretion in the

79 — See also recital 55 in the preamble to the Directive.

80 — See above, point 109 of this Opinion.

81 — See my Opinion delivered today in *Poland* v *Parliament and Council* (C-358/14, points 141 to 171, in particular points 152, 153 and 165).

82 — This complaint is raised in connection with both Article 24(3) of the Directive and Article 7 of the Directive. I will deal with the respective arguments of each side together in this section.

83 — See above, points 58 to 86, and additionally below, points 282 to 284 of this Opinion.

context of Article 114 TFEU,[84] to choose a gradual harmonisation of the Member States' laws, regulations and administrative provisions, such that some internal market problems are addressed by means of a harmonisation measure, whilst others — for now — are not. Accordingly, it cannot be regarded as inconsistent if the Union legislature bans tobacco products with characterising flavours throughout the European internal market, whilst for the time being it leaves it to the individual Member States to prohibit other harmful products.

c) Interim conclusion

132. All in all, there are therefore no indications, on the basis of the arguments presented to the Court, that Article 24(2) or (3) of the Directive was wrongly based on Article 114 TFEU.

4. Rules on distance sales (question 1(c)(iii))

133. With question 1(c)(iii) the referring court has in view Article 18 of the Directive, or more precisely paragraph 1 thereof, which gives the Member States the option to prohibit cross-border distance sales of tobacco products to consumers and calls on them to cooperate to prevent such sales.

134. This question stems from a complaint made by BAT in the main proceedings, claiming that that provision does not facilitate cross-border trade, but impairs it, and therefore runs counter to the objectives of Article 114 TFEU. Furthermore, the undertaking alleges that the choice left to the Member States will lead to divergences between national laws, regulations and administrative provisions. For both reasons BAT disputes that Article 18 of the Directive may have Article 114 TFEU as its legal basis.

135. It should be stated, first, that until now — before the entry into force of Directive 2014/40 — the Member States have also been free to prohibit or restrict cross-border distance sales of tobacco products within the European Union on the basis of the limits on the free movement of goods laid down in the Treaties.[85] Article 18(1) of the Directive is thus no more than a declaratory clause confirming the *status quo*.

136. Furthermore, according to the preamble to the Directive,[86] Article 18(1) also takes account of the fact that the rules of the Directive on the manufacture, presentation and sale of tobacco products could be easily circumvented through distance sales and also that young people could obtain access to tobacco products more easily through that sales channel. In general, the tobacco control legislation could thus be undermined.

137. It is recognised in case-law that a measure adopted under Article 114 TFEU may also incorporate rules which are able or intended to ensure, by means of prohibitions, that certain provisions are not circumvented.[87] Article 18(1) of the Directive serves precisely that purpose.

84 — Judgments in *REWE-Zentrale* (37/83, EU:C:1984:89, paragraph 20); *United Kingdom* v *Parliament and Council* (C-66/04, EU:C:2005:743, paragraph 45); *United Kingdom* v *Parliament and Council* (C-217/04, EU:C:2006:279, paragraph 43); and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 35).

85 — For example, in France and Lithuania there is a general prohibition on online sales of tobacco products, whilst some other Member States make distance sales of these products subject to an authorisation requirement and lay down age limits. See, in this regard, the overview in the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular part 4, p. 8.

86 — Recital 33 in the preamble to the Directive.

87 — Judgments in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 100) and *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 82).

138. A prohibition on cross-border distance sales, which some Member States have imposed or may yet impose on the basis of Article 18(1) of the Directive is, as it were, the price for the circulation in the European internal market of tobacco products which comply with the conditions laid down by the Directive and are sold in accordance with the objective of health protection pursued by that Directive.

139. Accordingly, Article 18(1) of the Directive could be adopted having recourse to the legal basis of Article 114 TFEU. [88]

5. Authorisation of the Commission to implement internationally agreed standards (question 1(c)(iv))

140. Question 1(c)(iv) relates to Article 3(4) and Article 4(5) of the Directive, in which the Commission is authorised to adopt delegated acts to integrate into Union law certain internationally agreed standards for maximum emission levels, emissions and measurement methods. In this regard, the referring court takes up a complaint made by JTI, claiming that under those provisions of the Directive legislative powers are delegated *de facto* to the WHO or to the Parties to the WHO Framework Convention, which is not compatible with Article 114 TFEU.

141. On closer inspection, the criticism of those two provisions of the Directive has a dual thrust. First, an alleged delegation of legislative powers to international institutions or bodies outside the EU's institutional framework is criticised. Second, it is questioned whether the functioning of the internal market can really be improved by any adaptation of EU law to international standards.

142. I will rebut the first criticism further below in connection with question 5. [89] As far as the second criticism is concerned, it is sufficient to note that according to settled case-law Article 114 TFEU may serve as the basis for the adaptation of existing internal market harmonisation measures to recent developments. [90] It is self-evident that such adaptation can also be based on requirements under international law or recommendations made by international bodies (see also the second sentence of Article 3(5) TEU).

143. That is precisely the situation here. Article 3 of the Directive already contains rules on maximum emission levels and emissions from tobacco products and Article 4 of the Directive already lays down rules on measurement methods. The Commission is authorised in each case to adapt or supplement those rules in the light of recent developments at international level. This ensures that new internationally agreed standards are applied uniformly and simultaneously throughout the European internal market, which improves the functioning of the internal market.

144. The objection that Article 114 TFEU cannot serve as the legal basis for Article 3(4) and Article 4(5) of the Directive is therefore unfounded.

B – *Principle of proportionality*

145. Questions 2 and 3 concern the principle of proportionality. On the one hand, on the basis of a complaint made by BAT, the prohibition on tobacco products with characterising flavours is addressed (question 3(a)) and, on the other, following complaints raised by several participating undertakings, the focus is on various requirements which the Directive imposes on the labelling and packaging of tobacco products (question 2 and question 3(b) and (c)).

88 — The question whether Article 18(1) of the Directive complies with the principle of proportionality is not at issue in these preliminary ruling proceedings.

89 — See below, points 258 to 263 of this Opinion.

90 — Judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 77 to 80) and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 34); see also above, points 89 and 90 of this Opinion.

146. According to settled case-law, the principle of proportionality is one of the general principles of EU law. It requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not go beyond what is necessary in order to achieve those objectives;[91] when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.[92]

147. It should be borne in mind in connection with the judicial review of the proportionality of EU measures that the extent of the EU legislature's discretion may prove to be limited, depending on a number of factors, where fundamental rights are at issue. Those factors include, in particular, the area concerned, the nature of the fundamental right at issue, the nature and seriousness of the interference and the object pursued by the interference.[93]

1. Interferences with the freedom to conduct a business

148. Most of the problems raised in questions 2 and 3 concern the fundamental right of freedom to conduct a business (Article 16 of the Charter of Fundamental Rights). According to settled case-law, that fundamental right may be subject to a broad range of interventions on the part of public authorities which may limit the exercise of economic activity in the public interest[94] and the Union legislature has a broad discretion in an area which involves political, economic and social choices and in which it is called upon to undertake complex assessments and evaluations.[95]

149. It is undeniable that in adopting Directive 2014/40 the Union legislature was faced with precisely these kinds of complex economic, social and political questions and, moreover, this is not seriously called into question by any of the parties. Consequently, the Union legislature had to be allowed a broad discretion in respect of the assessments underlying the Directive, not least with regard to the measures which are best able to achieve the high level of health protection prescribed in the European internal market (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), especially since forecasts of future market activity may be reviewed as to their plausibility at most.

150. That discretion means that an infringement of the principle of proportionality by the Union legislature can be taken to exist only where the EU measure concerned is *manifestly disproportionate*, that is to say, where it is manifestly inappropriate for attaining the legitimate objectives pursued, goes manifestly beyond what is necessary to achieve those objectives or entails disadvantages which are manifestly disproportionate to its objectives.[96] It is irrelevant, on the other hand, whether the measure adopted in the legislative act is the only conceivable measure or even only the most appropriate.

151. A review of the prohibition on tobacco products with characterising flavours and certain of the requirements for the labelling and packaging of tobacco products raised by the referring court should be conducted subject to that proviso.

91 — Judgments in *Maizena and Others* (137/85, EU:C:1987:493, paragraph 15); *United Kingdom* v *Council* (C-84/94, EU:C:1996:431, paragraph 57); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 122); *Digital Rights Ireland* (C-293/12 and C-594/12, EU:C:2014:238, paragraph 46); and *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 67).

92 — Judgments in *Schräder HS Kraftfutter* (265/87, EU:C:1989:303, paragraph 21); *Jippes and Others* (C-189/01, EU:C:2001:420, paragraph 81); and *ERG and Others* (C-379/08 and C-380/08, EU:C:2010:127, paragraph 86); see also, in the same vein, judgment in *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 91).

93 — Judgment in *Digital Rights Ireland* (C-293/12 and C-594/12, EU:C:2014:238, paragraph 47).

94 — Judgment in *Sky Österreich* (C-283/11, EU:C:2013:28, paragraph 46).

95 — Judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 123); *S.P.C.M. and Others* (C-558/07, EU:C:2009:430, paragraph 42); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 52); and *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 67).

96 — Judgment in *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraphs 74, 81 and 91); see also, in the same vein, judgments in *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 52); *S.P.C.M. and Others* (C-558/07, EU:C:2009:430, paragraph 42); and *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 46).

a) The prohibition on tobacco products with characterising flavours (question 3(a))

152. The prohibition on tobacco products with characterising flavours, the proportionality of which is raised before the Court in question 3(a), stems from Article 7(1) and (7) of the Directive.

153. That prohibition is intended to help to ensure a high level of health protection in the European internal market. All characterising flavours — whether menthol or other flavours — can, as a rule, reduce or camouflage the generally very bitter and even pungent taste of tobacco smoke. In the view of the Union legislature, this creates a serious risk that flavoured tobacco products will facilitate initiation of tobacco consumption for non-smokers [97] and make it more difficult for habitual smokers — or at least some of them — to escape nicotine addiction. [98]

154. The prohibition on *menthol cigarettes* which applies from 20 May 2020 under the abovementioned provision [99] is of particular practical relevance in this connection. It is only with regard to this prohibition on menthol cigarettes that the order for reference and the observations of the participating undertakings contain substantiated arguments from the perspective of proportionality. Consequently, in considering the legal problems raised, I will concentrate below on the proportionality of the prohibition on menthol cigarettes.

i) Appropriateness of the prohibition

155. The appropriateness of the prohibition on menthol cigarettes for achieving the improved health protection pursued by the Directive is in dispute. The parties disagree on the controversial question of how a prohibition on menthol cigarettes will affect the consumer habits of current and potential smokers. All the parties base their arguments on scientific studies and each accuses the opposite side of having insufficient scientific evidence for their submissions.

156. In assessing the lawfulness of Directive 2014/40, and in particular the proportionality of the contested provisions, however, it is immaterial whether the health considerations relating to menthol cigarettes cited by the Union legislature — considerations which seem very plausible to me personally — can be proven with sufficient accuracy in the current state of scientific research.

157. The Union legislature was required to take account of the precautionary principle when it adopted the Directive. [100] Precisely where 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 if the risk materialises, the precautionary principle justifies the adoption of restrictive measures, provided those measures are non-discriminatory and objective. [101]

158. The call made within the framework of the WHO to limit or prohibit internationally the use in tobacco products of ingredients which may improve their taste, including the use of menthol, [102] is also nothing other than an expression of the precautionary principle.

97 — See also recital 16 in the preamble to the Directive.

98 — See, in this regard, the reference to consumption patterns in recital 16 in the preamble to the Directive.

99 — The date of 20 May 2020 comes from Article 7(14) of the Directive, as Union-wide sales of menthol cigarettes exceed 3% according to the concurring statements of the parties.

100 — See, to that effect, judgment in *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 68), in which the Court states that the Union legislature must 'take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health'.

101 — Judgments in *United Kingdom* v *Commission* (C-180/96, EU:C:1998:192, paragraph 99); *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraphs 52 and 53); *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 93); *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 60 to 62); and *Acino* v *Commission* (C-269/13 P, EU:C:2014:255, paragraph 57).

102 — See above, points 74 to 76 of this Opinion.

159. Against this background, it was perfectly reasonable and possibly even necessary, in accordance with the precautionary principle, to lay down generally strict rules on the use of characterising flavours in tobacco products, especially since under primary law a *high* level of health protection was to be ensured (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights).

160. Under no circumstances can a prohibition of characterising flavours — including menthol — in tobacco products be regarded as *manifestly* inappropriate for attaining the abovementioned objective and thus for contributing to a high level of health protection in the European internal market. This applies *a fortiori* if, in addition to the precautionary principle, regard is had to the broad discretion which the Union legislature enjoys in choosing the measures which are best able to achieve the high level of health protection prescribed in the internal market.

ii) Necessity of the prohibition

161. Some of the undertakings taking part in the proceedings and Poland also dispute that a prohibition on the placing on the market of menthol cigarettes is necessary in order to achieve the high level of health protection in the European internal market pursued by the Directive.

162. The arguments put forward in this connection can be classified under two headings. They concern, first, the question whether a general prohibition of all characterising flavours, including menthol, was necessary and, second, the question whether more moderate, less restrictive means than a prohibition were available to the Union legislature.

– The necessity of a general prohibition of all characterising flavours

163. With regard to the first of these headings, I have already explained above, in connection with Article 114 TFEU, that the arguments of some of the undertakings taking part in the proceedings regarding the purported special status of menthol cigarettes in the flavoured cigarettes market segment are not very convincing. [103]

164. Contrary to the view taken by BAT, the necessity of a prohibition on characterising flavours in order to achieve a high level of health protection in the internal market also cannot be called into question by the simple suggestion that the health risks associated with smoking are well known, especially among young people.

165. The mere fact that many people know about certain risks does not mean that the public authorities should remove existing safeguards or refrain from introducing new safeguards. No one would, for example, entertain the idea of abolishing the helmet requirement for motorcyclists or the seatbelt requirement for motor vehicle drivers and passengers merely because the vast majority of them are now sufficiently aware of the dangers of road traffic and act sensibly of their own volition.

166. Furthermore, by the prohibition on all characterising flavours, the Directive follows the stipulations laid down within the framework of the WHO, as is clear in particular from Article 1 and from its preamble. [104] These may not be legally binding, as is rightly stated by BAT, Mane and Poland, but they do undoubtedly constitute recommendations, including and especially with regard to the

103 — See above, point 65 of this Opinion.

104 — Recital 7 in the preamble to the Directive.

regulation of menthol.[105] It is self-evident that, within the scope of the broad discretion which it enjoys in the adoption of internal market harmonisation measures under Article 114 TFEU, the Union legislature was permitted to take measures which the Union is not actually required to adopt at international level, but which are recommended.

167. If the Union legislature had not included menthol in the prohibition on characterising flavours, as has already been mentioned,[106] the Directive could have made a much smaller contribution to achieving a high level of health protection. Menthol cigarettes would have continued to be available in the internal market as an alternative for current or potential consumers of flavoured tobacco products, which could make it easier for adolescents and young adults to initiate tobacco consumption and at the same time make it more difficult for habitual smokers to escape nicotine addiction.[107]

168. Furthermore, the European Union would possibly have been at risk of proceedings within the framework of the World Trade Organisation (WTO) if it had not prohibited menthol cigarettes in the same way as other flavoured cigarettes. In a report delivered in 2012 the WTO dispute settlement body held it to be an infringement of the WTO rules that the United States of America prohibited the sale of clove-flavoured cigarettes whereas menthol cigarettes could still be marketed there.[108] Contrary to the view taken by BAT, it is not impossible, but is even very reasonable, to transpose that WTO report to the problem at issue in this case, especially since the report expressly considers clove-flavoured cigarettes and menthol-flavoured cigarettes to be comparable (as 'like products' within the meaning of the WTO Agreement on Technical Barriers to Trade).

169. If these circumstances are taken into consideration, the necessity of a prohibition on *all* characterising flavours, including menthol, cannot seriously be called into question.[109] In any case, a general prohibition of this kind does not *manifestly* go beyond what is necessary to achieve a high level of health protection in the European internal market.

170. That conclusion is also not affected by the fact that under Article 7(12) of the Directive certain tobacco products — in particular cigars — are exempted from the prohibition on characterising flavours for the time being, as the broad discretion which the Union legislature enjoys within the framework of Article 114 TFEU[110] certainly does not preclude a gradual harmonisation of the Member States' laws, regulations and administrative provisions. Furthermore, the Parliament and the Council could legitimately take the view in the present situation that the health risks associated with characterising flavours arise especially in the case of cigarettes and roll-your-own tobacco because those tobacco products are particularly attractive to young people.[111]

105 — See above, point 76 of this Opinion.

106 — See above, point 69 of this Opinion.

107 — This finding is not called into question by the fact that, according to one study cited by Poland, menthol is reportedly the reason given least often for people starting smoking. The elimination of even such a minor cause can help to achieve a high level of health protection in the internal market for tobacco products.

108 — Report of the WTO Appellate Body of 4 April 2012 (WT/DS406/AB/R, 'United States — Measures affecting the production and sale of clove cigarettes', available on the WTO website at www.wto.org), in particular paragraph 298.

109 — See, in the same vein — with regard to the prohibition on the marketing of tobacco products for oral use — judgments in *Arnold André* (C-434/02, EU:C:2004:800, paragraph 47) and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 49).

110 — Judgments in *REWE-Zentrale* (37/83, EU:C:1984:89, paragraph 20); *United Kingdom* v *Parliament and Council* (C-66/04, EU:C:2005:743, paragraph 45); *United Kingdom* v *Parliament and Council* (C-217/04, EU:C:2006:279, paragraph 43); and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 35).

111 — Recital 19 in the preamble to the Directive.

– The allegedly more moderate means

171. Some of the parties, in particular Von Eicken and Poland, put forward allegedly more moderate measures which, in their view, the Union legislature should have adopted rather than a prohibition on tobacco products with characterising flavours: the introduction of age limits for the sale of flavoured tobacco products, targeted information campaigns and the definition of a list of permitted or prohibited flavouring substances at Union level (a kind of 'positive list' or 'negative list').

172. It should be noted in this regard that in a proportionality test consideration may be given to possible less restrictive means than the measure adopted by the Union legislature only if they are equally suitable for achieving the objective pursued by the EU measure in question. [112]

173. That is not the case with the abovementioned age limits. As the EU institutions taking part in the proceedings and several of the participating Member States have argued convincingly, age limits in trade can be easily circumvented and it is extremely difficult to monitor compliance. [113]

174. Nor can possible information campaigns on the danger of tobacco products with characterising flavours be regarded as equally suitable as a prohibition on the marketing of all tobacco products with characterising flavours. Furthermore, as the Commission rightly observes, such information campaigns are not capable of removing obstacles to trade which exist on account of divergent national rules on the use of characterising flavours in accordance with Article 114 TFEU or of preventing them from arising.

175. The adoption of a positive or negative list of flavouring substances, also put forward by Von Eicken as an alternative to Article 7 of the Directive, would have had the significant disadvantage that such a regulatory technique would be cumbersome and susceptible to circumvention and, moreover, the list would need to be constantly updated in view of the rapid developments in the sector. Such an approach would also unduly restrict the national authorities' remaining freedom of action in contravention of the principle of proportionality (Article 5(4) TEU).

iii) Proportionality in the strict sense

176. Lastly, some of the parties criticise the prohibition on menthol cigarettes from the perspective of proportionality in the strict sense. They complain about economic and social hardships associated with that prohibition, in particular for suppliers to the tobacco industry and manufacturers of niche products, but also for some farmers engaged in tobacco cultivation.

177. First of all, the criticism made by Benkert that the Commission did not sufficiently consult undertakings operating in upstream markets in the run-up to the drafting of its proposal for a directive must be rejected. [114] Even though the Commission's impact assessment can offer support for the Union legislature, [115] it is not legally binding. [116] Any errors in the consultation process on which that impact assessment is based do not necessarily therefore result in the unlawfulness of the Directive. In addition, Benkert has specifically conceded that the undertaking did actually put forward its views to the Commission. The fact that Benkert's view did not have the desired effectiveness from an objective point of view cannot be seriously regarded as an indication of a deficiency in the preparations for the legislative procedure.

112 — Judgments in *Arnold André* (C-434/02, EU:C:2004:800, paragraph 55) and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 56).

113 — See my Opinions delivered today in *Poland* v *Parliament and Council* (C-358/14, points 120 and 121) and *Pillbox 38* (C-477/14, points 144 and 145).

114 — A similar criticism is made by Tann in connection with Article 114 TFEU.

115 — The Court sometimes also pays attention to such Commission impact assessments in reviewing the validity of EU measures (see, for example, judgment in *Vodafone and Others*, C-58/08, EU:C:2010:321, paragraphs 55 and 65).

116 — Judgment in *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 57).

178. From a substantive point of view, the disappearance of menthol cigarettes from the market as a result of the prohibition under EU law on the marketing of tobacco products with characterising flavours may temporarily have negative effects on the economic situation of some farmers engaged in tobacco cultivation, some suppliers to the tobacco industry and some undertakings engaged in the manufacture and marketing of tobacco products, even including some job losses.

179. It should be borne in mind, however, that the protection of human health has considerably greater importance in the value system under EU law than such essentially economic interests (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), with the result that health protection may justify even substantial negative economic consequences for certain economic operators. [117]

180. Moreover, the fact that the prohibition on menthol cigarettes will possibly hit some undertakings, or even whole industry sectors in certain Member States, harder than other undertakings or other Member States' economies does not make the prohibition of characterising flavours under the Directive disproportionate. In view of the differences in the Member States' economic structures, it is almost impossible to think of a case in which an EU legislative act affects all undertakings and all Member States in exactly the same way. [118] As the EU institutions taking part in the proceedings before the Court rightly state, the approximation of laws in the European internal market would be rendered largely meaningless if it could occur only where largely similar conditions already exist in any case in all the Member States and between all undertakings concerned.

181. Aside from this, any economic and social hardships that may be associated with the prohibition on menthol cigarettes are attenuated by the generous transitional period up to 20 May 2020, a period of four years in addition to the period for transposition of the Directive. With regard specifically to the farmers concerned, they may also possibly receive income support under the common agricultural policy.

182. As regards the increase in smuggling and the flourishing of the black market predicted by some parties, I consider that argument to be just as unconvincing in the present context as in connection with Article 114 TFEU. [119]

183. All in all, it was therefore perfectly justifiable — and in any case not *manifestly disproportionate* — for the Union legislature, in adopting the Directive, to give precedence to the desired high level of health protection over economic and social considerations, such as those put forward by individual parties in the present case.

184. Consequently, the view that the prohibition on menthol cigarettes infringes the principle of proportionality is unfounded.

b) The requirements for the labelling and packaging of tobacco products (question 3(b) and (c))

185. Parts (b) and (c) of question 3 concern various requirements for the labelling and packaging of tobacco products as laid down in Articles 8(3), 9(3), 10(1)(a), (c) and (g) and Article 14 of the Directive. In response to a complaint raised by BAT, the referring court asks the Court about the proportionality of the 'pack standardisation measures' stemming from those provisions.

117 — See, in the same vein, judgment in *Nelson and Others* (C-581/10 and C-629/10, EU:C:2012:657, paragraph 81) with regard to consumer protection.

118 — For example, environmental protection requirements for automobiles in EU law have a greater impact on Member States in which the automobile industry plays an important role. Similarly, EU measures on the manufacture and marketing of beer would have a greater impact in Member States which produce substantial amounts of that beverage and in which beer consumption is highest.

119 — See above, points 84 and 85 of this Opinion.

i) Shape, size and minimum content of cigarette packets (question 3(b))

186. It is clear from an overview of Articles 8(3), 9(3), 10(1)(g) and Article 14 of the Directive that, in essence, cigarette packets must have a cuboid shape, respect certain dimensions, include at least 20 cigarettes and carry combined health warnings (containing one of the stipulated texts and a corresponding colour photograph). [120] The warnings must respect certain dimensions and be irremovably printed, indelible and fully visible and also must remain intact when opening the unit packet. The efficacy of those warnings is thus intended to be maximised. [121]

187. It is essentially common ground between the parties that uniform requirements for the labelling and packaging of tobacco products are appropriate for attaining the overall objective of Directive 2014/40, which is to improve the functioning of the internal market, whilst at the same time ensuring a high level of health protection. [122] In simple terms, uniform standards for the labelling and packaging of a product increase its capacity for circulation in the internal market and at the same time highly visible warnings promote health protection.

188. Nevertheless, BAT objects to the requirements laid down in the Directive regarding the shape, size and minimum content of cigarette packets. The undertaking takes the view that for the purposes of health protection it would have been sufficient to prescribe that the necessary warnings must be fully visible and not distorted by packet shapes.

189. A simple visibility requirement for warnings, which BAT seems to have in mind, is undoubtedly a less restrictive measure than the very detailed requirements of Directive 2014/40 relating to the shape, size and minimum content of cigarette packets. As has been rightly stated by the EU institutions taking part in the proceedings, however, a general visibility requirement of that kind is relatively indefinite and liable to give rise to conflict in respect of compliance and monitoring. It would thus be much less effective than the package of measures actually adopted by the Union legislature, which, in addition to the general visibility requirement, also includes specific requirements relating to the shape, size and minimum content of cigarette packets.

190. In short, warnings are more visible on larger packets than on smaller packets and more legible on cuboid packets than on packets of other shapes. Consequently, the requirements contained in the Directive relating to the shape, size and minimum content of cigarette packets make a particular contribution to increasing the visibility of health warnings and maximising their efficacy.

191. I would add that standardising the shape and size of cigarette packets can also help to increase health protection in the European internal market in other ways, and completely irrespective of the visibility and legibility of health warnings. The less extravagant the packaging of a product is, the less consumers, and above all young consumers, will be tempted to purchase it. The coolness or fun factor that may be associated with unusual or particularly striking packaging and the curiosity that may be inherent in new or unusual packaging (one might think, for instance, of the possible attraction of cigarette packets that adapt the shape of a lipstick for young female consumers) then has a lesser influence on the decision to purchase.

120 — The requirements applying to the packaging of roll-your-own tobacco are not specifically at issue in the present case. For reasons of simplicity, I will not therefore examine them in further detail. It is clear, however, that the statements made below are applicable *mutatis mutandis* to roll-your-own tobacco.

121 — See also recital 28 in the preamble to the Directive.

122 — With regard to this objective, see in particular the end of Article 1 and recitals 5, 6, 8 and 36 in the preamble to the Directive.

192. It is a similar situation with the minimum content of cigarette packets. If it is set, as in Article 14 of the Directive, at a minimum of 20 cigarettes, then the psychological barrier to making a purchase is higher, particularly for adolescents and young adults, than has been the case with the smaller unit packets which have thus far been available in many places. Smaller sales units tend to develop into a gateway to tobacco consumption because they are cheaper and they introduce the consumer to the product in smaller steps.

193. Certainly, the standardisation of the shape, size and minimum content of cigarette packets brought about by the Directive means a loss of diversity, marketing opportunities and competitive potential for manufacturers of tobacco products. However, the purely economic interest in the greatest possible inter-product and inter-brand competition must be secondary to the protection of human health, which, as has already been stated, has considerably greater importance in the value system under EU law (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights).

ii) The size of the combined health warnings (question 3(c))

194. It also follows from Article 10(1)(a) and (c) of the Directive that cigarette packets must carry combined health warnings which contain a certain prescribed text and a corresponding colour photograph (point (a)) and account for 65% of both the external front and back surface of the unit packet (point (c)).

195. BAT considers the abovementioned obligation to use 65% of the surface for combined health warnings to be arbitrary and disproportionate.[123] The undertaking, and following it the referring court, thus essentially objects to Article 10(1)(c) of the Directive, and not so much to the principle of combined health warnings per se, as established in Article 10(1)(a) of the Directive.

– The appropriateness of large warnings for health protection

196. BAT, supported by Von Eicken, claims first and foremost that the incremental benefit of large combined warnings for the high level of health protection to be pursued in the European internal market is not scientifically proven.

197. It should be noted in this regard that in the past the Court has regarded the duty to carry warnings on cigarette packets as ‘a recognised means of encouraging consumers to reduce their consumption of tobacco products or of guiding them towards such of those products as pose less risk to health’.[124] It seems reasonable to apply that case-law to the present case and to assume that the more visible warnings are and the larger the proportion of the surface reserved for them, the more effective the warnings are.

198. Furthermore, it is clear that, in adopting the contested provision, the Union legislature relied on ‘new scientific evidence’ and other ‘evidence’ to justify the need to adapt the rules on labelling in general and the obligation to introduce ‘large combined health warnings’ in particular.[125] It may be that other studies, in particular those cited by BAT and Von Eicken, allow different conclusions to be drawn. This does not mean, however, that the requirements laid down in Article 10(1)(a) and (c) of the

123 — On the other hand, the additional obligation under the last subparagraph of Article 9(3) of the Directive to carry on the *sides* of each unit packet of cigarettes a general warning and an information message which must each cover 50% of the surfaces on which they are printed is not at issue in these proceedings.

124 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 131).

125 — Recital 25 in the preamble to the Directive.

Directive are *manifestly inappropriate* for contributing to the attainment of the objective of the directive. This applies *a fortiori* if regard is had to the precautionary principle and the broad discretion enjoyed by the Union legislature in choosing the measures which are best able to achieve the high level of health protection prescribed in the internal market. [126]

199. Moreover, with the requirement of large combined warnings, as is clear in particular from Article 1 and from the preamble, [127] the Directive is following the recommendations drawn up within the framework of the WHO, which are in turn based expressly on scientific evidence of the effectiveness of combined health warnings. [128]

– The necessity of large warnings

200. Nevertheless, BAT and Von Eicken argue that combined warnings covering 65% of the surface are not necessary to comply with the EU's international obligations within the framework of the WHO. Both undertakings consider it sufficient to retain the rules which have applied thus far in the European Union and to carry health warnings with a coverage of 30% of the front surface of the unit packet and 40% of the back surface of the unit packet. [129]

201. It is correct that neither the WHO Framework Convention nor the Guidelines pertaining thereto lays down a specific obligation to allow 65% of the surface for combined health warnings on cigarette packets. Rather, Article 11(1)(b)(iv) of the Framework Convention merely prescribes that the warnings 'shall' be no less than 30% of the main surfaces of a cigarette packet. At the same time, however, the same provision contains the additional statement that the warnings 'should' be 50% or more of the main surfaces of cigarette packets. Consequently, the 65% coverage ultimately adopted in the Directive is fully consistent with what is regarded as desirable at international level.

202. Furthermore, it is clear that the Union legislature had the power, within the framework of the broad discretion which it enjoys in the adoption of internal market harmonisation measures under Article 114 TFEU, to lay down more extensive duties for manufacturers and importers of tobacco products than are prescribed at international level. In any case, the 65% coverage for combined health warnings laid down in Article 10(1)(c) of the Directive does not *manifestly* go beyond what is necessary, having regard to the international context, in order to achieve a high level of health protection in the European internal market.

203. The prohibition on sales of tobacco products to minors, put forward by BAT and Von Eicken as a more moderate alternative, is not an equally suitable means of ensuring a high level of health protection. First, such a rule would apply only to young people, whereas large combined warnings on cigarette packets are directed at all consumers. Second, as was explained above, [130] an age limit can be easily circumvented and it is extremely difficult to monitor compliance.

– Proportionality in the strict sense and the allegation of arbitrariness

204. Lastly, the argument made by BAT and Von Eicken that the 65% coverage for combined health warnings which is now prescribed unduly restricts the freedom of the undertakings concerned to design the packaging of their tobacco products, and thus inter-product and inter-brand competition, must also be rejected. It should be borne in mind, as has already been mentioned, that the protection

126 — See above, points 148 to 151 and 157 of this Opinion.

127 — Recital 24 in the preamble to the Directive.

128 — See paragraphs 12 and 14 of the Guidelines for Implementation of Article 11 of the WHO Framework Convention, adopted by the Conference of the Parties at its third session in Durban (2008) FCTC/COP/3(10).

129 — Article 5(5) of Directive 2001/37.

130 — See above, point 173 of this Opinion.

of human health has considerably greater importance in the value system under EU law than the essentially economic interests of undertakings (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights) with the result that health protection may justify even substantial negative economic consequences for certain economic operators. [131]

205. As, moreover, around one third of the surface of a cigarette packet is still available for displaying product-specific information and it is also still possible to use trade marks as such in marketing tobacco products, neither the freedom to conduct a business nor the intellectual property of the undertakings concerned are affected in their essence by Article 10(1)(c) of the Directive. [132]

206. It is true that the broad discretion which the Union legislature enjoys with regard to such matters does not relieve the Parliament and the Council of the duty to base their choice on objective criteria. [133] However, contrary to BAT's view, the mere fact that the Parliament and the Council defined a quantified proportion of the surface — here 65% — for displaying warnings is not an expression of arbitrariness. In fact, it is in the nature of things and, furthermore, consistent with the requirements of legal certainty that after assessing all the conflicting interests and legally protected rights and having regard to all relevant circumstances a specific figure had to be laid down.

207. By the proportion of 65% of the surface ultimately adopted by the Parliament and the Council that assessment turned out more favourably for the undertakings concerned than in the Commission's proposal for a directive, which had specified 75%. [134]

208. In particular, by reducing the proportion of the surface reserved for warnings, the Union legislature did not act arbitrarily but, within the scope of the discretion conferred on it, attached slightly greater importance than the Commission to the economic interests of manufacturers and importers of tobacco products in relation to the requirements of a high level of health protection and therefore accommodated the undertakings concerned.

209. All in all, it was thus neither *arbitrary* nor *manifestly disproportionate*, in adopting the Directive, to give precedence to the desired high level of health protection over economic considerations and to reserve 65% of the surface of cigarette packets for displaying combined health warnings.

iii) Interim conclusion

210. In summary, it is not therefore possible to establish any infringement of the principle of proportionality in the requirements for the labelling and packaging of tobacco products as laid down in Articles 8(3), 9(3), 10(1)(a), (c) and (g) and in Article 14 of the Directive.

131 — See, in the same vein, judgment in *Nelson and Others* (C-581/10 and C-629/10, EU:C:2012:657, paragraph 81) with regard to consumer protection.

132 — See, in the same vein, with regard to the predecessor rules, judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 132).

133 — Judgments in *Arcelor Atlantique et Lorraine and Others* (C-127/07, EU:C:2008:728, paragraph 58) and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 53).

134 — See Article 9(1)(c) of the Commission's 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, submitted on 19 December 2012, COM(2012) 788 final.

2. Interferences with freedom of expression (question 2)

211. Freedom of expression (Article 11 of the Charter of Fundamental Rights) is addressed in just one aspect of these preliminary ruling proceedings, in question 2, which refers to Article 13 of the Directive. On the other hand, remarkably, the referring court has *not* queried the obligation to carry large combined health warnings, the subject of question 3(c), in the light of freedom to hold opinions. Just for the sake of completeness, I would point out that the following statements on freedom of expression [135] can also be applied to the latter issue. [136]

212. Article 13 of the Directive has the heading 'Product presentation'. In simple terms, that provision prohibits misleading advertising being placed on the unit packet and any outside packaging of tobacco products or the impression being created that the tobacco products concerned are healthy, ecologically beneficial or less harmful than other tobacco products (Article 13(1)). Furthermore, the unit packets and any outside packaging must not suggest economic advantages (Article 13(2)).

213. The background to the questions referred on the subject of Article 13 of the Directive appears to be that some of the undertakings taking part in the main proceedings (namely PMI, BAT and Von Eicken) have or intend to incorporate novel tobacco products or niche products in their range and, in order to market them more effectively, they wish to inform consumers by including relevant details on the product packaging. Examples are (allegedly) reduced-risk tobacco products, [137] but also products made from organically farmed tobacco or products with more biodegradable filters.

a) The interpretation of Article 13 of the Directive (question 2(a))

214. In question 2(a) the referring court is seeking clarification whether Article 13 of the Directive prohibits 'true and non-misleading statements about tobacco products on the product packaging'.

215. In order to answer this question it is sufficient to consider the first half of Article 13(1)(a) of the Directive, on the one hand, and the rest of Article 13(1), on the other. As the referring court does not make any statements at all regarding Article 13(2) of the Directive, there is no need to take a view on that latter provision.

216. With regard to the first half of Article 13(1)(a) of the Directive, it is clear from the wording of that provision that it prohibits only misleading information on unit packets and any outside packaging which promotes a tobacco product or encourages its consumption. True and non-misleading statements are not therefore prohibited under that provision.

217. By contrast, the subsequent grounds for prohibition in the second half of Article 13(1)(a) and Article 13(1)(b) to (e) of the Directive are not expressly restricted to misleading information, if regard is had solely to their wording.

218. Certainly, those provisions are also intended, as is clear from the preamble to the Directive, [138] to protect consumers from misleading statements. However, contrary to the view apparently taken by some of the undertakings taking part in the proceedings, this notion of misleading is not to be interpreted strictly. In particular, the notion of misleading, as it is used in the Directive, cannot be understood to mean that true statements regarding tobacco products on their product packaging would be permitted in all cases.

135 — See below, points 226 to 237 of this Opinion.

136 — In so far as some of the undertakings taking part in the preliminary ruling proceedings put forward arguments relating to freedom of expression in the context of other questions, my answer in that regard can also be inferred from the following statements (points 226 to 237).

137 — In this regard, in the proceedings before the Court PMI has mentioned a novel product in which tobacco is not burnt, but merely heated.

138 — The second sentence of recital 25 and recital 27 in the preamble to the Directive.

219. As the EU institutions taking part in the proceedings and also Ireland and France rightly state, the risk of misleading consumers or of undesired incitements for consumers can also arise in the case of true statements from the overall context in which they are made or from the interaction between several statements contained on the product packaging.

220. Even a statement which, when considered in isolation, may be perfectly accurate — for example a reference to organically farmed tobacco or more biodegradable filters — may lead some consumers to assume that it is worthwhile to purchase and consume the tobacco product in question. In that situation, the considerable health risks associated with smoking could, despite all the warnings on the product packaging, recede into the background or at least appear to be relativised in the eyes of those consumers. [139]

221. The aim of Article 13(1) of the Directive, on the other hand, is to eliminate any inducements to purchase a tobacco product that are connected with its allegedly positive characteristics or its allegedly positive image and thus to contribute to a high level of health protection in the European internal market. With Article 13(1)(b) to (e) of the Directive specifically, it is intended to prevent the purchase and consumption of a tobacco product being cast in a deceptively positive light for consumers by certain information on the product packaging and thus an additional inducement being created to purchase and consume the product.

222. An 'organic cigarette' is still a product that is extremely harmful to health. Information on the product packaging should not suggest even to consumers who are aware of the health risks of smoking — even merely subconsciously — that it is desirable for them or beneficial to the environment to smoke 'organic cigarettes'. In addition, any poor conscience on the part of smokers on account of the health risks associated with the consumption of tobacco products should not be appeased by the fact they are doing something good for themselves or for the planet by turning to 'organic cigarettes' rather than conventional cigarettes.

223. In answer to this relatively strict interpretation of Article 13(1)(b) to (e) of the Directive it cannot be objected that in EU law the model is normally that of a reasonable, well-informed consumer. In the case of products which can cause considerable health risks, it is justified to regulate commercial communication more heavily than would otherwise be the case. This applies *a fortiori* where — as in this case — the rules focus on protecting adolescents and young adults. [140]

224. Certainly, Article 13(1) of the Directive does not prohibit all kinds of factually accurate information regarding the properties of a tobacco product on its product packaging. It could be considered, for example, to interpret Article 13(1)(c) of the Directive restrictively such that it permits the indication of flavours on the packaging in a neutral and non-promotional form, where the use of such flavours is exceptionally permitted under Article 7(12) of the Directive. How otherwise should consumers choose between flavoured and non-flavoured tobacco products? That notwithstanding, Article 13(1) of the Directive bans all — including true — information or statements on the product packaging, which, viewed objectively, are capable of producing one or more of the effects described in that provision.

225. In summary, the answer to question 2(a) must therefore be:

Article 13(1) of Directive 2014/40 is to be interpreted as also prohibiting true statements on product packaging where those statements, viewed objectively, are capable of producing one or more of the effects described in that provision.

139 — Similarly, judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 137 and 138) and *Deutsches Weintor* (C-544/10, EU:C:2012:526, paragraphs 51 and 52).

140 — The end of Article 1 and recitals 8 and 19 in the preamble to the Directive.

b) The validity of Article 13 of the Directive (question 2(b))

226. In question 2(b) the national court refers to this Court the issue of the validity of Article 13 of the Directive. This part of the question is asked only in the event that question 2(a) is answered in the affirmative. If question 2(a) is answered as I propose, it is then necessary to consider question 2(b).

227. On the basis of corresponding complaints raised by PMI and BAT in the main proceedings, the referring court is essentially seeking to ascertain whether Article 13(1) of the Directive violates freedom of expression and the principle of proportionality.

228. Freedom of expression is enshrined in Article 11 of the Charter of Fundamental Rights. It includes freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of national frontiers.

229. There may be an interference with that fundamental right if an undertaking is prohibited from providing certain information on the packaging of its product about its properties, as is the case with Article 13(1) of the Directive on the abovementioned interpretation. This makes it more difficult for the undertaking itself to disseminate opinions and information regarding its products as part of its commercial communication and more difficult for consumers to obtain comprehensive information about those products.

230. Such interference may be justified under the conditions mentioned in Article 52(1) of the Charter and in the first sentence of Article 52(3) of the Charter in conjunction with Article 10(2) ECHR. The only point at issue in this case is whether the Directive — a legislative act of the European Union (Article 289(3) TFEU) [141] — respects the principle of proportionality.

231. Of course, the Union legislature cannot be accorded the same broad margin of discretion with regard to the restriction of freedom of expression and information, in view of the foundational role played by that fundamental right in a democratic society, as it enjoys with regard to interferences with the freedom to conduct a business, for example. [142] It is true that the European Court of Human Rights (ECtHR), whose case-law must be taken into consideration in accordance with the first sentence of Article 52(3) of the Charter, also recognises in principle the existence of a margin of discretion in this area. [143] In the light of the importance of freedom of expression in a market economy, however, the ECtHR has for some time proceeded to examine in detail restrictions on commercial communications of undertakings and to weigh the conflicting interests against each other having regard to all the relevant circumstances of the specific case. [144] The Court of Justice should also conduct its proportionality test in the present case on that basis.

232. There is nothing in this case to suggest that the requirements contained in Article 13(1) of the Directive for the labelling of the unit packet and any outside packaging of tobacco products might not be appropriate or necessary for contributing to the objective pursued by the Union legislature of a high level of health protection in the European internal market. In particular, the additional warnings

141 — The requirement of legal enactment is fulfilled by Article 13 of the Directive, an express legal provision in an EU legislative act. See also, to that effect, judgment in *Digital Rights Ireland* (C-293/12 and C-594/12, EU:C:2014:238, paragraph 38 et seq.), in which the Court considered whether a directive was consistent with fundamental rights and found *no* infringement of the requirement of legal enactment under Article 52(1) of the Charter of Fundamental Rights.

142 — The Court recently found in the judgment in *Digital Rights Ireland* (C-293/12 and C-594/12, EU:C:2014:238, paragraph 47) that regard must always be had to the fundamental right in question and the circumstances of the individual case. With regard to the broad discretion of the EU institutions in the case of interferences with the freedom to conduct a business, see above, points 148 to 151 of this Opinion.

143 — ECHR, judgments in *markt intern Verlag and Beermann v. Germany* (ECLI:CE:ECHR:1989:1120JUD001057283, ECHR 33) and *Casado Coca v. Spain* (ECLI:CE:ECHR:1994:0224JUD001545089, ECHR 50).

144 — ECHR, judgments in *Casado Coca v. Spain* (ECLI:CE:ECHR:1994:0224JUD001545089, ECHR 51) and *Stambuk v. Germany* (ECLI:CE:ECHR:2002:1017JUD003792897, ECHR 39).

suggested by some of the undertakings taking part in the preliminary ruling proceedings (such as clarifications that 'organic cigarettes' are no less harmful to health than other cigarettes) cannot be regarded as an equally suitable means of protecting the health of consumers as a blanket prohibition on the information covered in Article 13(1) of the Directive.[145]

233. In addition, an overall assessment of the conflicting interests does not support the view taken by PMI, BAT and Von Eicken. First of all, the dissemination of opinions and information which — as in this case — are intended to pursue solely business interests generally warrants less protection as a fundamental right than other expressions of opinion in the economic sphere or even political expressions of opinion. Second, by Article 13(1) of the Directive the Union legislature pursues a general interest objective — to ensure a high level of health protection in the European internal market — which has been recognised as having a particularly high importance (see Article 9 TFEU, Article 114(3) TFEU, Article 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights).

234. Under these circumstances, the restrictions imposed on manufacturers of tobacco products by Article 13(1) of the Directive in respect of their commercial communications are not disproportionate to the health protection objectives pursued by that provision, especially since the products in question entail considerable health risks.

235. The undertakings concerned must, in the interest of a high level of health protection, accept the limitation under Article 13(1) of the Directive of their opportunities to promote their products with inherently true statements and to compete with other undertakings with those products.[146] Consumers can also expect, taking into account the protection of public health, to obtain from manufacturers of tobacco products only information which does not mislead them and does not cast the purchase of such products in a deceptively positive light.

236. The essence of freedom of expression (first sentence of Article 52(1) of the Charter of Fundamental Rights) is likewise not affected if commercial communications by undertakings which are intended solely to promote sales are restricted by an EU legislative act.

237. All in all, the Court should therefore give the same ruling here as with regard to the predecessor rules to Article 13(1) of the Directive[147] and declare that there is no infringement of the principle of proportionality and thus also no violation of freedom of expression and information.

C – *Delegation of legislative and implementing powers*

238. Questions 4 to 6 essentially raise the issue whether, in various provisions of the Directive, the Union legislature has conferred on the Commission too extensive powers to adopt delegated acts and implementing acts. Since I have found those questions to be inadmissible,[148] I will confine myself hereinafter to considering only briefly a few particularly important aspects of this extremely multi-faceted subject.

145 — See judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 140); see, in the same vein, my Opinion delivered today in *Poland* v *Parliament and Council* (C-358/14, point 122).

146 — See, in the same vein, judgment in *Deutsches Weintor* (C-544/10, EU:C:2012:526, paragraphs 52 and 53); with regard to the restriction of factual, truthful advertising, see also ECHR, judgments in *markt intern Verlag and Beermann v. Germany* (ECLI:CE:ECHR:1989:1120JUD001057283, § 35); *Casado Coca v. Spain* (ECLI:CE:ECHR:1994:0224JUD001545089, § 51), and *Stambuk v. Germany* (ECLI:CE:ECHR:2002:1017JUD003792897, § 39).

147 — Judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 133 to 141).

148 — See above, points 44 to 47 of this Opinion.

239. In considering this issue, the opinion of the European Parliament's Committee on Legal Affairs, with which several parties have engaged in depth, does not play a crucial role. It may be that that committee was critical of the provisions of the Directive by which the power to adopt delegated acts and implementing acts was ultimately conferred on the Commission. However, a committee's opinion is merely a preparatory document which does not necessarily reflect the opinion of the Parliament as co-legislator and also cannot be relied on against it before the Court.

1. The requirements of Article 290 TFEU relating to powers to adopt delegated acts (question 4)

240. Question 4 seeks an examination of various powers to adopt delegated acts conferred on the Commission by the Directive, namely those in Articles 3(2) and (4), 4(5), 7(5), 7(11) and (12), 9(5), 10(1)(f), 10(3), 11(6), 12(3), 15(12) and 20(11) and (12) of the Directive. They relate to a wide variety of subjects, in particular emissions from tobacco products and their measurement, ingredients of tobacco products, health warnings and electronic cigarettes.

241. Under the first subparagraph of Article 290(1) TFEU, the Union legislature may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend a basic legislative act (*delegated acts*).

242. Under the second subparagraph of Article 290(1) TFEU, such delegation of legislative powers is subject to two conditions. First, the objectives, content, scope and duration of the delegation of power must be explicitly defined in the legislative act in question. Second, the essential elements of an area must be reserved for the basic legislative act and may not therefore be the subject of a delegation. Ultimately, the purpose of granting a delegated power is thus to achieve the adoption of rules coming within the regulatory framework as defined by the basic legislative act. [149]

243. The national court refers in this connection to the arguments made by the applicants in the main proceedings claiming that the contested delegations of powers to the Commission, contrary to the requirements of Article 290 TFEU, extend to essential elements of the matters regulated and that their objectives, content and scope are not sufficiently defined.

244. In essence, the point in dispute underlying question 4 hinges on whether the powers delegated to the Commission affect essential elements of the matters regulated in the Directive.

245. Through the express prohibition of the delegation of powers in relation to essential elements contained in Article 290 TFEU, the settled case-law according to which the adoption of essential rules on the subject-matter in question is reserved for the Union legislature was incorporated into the Treaties. [150] Such essential rules must therefore also be laid down in the basic legislative act itself and may not be delegated. [151]

246. Ascertaining which elements of a matter must be categorised as essential must be based on objective factors amenable to judicial review. It is necessary to take account of the characteristics and particularities of the domain concerned. [152]

149 — Judgments in *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraph 38) and *Commission* v *Parliament and Council* (C-88/14, EU:C:2015:499, paragraph 29); see, in the same vein, from the period before the entry into force of Article 290 TFEU, judgment in *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 90), according to which, when the Community legislature wished to delegate its power to amend aspects of the legislative act at issue, it had to ensure that that power was clearly defined and that the exercise of the power was subject to strict review in the light of objective criteria fixed by it.

150 — See judgments in *Köster* (25/70, EU:C:1970:115, paragraph 6); *Germany* v *Commission* (C-240/90, EU:C:1992:408, paragraph 36); *Atlanta* v *European Community* (C-104/97 P, EU:C:1999:498, paragraph 76); and *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraph 64).

151 — See judgments in *Romkes* (46/86, EU:C:1987:287, paragraph 16); *Parliament* v *Commission* (C-156/93, EU:C:1995:238, paragraph 18); *Söhl & Söhlke* (C-48/98, EU:C:1999:548, paragraph 34), and *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraph 64).

152 — See judgment in *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraphs 67 and 68).

247. The Court has always interpreted the notion of essential rules strictly. Thus, it has understood that notion in particular as encompassing only provisions which give concrete shape to the fundamental guidelines of EU policy. [153] Alongside this, generous standards were applied in monitoring the delegation of regulatory powers to the Commission, where the Court — adopting a functional understanding — was guided in particular by practical requirements. [154]

248. Continuing and refining this earlier case-law, the Court recently ruled that it is not possible to delegate provisions which, in order to be adopted, require political choices calling for the conflicting interests at issue to be weighed up and therefore fall within the responsibilities of the EU legislature. [155] At the same time, it defined the notion of 'essential' much more clearly, considering the involvement of the Union legislature to be required where in conferring powers of public authority the fundamental rights of individuals are to be interfered with to a considerable extent. [156]

249. Ultimately, the requirements governing delegation of powers in accordance with Article 290 TFEU and the case-law pertaining thereto are an expression of the separation of powers and the institutional balance within the European Union.

250. In the request for a preliminary ruling in this case no specific evidence has been put forward to suggest that the contested provisions of the Directive are not consistent with those requirements. In addition, in the light of the arguments on this subject put forward by the parties in the written and oral procedures, I have no doubt that in each of the abovementioned areas in the Directive the Union legislature regulated the essential elements itself and made any choices which were politically significant or otherwise highly sensitive itself.

251. Furthermore, the Union legislature has also clearly defined the objectives of the powers delegated to the Commission having regard to the high level of health protection to be pursued in the internal market. The Union legislature itself made the fundamental choices that emissions from tobacco products must be limited and are to be further reduced, that their measurement must meet certain predetermined standards, that ingredients of tobacco products are to be regulated and, in particular, characterising flavours are to be prohibited, and it laid down the requirement of health warnings on product packaging, including the special requirement of *combined* warnings on cigarette packets.

252. The delegated legislative powers which the Union legislature confers on the Commission in this connection under Article 290 TFEU are principally intended constantly to adapt the rules applying within the European internal market to tobacco and related products to the latest scientific evidence in certain particularly technical areas and, in doing so, to satisfy the objective of a high level of health protection laid down in primary law. [157]

253. In so far as the powers delegated to the Commission exceptionally extend to less technical areas of the Directive, these nevertheless always concern elements of the basic legislative act which have no essential importance for the overall legislative framework. This holds in particular for the Commission's power under Article 7(12) of the Directive to extend the prohibition on characterising flavours which already exists for cigarettes and roll-your-own tobacco to other categories of tobacco products such as cigars, as the fundamental political choice to prohibit characterising flavours, with a view to achieving a high level of health protection, for young people in particular, has already been

153 — See judgments in *Germany* v *Commission* (C-240/90, EU:C:1992:408, paragraph 37) and *Molkereigenossenschaft Wiedergeltingen* (C-356/97, EU:C:2000:364, paragraph 21).

154 — See, for example with regard to agricultural market legislation, judgments in *Rey Soda* (23/75, EU:C:1975:142, paragraphs 10 to 14); *Vreugdenhil* (22/88, EU:C:1989:277, paragraph 16), and *Belgium and Germany* v *Commission* (C-9/95, C-23/95 and C-156/95, EU:C:1997:50, paragraph 36), or, with regard to the rules on foreign trade, judgment in *Portugal* v *Commission* (C-159/96, EU:C:1998:550, paragraph 41).

155 — See judgment in *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraphs 65 and 76).

156 — See judgment in *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraph 77).

157 — See also recital 51 in the preamble to the Directive.

made by the Union legislature in the Directive itself.[158] Article 7(12) of the Directive does not confer political discretion on the Commission, but the largely technical task of coherently developing the prohibition on characterising flavours whilst constantly monitoring market conditions wherever such flavours in tobacco products other than cigarettes can also lead to a risk to the health of consumers, and young people in particular.

254. The mere fact that in practice some of the technical aspects to be regulated by the Commission may be of considerable and even existential importance to certain undertakings (for example the question which maximum levels are applicable for emissions from tobacco products, which ingredients are permitted and how precisely warnings are to be displayed on the product packaging) does not make those matters essential elements of the legislation within the meaning of Article 290(1) TFEU, contrary to the view taken by PMI, BAT and Mane. As has already been mentioned, the relevant factor is not the subjective perceptions of those affected, but an objective analysis.[159]

255. The claim made by JTI that the delegations of power do not have adequate fundamental procedural safeguards must also be rejected. In this connection it is sufficient to look at Article 27 of the Directive, which lays down detailed rules for the exercise of each of the delegated powers. It is also possible to identify from that provision the powers for which the co-legislators have reserved a right of revocation (Article 27(3) of the Directive in conjunction with Article 290(2)(a) TFEU) and the powers which may be exercised only if no objection has been expressed by either the Parliament or the Council within a specified period (Article 27(5) of the Directive in conjunction with Article 290(2)(b) TFEU).

256. In particular, the co-legislators' right of revocation under Article 27(3) of the Directive and their right of objection under Article 27(5) of the Directive also ensure that the Parliament and the Council are able to intervene if, in their view, the Commission intends in future to set such strict maximum emission levels that this would amount to or at least border on the total ban on cigarettes feared by BAT.

257. Lastly, PMI criticises the fact that, specifically for the regulation of ingredients in Article 7(5) and (11) of the Directive and for the establishment of the picture library for combined health warnings in Article 10(3)(b) of the Directive, delegated acts within the meaning of Article 290 TFEU are not required, but implementing acts within the meaning of Article 291 TFEU. In this regard it is sufficient to refer to the discretion of the Union legislature in choosing between those two kinds of delegation to the Commission.[160] Neither the referring court nor PMI has put forward substantiated arguments regarding the extent to which, by conferring powers on the Commission to adopt delegated acts, the Union legislature might have exceeded the limits of its discretion and committed a manifest error of assessment in this case.

2. The alleged delegation of powers to international bodies outside the European Union (question 5)

258. Question 5 concerns Articles 3(4) and 4(5) of the Directive, in which the Commission is authorised to adopt delegated acts within the meaning of Article 290 TFEU to integrate into Union law certain standards agreed at international level for maximum emission levels, emissions and measurement methods. On the basis of complaints made by the applicants in the main proceedings, with which JTI concurs, it is suggested that the wording of those provisions of the Directive is too vague and that they unlawfully delegate legislative powers to international institutions or bodies outside the EU's institutional framework.

158 — See also recitals 19 and 26 in the preamble to the Directive.

159 — See above, point 246 of this Opinion.

160 — Judgments in *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraph 40) and *Commission* v *Parliament and Council* (C-88/14, EU:C:2015:499, paragraph 28).

259. With regard, first, to the allegation of vagueness, it is directed at the reference made in Articles 3(4) and 4(5) of the Directive to 'standards agreed' by the parties to the WHO Framework Convention or by the WHO which the Commission is to integrate into Union law. BAT and JTI maintain that it is unclear whether this can be interpreted as extending to guidelines and possibly even statements of intent by individual parties or by the WHO.

260. That allegation must be rejected. 'Standards agreed' cannot mean unilateral statements of intent, as by their nature no agreement exists on such statements. On the other hand, the reference to 'standards agreed' can and should extend to guidelines, which play an important role in connection with the WHO Framework Convention. The fact that such guidelines do not have legally binding effects, but only constitute recommendations,[161] certainly does not prevent them from including 'standards agreed' by the Parties in accordance with the procedural rules of the WHO Framework Convention, by which the Union and its Member States are to be guided.[162]

261. Contrary to the view taken by PMI, BAT and JTI, that reference to 'standards agreed' at international level does not constitute an unlawful delegation of powers to international bodies outside the European Union,[163] as the measures to implement those standards for the European internal market will continue to be adopted by EU institutions — in the case of Articles 3(4) and 4(5) of the Directive by the Commission.

262. Furthermore, with their categorical wording '[t]he Commission shall adopt', Articles 3(4) and 4(5) of the Directive cannot be misconstrued to mean that that EU institution would have its hands tied as regards substance and that the unchecked integration of internationally agreed standards into Union law would be automatic. Instead, Articles 3(4) and 4(5) of the Directive must be interpreted in a manner which does not affect their compatibility with primary law.[164] This requires the Commission fully to perform the task conferred on it in the EU Treaty and in the FEU Treaty, in particular in Article 290 TFEU, with regard to shaping the content of EU legislation and its role as guardian of the Treaties in general.

263. Accordingly, the wording '[t]he Commission shall adopt' is to be regarded, in accordance with primary law, as a *task* imposed by the Union legislature, in which the Commission is indeed *supposed*, as a rule, to integrate the internationally agreed standards. However, in performing that task conferred on it, the Commission must ensure that those standards are incorporated into Union law *in a manner consistent with its overall system*. This is also suggested by the wording of Article 3(4) and 4(5) of the Directive, under which the Commission is instructed to 'integrate' internationally agreed standards into Union law. In doing so, it must comply with EU primary legislation, in particular EU fundamental rights (Article 6 TEU), the general principles of EU law and the obligation to ensure a high level of health protection (Article 9 TFEU, Article 114(3) TFEU, Article 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights).

161 — See points 76 and 166 of this Opinion.

162 — See also, to that effect, the last sentence of recital 7 in the preamble to the Directive, in which the Union legislature itself expressly highlights the importance of those guidelines.

163 — With regard to the prohibition of such delegation, see the leading judgment in *Meroni* v *High Authority* (9/56, EU:C:1958:7) and also, more recently, judgment in *United Kingdom* v *Council and Parliament* (C-270/12, EU:C:2014:18, in particular paragraphs 42 and 43).

164 — Judgments in *Commission* v *Council* (218/82, EU:C:1983:369, paragraph 15); *Ordre des barreaux francophones et germanophone and Others* (C-305/05, EU:C:2007:383, paragraph 28); review in *Commission* v *Strack* (C-579/12 RX-II, EU:C:2013:570, paragraph 40); and *Parliament* v *Council* (C-540/13, EU:C:2015:224, paragraph 39).

3. The requirements of Article 291 TFEU relating to powers to adopt implementing acts (question 6)

264. Lastly, by question 6 the referring court presents to the Court the criticism made by some of the undertakings taking part in the main proceedings with regard to Articles 6(1), 7(2) to (4), 7(10), 9(6) and 10(4) of the Directive. All those provisions give the Commission the power to adopt certain implementing acts within the meaning of Article 291 TFEU. It is alleged in this regard that the Union legislature did not define the necessary legal conditions for the adoption of implementing acts sufficiently clearly and made provision for such acts even in areas in which uniform implementation was 'neither needed nor justified'.

265. With regard, first, to the need for implementing measures, the EU legislature has discretion whether and in what areas of an EU legislative act it is necessary to confer on the Commission a power to adopt implementing acts within the meaning of Article 291 TFEU with a view to uniform implementation. The review by the EU Courts of the exercise of that discretion is limited to manifest errors of assessment. [165]

266. In the present case, neither the referring court nor the undertakings taking part in the proceedings have put forward any objective evidence why the contested areas of the Directive should not require any implementing measures. Their purely subjective view that implementing acts were 'neither needed nor justified' is in any case not sufficient to defeat the provisions of the Directive in question. [166]

267. With regard, second, to the specific legal conditions for the adoption of the implementing acts in question, it has already been clarified in case-law that the basic legislative act adopted by the Parliament and the Council as co-legislators — in this case the Directive — must define a complete legal framework which, in order to be implemented, needs only the addition of further detail. [167] Within the framework of its implementing powers, the Commission is authorised to adopt all the measures which are necessary or appropriate for the implementation of that basic legislative act, provided that they are not contrary to it. [168] Furthermore, in exercising its implementing power, the Commission may neither amend nor supplement the legislative act. [169]

268. It is not clear to what extent the contested provisions of the Directive are purported to infringe the abovementioned principles. With regard to the priority list of additives (Article 6 of the Directive), the regulation of ingredients (Article 7 of the Directive) and warnings (Articles 9 and 10 of the Directive), the Union legislature itself established the guiding principle in each case and made all the essential decisions or political choices itself. [170] In particular, the Union legislature itself determined that characterising flavours are to be prohibited and that (combined) health warnings of a certain kind and size are to be carried on the product packaging. It is merely left to the Commission in this connection, in accordance with Article 291 TFEU, to adopt rules to clarify specific technical details of implementation.

165 — Judgments in *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraph 40) and *Commission* v *Parliament and Council* (C-88/14, EU:C:2015:499, paragraph 28).

166 — With regard to the need for an objective analysis, see also judgment in *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraph 67).

167 — Judgment in *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, paragraphs 40 and 48); see also judgment in *Parliament* v *Commission* (C-65/13, EU:C:2014:2289, paragraph 46).

168 — Judgment in *Parliament* v *Commission* (C-65/13, EU:C:2014:2289, paragraphs 43 and 44).

169 — Judgment in *Parliament* v *Commission* (C-65/13, EU:C:2014:2289, paragraph 45).

170 — With regard to these criteria, see judgment in *Commission* v *Parliament and Council* (C-427/12, EU:C:2014:170, in particular paragraphs 38 and 43) and, additionally, judgment in *Parliament* v *Council* (C-355/10, EU:C:2012:516, paragraph 65).

4. Interim conclusion

269. All in all, the points raised in questions 4 to 6 do not therefore give any reason to call into question the lawfulness of Directive 2014/40 or specific provisions of that directive.

D – *Principle of subsidiarity*

270. Lastly, by question 7 the referring court is seeking to ascertain whether the Directive as a whole and in particular Articles 7, 8(3), 9(3) and 10(1)(g) and Articles 13 and 14 are invalid for failure to comply with the principle of subsidiarity.

271. Under the principle of subsidiarity, as enshrined in the second sentence of Article 5(1) TEU in conjunction with Article 5(3) TEU, in areas which do not fall within its exclusive competence, the Union may act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level (Article 5(3) TEU).

272. Since the Union does not have a general competence to regulate the internal market [171] and the internal market falls within the area of shared competences between the Union and its Member States (Article 4(2)(a) TFEU), the principle of subsidiarity applies to harmonisation measures pursuant to Article 114 TFEU, including the Directive. [172]

273. Compliance with the principle of subsidiarity is subject to legal review by the Courts of the European Union. [173] That review covers two aspects in particular: first, the substantive compatibility of EU measures with the principle of subsidiarity and, second, their statement of reasons in the light of the principle of subsidiarity. The order for reference touches on both aspects only briefly, on the basis of the complaints raised by the applicants in the main proceedings and two of their interveners, Benkert and Mane. Accordingly, I will base my statements regarding the principle of subsidiarity in the present case on the arguments presented to the Court in relation to question 7 and refer to my two other Opinions delivered today, which contain some more extensive statements on the issue of subsidiarity, the role of the EU Courts of the European Union and the criterion of judicial review. [174]

1. Substantive compatibility of the Directive with the principle of subsidiarity

274. First of all, the order for reference voices various criticisms made by the parties in the main proceedings in which they deny the substantive compatibility of the Directive, and in particular the ‘menthol ban’ contained in Article 7, with the principle of subsidiarity.

171 — Judgment in *Germany* v *Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 83).

172 — See also the earlier case-law relating to the period before the entry into force of the Treaty of Lisbon; judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 179) and *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 75).

173 — See in particular judgments in *Germany* v *Parliament and Council* (C-233/94, EU:C:1997:231, paragraphs 23 to 29); *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 177 to 185); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraphs 72 to 79); and *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraphs 44 to 55).

174 — See my Opinions delivered today in *Poland* v *Parliament and Council* (C-358/14, points 137 to 188) and *Pillbox 38* (C-477/14, points 156 to 180).

275. A two-stage test is relevant under Article 5(3) TEU for the purposes of the practical implementation of the principle of subsidiarity:

— First, the EU institutions must satisfy themselves that they are acting only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States (*negative component* of the test).

— Second, action by the Union is permissible only if and in so far as the objectives of the proposed action can, by reason of the scale or effects of the proposed action, be better achieved at Union level (*positive component* of the test).

These two components of the subsidiarity test ultimately address a single question from two different angles, namely whether action should be taken at Union level or at national level in order to achieve the envisaged objectives.

276. Neither the referring court in its request for a preliminary ruling nor the applicants in the main proceedings and their interveners examines these two components of the subsidiarity test to any significant degree.[175] What is more, their statements are largely so general that even on a favourable reading they lack the necessary substantiation for a review by the Court.[176] I will therefore address below only the three main arguments, which all concern the prohibition on the use of menthol as a characterising flavour in tobacco products.

277. According to the first and most important of those arguments, the Union legislature should have assessed the issue of subsidiarity specifically with regard to the use of menthol in tobacco products.

278. That argument is not valid. Determination of compliance with the principle of subsidiarity should in principle be made for the Directive as a whole and not for each of its provisions individually.[177] As is suggested by the wording of Article 5(3) TEU, the *action* laid down in the Directive must be assessed having regard to the *objectives* pursued. Consequently, in this case the question of subsidiarity is to be examined not only in respect of *menthol cigarettes*, since — as has already been explained in detail above[178] — the prohibition of this specific kind of cigarette cannot be regarded as an autonomous and separate measure in relation to the prohibition of all tobacco products with characterising flavours.

279. The second argument is that the public health objective allegedly pursued by the menthol ban could have been better achieved at national level.

280. That argument is not convincing simply because neither the Directive in general nor the contested prohibition on menthol cigarettes in particular was introduced purely on public health grounds. Rather, the aim is to remove obstacles to trade for tobacco products whilst at the same time ensuring a high level of health protection.

175 — Tann alone mentions that the subsidiarity test has two components, but likewise fails to conduct a substantiated examination of either the first or the second component.

176 — See, in this regard, judgment in *Luxembourg* v *Parliament and Council* (C-176/09, EU:C:2011:290, paragraph 80).

177 — See also, to that effect, judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraph 51).

178 — See above, points 62 to 66 of this Opinion.

281. As has already been mentioned,[179] the prohibition on all characterising flavours is the price for the circulation of tobacco products in the internal market whilst at the same time ensuring a high level of health protection. Both objectives are therefore closely connected and interrelated, contrary to the view taken by Benkert and Mane. However, where a directive simultaneously pursues two objectives between which there is an interdependence, as is the case here, those objectives cannot be considered separately in the subsidiarity test, but must be assessed together.[180]

282. Lastly, the third argument claims that market conditions — in particular market shares — for menthol cigarettes differ from one Member State to the next and that for that reason there is no cross-border problem and it is for the Member States to take any necessary measures themselves.

283. This argument is no more successful that the arguments already mentioned above. The fact that market conditions differ from one Member State to the next cannot in itself rule out the existence of a problem with a cross-border dimension. The crucial factor is whether a notable cross-border trade exists or is to be expected in the relevant sector and whether the obstacles to such trade which exist or are to be expected can be effectively removed by the Member States alone.

284. In the present case it is clear that the market for tobacco products is characterised by a flourishing cross-border trade,[181] that there are appreciable differences in the rules on the use of characterising flavours which apply in the Member States and that further divergences are to be expected.[182] Under these circumstances, the Union legislature cannot be accused of having committed a manifest error of assessment[183] if it takes the view that there is a problem that has a cross-border dimension which cannot be resolved by action taken by the Member States alone, but requires action to be taken at Union level.[184]

285. In summary, no substantive infringement of the principle of subsidiarity can therefore be established on the basis of the arguments presented by the referring court and by the undertakings taking part in the proceedings. The Court should therefore give the same ruling on the issue of subsidiarity with regard to the contested directive as with regard to its predecessor.[185]

2. Adequate statement of reasons for the Directive in the light of the principle of subsidiarity

286. Second, the order for reference makes the criticism that in the Directive the Union legislature did not take sufficient account of subsidiarity requirements, but merely records ‘boilerplate language’ asserting compliance with the principle of subsidiarity. By that criticism it is ultimately suggested that the Directive is vitiated by a defective statement of reasons.

179 — See above, point 83 of this Opinion.

180 — See, to that effect, judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraphs 46 to 48).

181 — Recital 6 in the preamble to the Directive; see also, in the same vein, judgments in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraph 64); *Arnold André* (C-434/02, EU:C:2004:800, paragraph 39); and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 38).

182 — See above, points 67 and 68 and 74 to 80 of this Opinion.

183 — With regard to the criterion of the manifest error of assessment, see also my Opinion delivered today in *Poland* v *Parliament and Council* (C-358/14, points 146 to 148).

184 — See in particular, in this regard, recital 60 in the preamble to the Directive.

185 — See, in this regard, judgment in *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 181 to 185).

287. The Court has consistently held that the statement of reasons required by the second paragraph of Article 296 TFEU must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the Union institution which adopted the measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Court to exercise its power of review. [186]

288. Where compliance with the principle of subsidiarity is under examination, it must be clear from the statement of reasons for the EU measure whether the Union legislature gave sufficient consideration to questions relevant to the principle of subsidiarity and, if so, what conclusions it reached with regard to subsidiarity.

289. Recital 60 in the preamble to the Directive merely contains the succinct statement that 'the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level' and concludes that 'the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU'.

290. Such a wording, which ultimately simply reproduces as a standard formula the text of the relevant provision from the EU Treaty, is not exactly a shining example of the frequently invoked technique of 'better regulation', to which the EU institutions have for some time been committed.

291. Certainly, the mere existence of such a standard formula in the preamble to an EU measure should not lead to premature conclusions being drawn as regards compliance with the requirements governing the statement of reasons. Nevertheless, such a formula does suggest that the statement of reasons for that measure is defective. Whilst it can at least be inferred from it that the Union legislature itself was convinced of compliance with the principle of subsidiarity, it is not clear precisely what reasoning it followed with regard to the issue of subsidiarity or how comprehensively it addressed that subject.

292. However, an empty formula like that in the present case contained in recital 60 in the preamble to the Directive does not necessarily lead to a declaration of invalidity of the contested EU measure. Aspects relevant to the issue of subsidiarity can also be found in other recitals in the preamble, even if express reference is not made to the principle of subsidiarity in them. [187]

293. That is the situation here. The shortcomings of action at national level and the benefits of adopting an internal market harmonisation measure at Union level are a particular focus in recitals 4 to 7, 15, 16 and 36 in the preamble to the Directive. Even though the statements made there are aimed primarily at the requirements governing the application of Article 114 TFEU as a legal basis, they can also be applied to the principle of subsidiarity. There is a considerable overlap between the reasoning which the Union legislature is required to follow in the context of Article 114 TFEU and of Article 5(3) TEU.

294. Aside from this, it should be borne in mind that, according to settled case-law, the statement of reasons for an EU measure is not required to go into every relevant point of fact and law. In addition, the question whether the obligation to provide a statement of reasons has been satisfied must be assessed with reference not only to the wording of the measure but also to its context and the whole

186 — Judgments in *Atlanta Fruchthandelsgesellschaft and Others (II)* (C-466/93, EU:C:1995:370, paragraph 16); *AJD Tuna* (C-221/09, EU:C:2011:153, paragraph 58); and *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 70).

187 — See, to that effect, judgments in *Germany* v *Parliament and Council* (C-233/94, EU:C:1997:231, paragraphs 25 to 29) and *Netherlands* v *Parliament and Council* (C-377/98, EU:C:2001:523, paragraph 33).

body of legal rules governing the matter in question.[188] This applies *a fortiori* where — as in this case — it is intended to adopt rules having general application, the statement of reasons for which may be restricted to a fairly general description of the main features of the provision in question and of the objectives pursued by it.[189]

295. In the present case it is relevant that the Union legislature was able to rely, first, on the explanatory memorandum for the Commission proposal for a directive[190] and, second, on the comprehensive preparatory work by the Commission staff in connection with the impact assessment[191] for the Directive. The disadvantages of disparate national rules and the benefits of action at Union level are discussed in detail not only in the passages dedicated specifically to the principle of subsidiarity but also in numerous other parts of those two texts.

296. It is thus adequately documented that the legislative institutions had comprehensive material on which they could base their evaluation of compliance with the principle of subsidiarity.

297. In addition, it cannot be inferred from Article 5 of the Protocol on the application of the principles of subsidiarity and proportionality[192] that the 'detailed statement' which the Treaty of Lisbon recently made a requirement for legislation at Union level in matters of subsidiarity should necessarily be contained in the actual preamble to the measure adopted by the European Parliament and by the Council. In view of the complexity of the reasoning to be set out for that purpose, this would also not be very practicable and could easily go beyond the scope of such a preamble.

298. The crucial factor is that the 'detailed statement' required by Article 5 of Protocol No 2 is available to the competent EU institutions and the national parliaments *during* the legislative procedure as a basis for their respective decision-making, as indisputably happened in this case. This can even be seen, on closer inspection, from the wording of Article 5 of Protocol No 2. That provision refers solely to *draft legislative acts* and not to the end products of the legislative activity of the Parliament and the Council.

299. Accordingly, the allegation of a defective statement of reasons for the Directive in the light of the principle of subsidiarity is, as a whole, not valid.

3. Interim conclusion

300. All in all, an infringement of the principle of subsidiarity cannot therefore be established from either a substantive or a procedural point of view.

301. Nevertheless, it is strongly advisable that in future the Union legislature avoids set formulas like the one contained in recital 60 in the preamble to the Directive and instead enhances the preamble to the EU measure in question with sufficiently substantial statements regarding the principle of subsidiarity which are tailored to the measures in question.

188 — See again judgments in *Atlanta Fruchthandelsgesellschaft and Others (II)* (C-466/93, EU:C:1995:370, paragraph 16); *AJD Tuna* (C-221/09, EU:C:2011:153, paragraph 58); and *Gauweiler and Others* (C-62/14, EU:C:2015:400, paragraph 70); see also judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraphs 58, 59 and 61).

189 — See, to that effect, judgments in *United Kingdom* v *Council* (C-150/94, EU:C:1998:547, paragraphs 25 and 26); *AJD Tuna* (C-221/09, EU:C:2011:153, paragraph 59); and *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535, paragraph 29).

190 — COM(2012) 788 final, submitted by the Commission on 19 December 2012.

191 — Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final.

192 — Protocol No 2 to the EU Treaty and to the FEU Treaty ('Protocol No 2').

V – **Conclusion**

302. In the light of the foregoing considerations, I suggest that the Court answer the questions referred by the High Court of Justice (Administrative Court) as follows:

(1) Question 1(a), (b) and (c)(iii) and (iv) and questions 4 to 6 are inadmissible. Question 7 is inadmissible in so far as it refers to provisions 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 other than Article 7.

(2) As to the remainder, the questions should be answered as follows:

(a) Article 13(1) of Directive 2014/40 is to be interpreted as also prohibiting true statements on product packaging where those statements, viewed objectively, are capable of producing one or more of the effects described in that provision.

(b) Examination of the questions referred has not revealed any factors such as to affect the validity of Directive 2014/40.