Reports of Cases

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

Case C-358/14

Republic of Poland
v
European Parliament
and

Council of the European Union

(Action for annulment — Approximation of laws — Directive 2014/40/EU — Manufacture, presentation and sale of tobacco and related products — Menthol cigarettes — Choice of Article 114 TFEU as the legal basis — Principle of proportionality — Principle of subsidiarity)

I – **Introduction**

1. Was the Union legislature permitted to prohibit the sale of menthol cigarettes in the European internal market with effect from 20 May 2020? This emotionally charged question[2] is essentially the legal problem which the Republic of Poland has brought before the Court in this case by its action for annulment of Directive 2014/40/EU.[3] The action is one of a series of legal disputes that have flared up over the years regarding the various rules enacted at Union level on the manufacture, presentation and sale of tobacco and related products in the European internal market.[4]

2. Unlike earlier cases, the present case does not call into question the suitability of Article 114 TFEU (formerly Article 95 EC and Article 100a of the EEC Treaty) as a legal basis for the new directive in principle, but addresses only certain detailed aspects of it. Consequently, legislative competence no longer plays such a central role as it previously did. Interest is now focused on the question whether a Union-wide prohibition on menthol cigarettes is compatible with the principle of proportionality. It is also necessary to clarify the requirements stemming from the principle of subsidiarity for provisions like those at issue.

1 — Original language: German.

2 — There have, for example, been media reports about measures taken by the late former German Chancellor faced with the impending disappearance of menthol cigarettes: 'Former Chancellor Schmidt Hoarding 200 Cartons of [Menthol] Cigarettes' (*Spiegel Online* — English Site — Germany — German Election — 9 July 2013).

3 — 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); 'the Directive'.

4 — 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).

3. A very basic problem ultimately underlies these legal questions, which seem, in Poland especially, to involve considerable economic interests and, moreover, 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)?

4. In addition to this action for annulment brought by Poland, two references for preliminary rulings are also currently pending, in which a UK court is asking the Court about the validity of Directive 2014/40. One of those cases [5] relates solely to the new rules on electronic cigarettes contained in Article 20 of the Directive; it raises legal questions concerning the principle of proportionality, the principle of subsidiarity and EU fundamental rights. The other [6] concerns a number of specific provisions of the Directive and focuses in particular on the choice of Article 114 TFEU as the legal basis, the principle of subsidiarity, the principles of proportionality and legal certainty, questions relating to EU fundamental rights and problems connected with Articles 290 TFEU and 291 TFEU in respect of the delegation of regulatory and implementing powers to the Commission. I am also delivering my Opinions in those two cases today.

II – **The contested provisions of Directive 2014/40**

5. According to the definition set out in Article 2(25) of the Directive, 'characterising flavour' means

'a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product'.

6. Article 6 of the Directive, under the heading 'Priority list of additives and enhanced reporting obligations', provides that enhanced reporting obligations apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list laid down and updated by the Commission. In this connection, Article 6(2) of the Directive provides:

'Member States shall require manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list … to carry out comprehensive studies, which shall examine for each additive whether it:

…

(b) results in a characterising flavour;

…'

7. Article 7 of the Directive contains rules on the 'Regulation of ingredients' and includes the following provisions:

'1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, ...

5 — Case C-477/14 *Pillbox 38*.

6 — Case C-547/14 *Philip Morris Brands and Others*.

...

2. The Commission shall, at the request of a Member State, or may, on its own initiative, determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3. The Commission shall adopt implementing acts laying down uniform rules for the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

4. An independent advisory panel shall be established at Union level. Member States and the Commission may consult this panel before adopting a measure pursuant to paragraphs 1 and 2 of this Article. The Commission shall adopt implementing acts laying down the procedures for the establishment and operation of this panel.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

5. Where the content level or concentration of certain additives or the combination thereof has resulted in prohibitions pursuant to paragraph 1 of this Article in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to set maximum content levels for those additives or combination of additives that result in the characterising flavour.

…

7. Member States shall prohibit the placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity. …

…

12. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

13. The Member States and the Commission may charge proportionate fees to manufacturers and importers of tobacco products for assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used ...

14. In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.

…’

8. With regard to ‘Product presentation’ Article 13 of the Directive includes the following provision:

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

…

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

…'

III – **Procedure and forms of order sought**

9. By written pleading of 22 July 2014, Poland brought the present action for annulment against the European Parliament and the Council of the European Union on the basis of Article 263 TFEU.

10. Romania was granted leave to intervene in support of the applicant; Ireland, the French Republic, the United Kingdom of Great Britain and Northern Ireland and the European Commission were granted to leave to intervene in support of the defendant.

11. Poland claims the Court should:

— declare invalid Article 2(25), Article 6(2)(b), Article 7(1) to (5), the first sentence of Article 7(7), Article 7(12) to (14) and Article 13(1)(c) of Directive 2014/40;

— order the Parliament and the Council to pay the costs.

12. Romania asks the Court to declare invalid Article 7(1) to (5), the first sentence of Article 7(7) and Article 7(12) to (14) of Directive 2014/40.

13. The Parliament and the Council each contend that the Court should:

— dismiss the application and

— order Poland to pay the costs.

14. The Commission asks the Court:

— to dismiss the application as unfounded and

— to order the applicant to pay the costs.

15. Ireland, France and the United Kingdom each claim that the Court should dismiss the application. Ireland further claims that the Court should order Poland to pay the costs of the proceedings.

16. In the event that the Court should grant the action brought by Poland, the Parliament, the Council and France further claim, in the alternative, that the effects of any annulled provisions of Directive 2014/40 should be maintained until a new directive enters into force within a reasonable period.

17. The action brought by Poland was examined before the Court on the basis of the written pleadings and, on 30 September 2015, at a hearing.

IV – **Assessment**

A – *Admissibility of the action*

18. Before I examine the substance of the complaints raised by Poland, it is necessary briefly to consider the admissibility of this action for annulment. First, the question arises whether the provisions on characterising flavours may be challenged in isolation. Second, it must be examined whether the applicant's claims regarding specific provisions of the contested directive are adequately substantiated. Third, it is necessary to examine the Council's criticism that Poland's arguments regarding the principle of equal treatment in the second round of pleadings — in Poland's reply to be precise — constitute a new plea in law which is inadmissible because it was submitted out of time.

1. The restriction of the action for annulment to specific articles of the Directive

19. Poland, supported by Romania, is not seeking the annulment of Directive 2014/40 as a whole, but challenges only specific provisions of that directive, namely all those relating to characterising flavours or simply flavours.

20. 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'). [7] There is no such severability where the partial annulment of the contested act would have the effect of altering its substance. [8]

21. The contested rules of Directive 2014/40 contain specific provisions on tobacco products with characterising flavours which exist independently of the other rules laid down in the Directive. Nothing has emerged before this Court to indicate that the provisions on such flavours contained in the Directive and the other provisions of the Directive should stand and fall together. Even if the Court were to declare specific provisions relating to flavours to be invalid in the present case, the other provisions contained in the Directive would still have their *raison d'être* and their scope would not be altered.

22. Accordingly, the provisions on characterising flavours must be considered to be a severable part of Directive 2014/40 and their potential annulment would not affect the substance of that directive.

23. For the same reasons, contrary to the assertion made by Poland at the hearing, there is nothing in theory to prevent the provisions of Directive 2014/40 on characterising flavours being annulled only partially, namely in so far as those provisions establish a prohibition on menthol cigarettes.

2. The question whether the applicant's claims are adequately substantiated

24. It is noteworthy that whilst Poland is seeking the annulment of a whole series of specific provisions of the Directive, it does not make any further statements on some of them, in particular Article 6(2)(b), Article 7(12) and (14) and Article 13(1)(c).

7 — 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).

8 — 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 also, 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).

25. The applicant's claims in its application must be adequately substantiated. It should be noted that, under Article 120(c) of the Court's Rules of Procedure and the case-law relating thereto, an application initiating proceedings must state the subject-matter of the dispute, the pleas in law and arguments relied on and a summary of the pleas in law on which the application is based. That statement must be sufficiently clear and precise to enable the defendant to prepare his defence and the Court to rule on the application. It is therefore necessary for the essential points of law and of fact on which a case is based to be indicated coherently and intelligibly in the application itself and for the heads of claim to be set out unambiguously so that the Court does not rule *ultra petita* or fail to rule on a claim. [9]

26. In the present case the application does not include any explanation at all why Poland is seeking specifically the annulment of Article 6(2)(b), Article 7(12) and (14) and Article 13(1)(c) of the Directive. The overall context of the action for annulment brought by Poland does not cast any light on this either.

27. On the contrary, according to the grounds put forward in the application and the oral explanations provided by Poland before the Court, Poland's claims are directed solely at the prohibition on menthol cigarettes under EU law. However, that prohibition is not actually contained as such in the abovementioned provisions of the Directive.

28. It can certainly be argued that any lifting of the prohibition on menthol cigarettes by the Court must necessarily also extend to the provisions of the Directive that are inseparably linked to that prohibition. However, of the abovementioned provisions this applies at most only to Article 13(1)(c) of the Directive, which prohibits the mention of taste, smell and flavourings on cigarette packaging. Should it still be lawful in future to sell menthol cigarettes — as Poland and Romania wish — it would have to be permitted to mention menthol as an ingredient on the packaging of such cigarettes. How else could consumers make a choice between menthol cigarettes and non-flavoured cigarettes?

29. Nevertheless, the other abovementioned provisions of the Directive do not have such a close link with the prohibition on menthol cigarettes that they would have to stand and fall with that prohibition. Thus, under Article 6(2)(b) of the Directive, manufacturers and importers of cigarettes and roll-your-own tobacco are required to carry out certain studies; this does not have any direct connection with a prohibition on menthol cigarettes. The same holds for Article 7(12) of the Directive, which regulates *exemptions* from the prohibition on the placing on the market of tobacco products with a characterising flavour. Lastly, with regard to Article 7(14) of the Directive, it likewise does not contain a prohibition on menthol cigarettes, but merely defers the commencement of certain prohibitions, including the prohibition on menthol cigarettes, to 20 May 2020.

30. Consequently, the action brought by Poland is inadmissible on grounds of inadequate substantiation in so far as it is directed at Article 6(2)(b) and Article 7(12) and (14) of the Directive.

3. The alleged existence of a new plea in law submitted out of time in respect of the principle of equal treatment

31. The Council complains, on the basis of Article 127(1) of the Rules of Procedure, that in the second round of pleadings — in the reply to be precise — Poland put forward a new plea in law submitted out of time, by which it claims an infringement of the principle of equal treatment, allegedly because the Directive treats menthol cigarettes in exactly the same way as other flavoured tobacco products despite the existence of objective differences.

9 — Settled case-law; see in particular judgments in *Commission* v *Parliament and Council* (C-411/06, EU:C:2009:518, paragraph 27); *United Kingdom* v *Council* (C-209/13, EU:C:2014:283, paragraph 30), and *Parliament* v *Council* (C-540/13, EU:C:2015:224, paragraph 9).

32. This complaint raised by the Council is manifestly based on a misreading of the applicant's claims in the written procedure. Poland does stress at various places in its written submissions the purported differences between menthol cigarettes and other flavoured tobacco products. However, as was also clear from the hearing, these claims do *not* constitute a separate plea in law, but arguments put forward in support of the three actual pleas in law made by the applicant. Such arguments were adduced for the first time in the application. Furthermore, it is clear from the reply that in the second round of pleadings Poland is merely replying, with a more detailed version of those arguments, to a specific submission made by the Parliament and the Council and attempting to clarify the subject-matter defined by the application. Such an approach is wholly permissible.

33. This complaint raised by the Council must therefore be rejected.

4. Interim conclusion

34. The action brought by Poland is inadmissible, for lack of substantiation, in so far as it challenges Article 6(2)(b) and Article 7(12) and (14) of the Directive. The remainder of the action is admissible.

B – *Substance of the action*

35. The action for annulment brought by the Republic of Poland is directed at a number of specific provisions of Directive 2014/40 which all relate to the use of characterising flavours in tobacco products. The aim of Poland's action is to overturn the prohibition on the placing on the market of menthol cigarettes in the European internal market, which, under Article 7(14) of the Directive, is to be applied from 20 May 2020. [10]

36. To that end, three pleas in law are raised. First, Poland asserts that the prohibition on menthol cigarettes should not have been based on Article 114 TFEU. Second, Poland alleges an infringement of the principle of proportionality. Third, Poland considers that the principle of subsidiarity is infringed.

1. The choice of Article 114 TFEU as the legal basis (first plea in law)

37. By its first plea in law, Poland claims that Article 114 TFEU is not an appropriate legal basis for a Union-wide prohibition on menthol cigarettes.

38. It should be noted in this regard that a legislative act adopted on the basis of that provision 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. [11] 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. [12]

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

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

12 — 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).

39. To that end, according to settled case-law, Article 114 TFEU permits the Union legislature to prohibit the placing on the market of a certain product in the entire European internal market if this helps to remove obstacles to trade for a class of products or is even merely intended to prevent the emergence of such obstacles to trade. [13]

40. 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. [14] In other words, tobacco products may in principle still be placed on the market in the European Union, but only without characterising flavours.

41. Accordingly, in this case Poland does not appear to dispute that in principle Article 114 TFEU can be an appropriate legal basis for internal market harmonisation measures relating to tobacco products, including the prohibition on the marketing of some products in a larger class of tobacco products.

42. With regard specifically to menthol cigarettes, however, in the view of Poland, at the time when the Directive was adopted neither was there a divergence between national laws, regulations and administrative provisions (first part of the first plea in law, see section (a) immediately below) nor was a different development of those rules to be expected (second part of the first plea in law, see section (b) below). Poland infers from this that it was not permissible to base the contested prohibition on menthol cigarettes on Article 114 TFEU. [15]

a) The removal of existing obstacles to trade (first part of the first plea in law)

43. The first part of the first plea in law is based, in essence, on the objection that the contested provisions of the Directive are not appropriate for removing existing obstacles to trade but, on the contrary, would lead to the creation of new obstacles to trade.

i) The divergence between national laws, regulations and administrative provisions

44. 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 [16] or to cause significant distortions of competition. [17]

45. Poland, supported by Romania, claims 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*.

13 — 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.

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

15 — In so far as Poland also puts forward the same arguments in connection with the second plea in law regarding the principle of proportionality, I will consider them together here and I will not examine them again further below.

16 — 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).

17 — 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).

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

47. 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.

– There was no reason to consider menthol cigarettes in isolation

48. Consideration of menthol cigarettes in isolation, as envisaged by Poland and Romania, would be conceivable at most only if menthol cigarettes enjoyed special status compared with other flavoured tobacco products.

49. It is true that in the proceedings before the Court Poland has attempted to claim precisely such special status for menthol cigarettes. However, those arguments are unconvincing. There are enough common features between menthol cigarettes, on the one hand, and other flavoured cigarettes, on the other, to allow the Union legislature to adopt a uniform approach in the Directive.

50. This is evident from a comparison of the two kinds of cigarettes in the light of all relevant circumstances. It must be borne in mind in this connection that the two products are similar in their objective characteristics [18] and also that they are in a comparable situation with reference to the purpose of the provisions at issue. [19]

51. If consideration is given first of all to the physical nature of the different types of cigarettes, no notable differences can be discerned between menthol cigarettes and other flavoured cigarettes. The way in which they are consumed is also the same. In all cases tobacco is combusted and the smoke puffed or inhaled. [20]

52. Nor are notable differences apparent if menthol cigarettes and other flavoured cigarettes are compared in the light of the overall objective of Directive 2014/40, which is to guarantee the circulation of tobacco products in the European internal market whilst ensuring a high level of health protection. [21] 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. This creates a serious risk that flavoured cigarettes will facilitate initiation of tobacco consumption for non-smokers [22] and make it more difficult for habitual smokers — or at least some of them — to escape nicotine addiction. [23]

18 — Judgments in *Rewe-Zentrale des Lebensmittel-Großhandels* (45/75, EU:C:1976:22, paragraph 12); *John Walker* (243/84, EU:C:1986:100, paragraph 11); *Arnold André* (C-434/02, EU:C:2004:800, paragraph 69), and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 71).

19 — Judgments in *Arcelor Atlantique et Lorraine and Others* (C-127/07, EU:C:2008:728, paragraphs 25 and 26); *Association Belge des Consommateurs Test-Achats and Others* (C-236/09, EU:C:2011:100, paragraph 29); *Ziegler* v *Commission* (C-439/11 P, EU:C:2013:513, paragraph 167), and *Feakins* (C-335/13, EU:C:2014:2343, paragraph 51).

20 — In this regard the present case is fundamentally different from *Pillbox 38* (C-477/14; see my Opinion delivered today in that case, points 47 to 49), in which the comparison is not between different types of conventional tobacco products but between conventional tobacco products on the one hand and electronic cigarettes on the other, revealing considerable differences in that case.

21 — See, in particular, the end of Article 1 and recitals 5, 6, 8 and 36 in the preamble to the Directive.

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

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

53. Poland argues unsuccessfully in this regard that menthol cigarettes are a 'traditional' product which have a longstanding presence on the market and are less attractive to adolescents and young adults than other flavoured cigarettes. [24]

54. First, there is no objective reason to apply lower standards of health protection for supposedly 'traditional' products that are established on the market than for novel products. It may possibly be justified to treat certain products more strictly than others or to introduce special rules for them specifically by reason of their novelty. [25] However, it cannot be concluded *a contrario* that as a general rule more relaxed rules should apply to products already established on the market than to novel products.

55. Second, Poland's argument completely disregards the fact that the objective of a high level of health protection in the European internal market pursued by the Directive certainly does not cease with the protection of adolescents and young adults, even if the Directive does focus on that group of people. [26] As was mentioned immediately above, [27] the Directive has in view, very broadly, a high level of protection of human health (see, for example, Article 1 of the Directive), which definitely includes supporting habitual smokers in escaping nicotine addiction.

56. Accordingly, it is not a crucial factor whether the contested prohibition on menthol cigarettes has positive effects specifically on the health of young people. Even if that were not the case to any appreciable degree, the prohibition on menthol cigarettes could have effects on other groups of consumers [28] and thus generally help to improve the level of health protection in the European internal market. This alone justifies the adoption of a uniform prohibition on the placing on the market of menthol cigarettes and other flavoured cigarettes in the Directive.

57. In summary, the argument put forward by Poland and Romania that menthol cigarettes have special status distinguishing them from other cigarettes with characterising flavours and calling for an exception to the Directive's Union-wide prohibition on marketing this class of tobacco products must therefore be rejected. [29]

– There were enough divergences between national rules

58. The sole crucial factor for recourse to Article 114 TFEU is therefore 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.

24 — Poland infers from this that young people are not led into tobacco consumption to any appreciable degree by menthol cigarettes.

25 — Judgments in *Arnold André* (C-434/02, EU:C:2004:800, paragraph 69), and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 71).

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

27 — See above, points 40 and 52 of this Opinion.

28 — See, in this regard, the Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular part 1, p. 101. It states in connection with the planned prohibition on characterising flavours that '… a certain impact is also expected for established smokers'.

29 — 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).

59. As is clear in particular from the detailed and unrefuted arguments made by the Council and the United Kingdom in the proceedings before the Court, a number of Member States had 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. [30] This patchwork quilt of national rules could result in considerable obstacles to trade in the internal market for tobacco products, which is characterised by a lively cross-border trade. [31]

60. 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. [32]

61. As the defendant EU institutions and some of their interveners rightly observe, 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. [33]

62. 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. [34] On the other hand, as far as can be seen, there were no such prohibitions in other Member States at the time. Poland's claim 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.

63. It should also be mentioned in this connection that the number of Member States which had legislated or had the intention of legislating in the field concerned on the date of the Commission's proposal is not, in itself, decisive for assessing whether the EU legislature's recourse to Article 114 TFEU was lawful if the conditions for recourse to that article were met on the date on which the legislative measure at issue was adopted. [35]

30 — 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.

31 — 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).

32 — 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 legal 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).

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

34 — 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.

35 — Judgment in *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:535, paragraph 24). See also, in the same vein, judgments in *Arnold André* (C-434/02, EU:C:2004:800, paragraph 38), and *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 37).

64. The conditions for intervention by the EU legislature under Article 114 TFEU are not quantitative, but qualitative. The adoption of a harmonisation measure does not depend so much on whether and in how many Member States a certain product is covered by rules or even by bans. Any existing or specifically anticipated disruption of trade in the internal market can justify a harmonisation measure, on condition that the general principles for the exercise of the powers of harmonisation — in particular the principles of subsidiarity and proportionality (Article 5(3) and (4) TEU) [36] — are respected. [37]

65. Consequently, Poland's first complaint in connection with this first part of the first plea in law must be rejected.

ii) The alleged creation of new obstacles to trade

66. Poland, supported by Romania, also complains in connection with this first part of the first plea in law that the scope *ratione materiae* of the prohibition on the placing on the market of tobacco products with a characterising flavour is not specified sufficiently in Article 7(1) of the Directive, as that provision does not contain a list of permitted or prohibited flavouring substances. According to Poland, this does not lead to the removal of any existing obstacles to trade but, on the contrary, to the creation of new obstacles to trade, because there is a risk that the Member States will exercise their discretion in respect of implementation differently.

67. However, this complaint is also unconvincing.

68. First, it is in the nature of things that imprecise legal terms are used in legislation. That applies *a fortiori* to rules in directives, which always need to be transposed into national law (see the third paragraph of Article 288 TFEU). In this regard the Union legislature has discretion as regards the method of approximation most appropriate for achieving the desired result. [38]

69. Second, it is in any case difficult to imagine how a prohibition of *all* tobacco products with characterising flavours, like the Union-wide prohibition in Article 7(1) of the Directive, might lead to such significant discrepancies in implementation in the Member States that there would be a serious risk of new obstacles to trade.

70. However, even if discrepancies were to arise in this regard, the Union legislature would have taken sufficient steps in the Directive to avoid them. Article 7(2) to (5) of the Directive allows the European Commission, under the conditions described in detail therein, to adopt implementing acts and delegated acts to eliminate any remaining uncertainties.

71. The adoption of a list of permitted or prohibited flavouring substances at Union level (a kind of 'positive list' and 'negative list'), suggested by Poland 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).

72. The first part of the first plea in law is therefore unfounded in its entirety.

36 — See my statements in connection with the second and third pleas in law.

37 — See my Opinion in *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:190, point 51).

38 — Judgments in *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).

b) The risk of a future different development of national laws, regulations and administrative provisions (second part of the first plea in law)

73. By the second part of the first plea in law, Poland claims that it is 'highly unlikely' that in future obstacles to trade will emerge in the European internal market as a result of national prohibitions on menthol cigarettes.

74. I will consider this issue below only in the alternative. It follows from my examination of the first part of the first plea in law 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.

75. In addition, it seems that Poland contradicts itself. Its assertion in connection with this second part of the first plea in law that a different development of national laws, regulations and administrative provisions is not to be expected is hardly compatible with the fear, previously expressed in the first part of the first plea in law, that there will be different national approaches to implementation of the prohibition on characterising flavours. [39]

76. 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. [40]

77. 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.

78. The defendant EU institutions and some of their interveners have argued convincingly that under the WHO Framework Convention on Tobacco Control [41] 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. [42]

79. 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. [43] They therefore also serve as a guide for the EU Member States which concluded that Framework Convention.

80. 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. This has been emphatically confirmed by Ireland and France in the proceedings before the Court in relation to their respective national practices. The reason for the fact, highlighted by Poland, that in reality hardly any national rules in

39 — See above, point 66 of this Opinion.

40 — 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).

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

42 — 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'.

43 — Ibid., Section 1.1.

this regard had been enacted in the EU Member States for a considerable period of time appears to be that the Commission [44] 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. [45]

81. 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 an 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.

82. Under these circumstances, the second part of the first plea in law is also unfounded.

c) Interim conclusion

83. The first plea in law must therefore be rejected in its entirety.

2. The principle of proportionality (second plea in law)

84. The second plea in law is devoted to the principle of proportionality. Poland argues that the contested provisions of the Directive are not compatible with the principle of proportionality, which is enshrined in Article 5(4) TEU.

a) General remarks on the principle of proportionality

85. According to settled case-law, the principle of proportionality is one of the general principles of EU law and is enshrined specifically with regard to the exercise of competences by the EU institutions in Article 5(4) TEU. 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; [46] 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. [47]

86. 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. [48]

44 — 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.

45 — 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).

46 — 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).

47 — 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).

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

87. In the present case, the fundamental right of freedom to conduct a business (Article 16 of the Charter of Fundamental Rights) is affected. According to settled case-law, the freedom to conduct a business 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 [49] 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. [50]

88. 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 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.

89. 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. [51] On the other hand, it is irrelevant whether the measure adopted in the legal act is the only conceivable measure or even only the most appropriate.

90. A review of the proportionality of the contested provisions of the Directive should be conducted subject to that proviso.

b) Appropriateness and necessity of a prohibition on sales (first and second parts of the second plea in law)

91. By the first two parts of this second plea in law, Poland complains that a prohibition on menthol cigarettes is neither appropriate nor necessary for achieving the high level of health protection pursued by the Union legislature through the Directive.

i) Preliminary remark regarding the precautionary principle

92. It should be noted, as a preliminary point, that none of the parties denies the health risks associated with smoking. [52] The view that characterising flavours facilitate or assist smoking and can therefore entail health risks [53] is shared by all the parties in principle.

93. There are, however, fierce disagreements between the parties on how a prohibition on menthol cigarettes will affect the consumer habits of current and potential smokers. Both sides base their arguments on scientific studies and accuse the opposite side of having insufficient scientific evidence for their submissions.

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

50 — 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).

51 — 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).

52 — The Court recognises that nicotine causes addiction and its toxicity is not disputed (judgments in *Arnold André*, C-434/02, EU:C:2004:800, paragraph 50, and *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 52).

53 — See above, point 52 of this Opinion.

94. 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.

95. The Union legislature was required to take account of the precautionary principle when it adopted the Directive.[54] 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.[55]

96. 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,[56] is nothing other than an expression of the precautionary principle.

97. Certainly, the precautionary principle requires that the Union legislature always bases its decisions on the most reliable scientific data available and the most recent results of international research[57] (see, in the same vein, Article 114(3) TFEU). However, neither Poland nor Romania has seriously questioned the Union legislature's fulfilment of this duty in the present case.[58] The parties merely disagree on the inferences to be drawn from the scientific evidence obtained. However, the Union legislature has broad discretion in this regard, the limits of which it certainly did not exceed here.

98. 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 second sentence of Article 35 of the Charter of Fundamental Rights).

ii) Appropriateness of a prohibition on sales (first part of the second plea in law)

99. Poland disputes the appropriateness of the prohibition on the placing on the market of menthol cigarettes for achieving the improved health protection pursued by the Directive — above all in respect of young people — with three arguments. First, it claims that menthol cigarettes are a 'traditional' product which are less attractive to young people than other flavoured tobacco products. Second, it argues that it is not objectively proven that a prohibition on menthol cigarettes would actually be apt to lead fewer young people into smoking or reduce the number of smokers in general. Third, it states that the black market in menthol cigarettes in Europe will flourish.

54 — See, to this 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'.

55 — 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).

56 — See above, points 77 to 79 of this Opinion.

57 — Judgments in *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 51); *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 92), and *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 60); see also judgment in *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 113).

58 — The WHO Guidelines (cited above in footnote 42), to which the Union legislature had regard according to Article 1 and recital 7 in the preamble to the Directive, draw on the 'best available scientific evidence and the experience of Parties' (see Section 1.1 of those Guidelines).

– The health effect of a prohibition on menthol cigarettes

100. As far as Poland's first two arguments are concerned, I have already explained above in connection with Article 114 TFEU that there is no objective reason to apply lower standards of health protection for supposedly 'traditional' products that are established on the market than for novel products.[59] As France rightly observes, the traditional character of a product does not justify its continued presence on the market if this makes it more difficult to achieve a high level of health protection.

101. Furthermore, I consider that Poland is incorrect in its argument that the EU institutions should prove objectively that under a prohibition on menthol cigarettes fewer young people will become smokers or that the number of smokers as a whole will be reduced.

102. As has already been mentioned, in assessing the appropriateness of the contested provisions it does not matter so much whether the effects, presumed by the Union legislature, of a prohibition of characterising flavours on consumer habits of (current or potential) smokers can be scientifically proven with sufficient accuracy. Forecasts of the future development of market activity naturally cannot be proven per se, but may be reviewed as to their plausibility at most.

103. It appears perfectly plausible that a prohibition on menthol cigarettes and other flavoured cigarettes, like that introduced by the Union legislature, makes the initiation of tobacco consumption less attractive to adolescents and young adults and, at the same time, makes it easier for habitual smokers — or at least some of them — to escape nicotine addiction. In short, if characterising flavours facilitate or assist smoking because they can reduce or camouflage the generally very bitter and even pungent taste of tobacco smoke, it is not unreasonable to assume that dispensing with such flavours may have the opposite effect and thus contribute to improved health protection.

104. Under no circumstances can a prohibition of characterising flavours 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 regard is had to the precautionary principle and 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.

– The alleged flourishing of the black market in menthol cigarettes

105. As regards a flourishing of the black market in menthol cigarettes predicted by Poland, this is no more than a mere assertion, with little by way of substantiation.

106. The defendant EU institutions and some of their interveners attempt to counter this assertion primarily by making reference to the new provisions in Articles 15 and 16 of the Directive, which set out detailed requirements for the traceability of cigarette packets and for security features to be attached to those unit packets.

107. Poland is correct to state that such safeguards are not capable as such of reliably preventing potential smuggling of menthol cigarettes from third countries or the sale of illegally imported or marketed menthol cigarettes on the black market within the European Union.

59 — See above, point 53 of this Opinion.

108. However, in my view, it is also irrelevant whether smuggling and black market trade can be effectively prevented in this way.[60] Two factors are crucial. First, illegal activities are made more difficult and their detection is made easier by Articles 15 and 16 of the Directive. Second — and above all — 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 militate in general against their appropriateness for attaining the objective pursued.

109. The first part of the second plea in law is therefore unfounded.

iii) Necessity of a prohibition on sales (second part of the second plea in law)

110. In addition, Poland disputes that a prohibition on the placing on the market of menthol cigarettes is necessary for achieving the high level of health protection in the European internal market pursued by the Directive.

111. The arguments put forward by Poland in this connection can be classified under two headings. First, they concern 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

112. With regard to the first of these headings, I have already explained above, in connection with Article 114 TFEU, that Poland's arguments regarding the purported special status of menthol cigarettes in the flavoured cigarettes market segment are not very convincing.[61]

113. In particular, even if it is assumed to be true, the 'traditional' character of menthol cigarettes compared with other kinds of flavoured cigarettes, claimed by Poland, cannot justify any reductions in the high level of health protection in the internal market for tobacco products which is generally to be pursued.

114. 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.[62] [63]

115. If the Union legislature had not included menthol in the prohibition on characterising flavours, 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 begin consuming tobacco and at the same time make it more difficult for habitual smokers to escape nicotine addiction.[64]

60 — 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).

61 — See above, points 48 to 57 of this Opinion.

62 — Recital 7 in the preamble to the Directive.

63 — See above, points 77 to 79 and point 96 of this Opinion.

64 — 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 contribute to the achievement of a high level of health protection in the internal market for tobacco products.

116. 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. [65] Contrary to the view taken by Poland, 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).

117. If these circumstances are taken into consideration, the necessity of a prohibition on *all* characterising flavours, including menthol, cannot seriously be called into question. [66] 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.

– The allegedly more moderate means mentioned by Poland

118. As regards the second of the abovementioned headings, Poland essentially puts forward three alternatives which, in its view, would be possible more moderate means than a blanket prohibition on menthol cigarettes: the introduction of age limits for the sale of such cigarettes, the affixing of specific warnings on their packaging and targeted information campaigns.

119. 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. [67]

120. That is not the case with the abovementioned age limits. As the EU institutions participating 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.

121. First, it is possible that minors will be supplied with flavoured cigarettes by adults from their family or from their circle of friends and acquaintances. Second, even a requirement that only adults may purchase flavoured cigarettes cannot ensure that young consumers who have only recently reached the relevant age limit will be properly protected from the risks of nicotine consumption. However, as has been convincingly argued in the proceedings before the Court, not only minors but also young adults who have reached the age of majority (above all the age group between 18 and 25 years) are at particular risk because commencement of consumption of nicotine-containing products can also often still occur and is observed in the phase up to the age of 25.

122. Similarly, an obligation on manufacturers and importers to affix warnings to the packaging of menthol cigarettes also cannot be regarded as equally suitable as a prohibition on the marketing of all tobacco products with characterising flavours in the light of the objective of a high level of health protection. Even if special warnings were created with the message that flavoured cigarettes are no less dangerous than unflavoured cigarettes, this would not affect the continued availability of those products for consumers at all. The sale of cigarettes with characterising flavours could therefore continue to act as an impediment to achieving a high level of health protection in the European

65 — 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.

66 — See, to that effect — with regard to the prohibition of 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).

67 — 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).

internal market. What is more, as Ireland rightly states, specifically flavour-related warnings could even be counterproductive because they possibly — not unlike an advertisement — direct the consumer's attention, in particular and more than mere information on contents, to the existence of characterising flavours.

123. The same holds true for the idea put forward by Poland of information campaigns on the danger of tobacco products with characterising flavours. In any event, as the Commission rightly observes, such information campaigns are not capable of removing obstacles to trade which exist on account of diverging national rules on the use of characterising flavours in accordance with Article 114 TFEU or of preventing them from arising.

124. The first two parts of this second plea in law therefore have no prospect of success.

c) Proportionality in the strict sense (third part of the second plea in law)

125. By the third part of this second plea in law, Poland focuses on proportionality in the strict sense. Poland complains that it will face much greater economic and social hardships on account of the prohibition on menthol cigarettes than other Member States. In addition, Poland claims in this regard that the Union legislature did not carry out a cost-benefit analysis or at least an analysis specifically in relation to menthol cigarettes.

126. Contrary to the view taken by the United Kingdom, the review of proportionality in the strict sense is a separate third stage in the context of the principle of proportionality. As has already been mentioned, it means that the disadvantages caused by an EU measure must not be disproportionate to the aims pursued.[68] The Union legislature must always therefore satisfy itself whether objectives pursued by the measure chosen are such as to justify even substantial negative economic consequences for certain operators[69] (see also — for draft legislative acts — the last sentence of Article 5 of the Protocol on the application of the principles of subsidiarity and proportionality).[70]

127. In the present case the Parliament and the Council, in their capacity as EU legislative institutions, were able to rely in particular on the Commission's impact assessment,[71] which also examined the economic and social consequences of the measures introduced by the Directive.[72]

128. Since, as has already been mentioned,[73] menthol cigarettes have *no* special status in the flavoured cigarettes market segment there was no need to conduct an impact assessment tailored to that specific product, contrary to the view taken by Poland.

129. 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 could temporarily have negative effects on the economic situation of some farmers engaged in tobacco cultivation and some undertakings engaged in the manufacture and sale of tobacco products and, at worst, may even lead to some job losses.

68 — 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).

69 — Judgments in *Arcelor Atlantique et Lorraine and Others* (C-127/07, EU:C:2008:728, paragraph 59); *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 53), and *Luxembourg* v *Parliament and Council* (C-176/09, EU:C:2011:290, paragraph 63).

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

71 — Impact Assessment submitted by the Commission staff on 19 December 2012, Doc. SWD(2012) 452 final, in particular part 1, p. 98 et seq., 120 et seq.

72 — 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).

73 — See above, points 48 to 57 of this Opinion.

130. 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. [74]

131. Moreover, the fact that the prohibition on menthol cigarettes will possibly hit the Polish economy harder than 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 the Member States in exactly the same way. [75] As the EU institutions participating 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.

132. In addition, the losses for Poland's agriculture and tobacco trade, [76] as forecast by that Member State — assuming them to be accurate — are relatively moderate and manageable, especially since they clearly represent only declines in sales and not, for example, losses of net profit.

133. 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.

134. 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 Poland in the present case.

135. The third part of the second plea in law is therefore also unfounded.

d) Interim conclusion

136. In summary, the second plea in law therefore has no prospect of success.

3. The principle of subsidiarity (third plea in law)

137. The third and last plea in law raised by Poland is based on the principle of subsidiarity, which is enshrined in the second sentence of Article 5(1) TEU in conjunction with Article 5(3) TEU.

74 — 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.

75 — For example, EU environmental protection legislation on automobiles has 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.

76 — According to the application, Poland is one of the Member States in which menthol cigarettes represent a relatively high share in terms of both production and consumption. In the event of a prohibition on menthol cigarettes, Poland assumes a decline in sales per tobacco-producing farmer of EUR 400 to EUR 500 per year. In addition, Poland considers a decline in sales for the generally small and medium-sized sales outlets for tobacco products to be likely, without putting a figure on the loss.

138. Under that principle of subsidiarity, 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).

139. Since the Union does not have a general competence to regulate the internal market [77] 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. [78]

140. Compliance with the principle of subsidiarity is subject to legal review by the Courts of the European Union. [79] That review covers two aspects in particular: first, the substantive compatibility of EU measures with the principle of subsidiarity (see section (a) immediately below) and, second, their statement of reasons in the light of the principle of subsidiarity (see section (b) below). Poland addresses both aspects in connection with its third plea in law.

a) Substantive compatibility of the Directive with the principle of subsidiarity

141. First of all, Poland, supported by Romania, alleges that the Union legislature failed to conduct a 'comparative efficiency test' prior to the adoption of the Directive.

142. Poland thus alludes to the two-stage test which 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.

143. Contrary to the view taken by the EU institutions participating in the proceedings, that test is certainly not met whenever the conditions for recourse to Article 114 TFEU as a legal basis for the adoption of internal market harmonisation measures are satisfied. It is true that many of the considerations arising in connection with Article 5(3) TEU are similar to those that are also relevant in connection with Article 114 TFEU. However, they are not fully congruent.

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

78 — 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).

79 — See, in particular, judgments in *Germany* v *Parliament and Council* (C-233/94, EU:C:1997:231, paragraphs 23 to 29); *Netherlands* v *Parliament and Council* (C-377/98, EU:C:2001:523, paragraphs 30 to 34); *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).

144. Article 114 TFEU sets out whether the Union actually has a competence to adopt internal market harmonisation measures. By contrast, the principle of subsidiarity under Article 5(3) TEU determines whether and in what manner the Union exercises that competence in a specific case. In other words, the *distribution of competences* between the Union and the Member States is based on Article 114 TFEU, while the principle of subsidiarity lays down legally binding guidelines for the EU institutions in *using their competences* (Article 5(1) TEU)

145. 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.[80] 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[81] — the prohibition of this specific kind of cigarette cannot be regarded as an autonomous and separate measure ('action') in relation to the prohibition of all tobacco products with characterising flavours.

146. In a case where the Courts of the European Union have to determine whether the substantive requirements of the principle of subsidiarity were complied with in the application of Article 114 TFEU, it should be borne in mind that the exercise of competences by the EU institutions in the adoption of internal market harmonisation measures involves political, economic and social choices in which complex assessments and evaluations have to be undertaken. Scrutiny of these measures is exercised primarily at political level, with the participation of the national parliaments, and for that reason the Treaty of Lisbon introduced a dedicated procedure in Protocol No 2. On the other hand, as I have already explained in connection with the principle of proportionality,[82] such considerations are subject to only limited judicial review.

147. The Court can reasonably review only whether the Union's political institutions have kept within the limits of the discretion conferred on them in the exercise of their competences in the light of the principle of subsidiarity. To that end, it examines whether those institutions were able to rely on an adequate factual basis for their appraisal of the question of subsidiarity in a specific case and whether they committed a manifest error of assessment in this regard.[83]

148. A stricter judicial review of subsidiarity may be necessary where an EU measure exceptionally affects matters of national identity of the Member States (Article 4(2) TEU).[84] In the present case, however, there is absolutely no suggestion of this and the review standard of a manifest error of assessment can therefore be retained.

i) Negative component of the subsidiarity test: action which cannot be sufficiently realised at national level

149. With regard, first, to the negative component of the subsidiarity test, it must be considered whether the objectives of the action to be taken in relation to the manufacture, presentation and sale of tobacco products could have been sufficiently achieved at national level.

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

81 — See above, points 48 to 57 of this Opinion.

82 — See above, points 89 and 90 of this Opinion.

83 — See, to that effect, some of the formulations used in recent case-law; judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraph 54: '…where … the legislature has concluded on the basis of detailed evidence and without committing any error of assessment that the general interests of the European Union could be better served by action at that level') and judgment in *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraph 78, which examines whether the legislature 'could legitimately take the view' that the adoption of certain rules at Union level was necessary).

84 — In this regard it is worth noting the case-law on the principle of proportionality, which applies a more or less strict standard of judicial review depending on the subject area or fundamental right at issue (see, for example, on the one hand, judgment in *Digital Rights Ireland*, C-293/12 and C-594/12, EU:C:2014:238, paragraph 47, and, on the other, judgment in *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 46).

150. In general terms, particular consideration should be given, in connection with this negative component of the subsidiarity test, to the following three aspects.

151. The first aspect is the technical and financial capabilities of the Member States. If some Member States are not actually capable of taking the necessary action to resolve a problem, that is an indication that the negative component of the subsidiarity test is satisfied.

152. Second, it must be ascertained whether national, regional or local features are central to the issue. If so, this tends to suggest that intervention should be at the level of the Member States and that the matter should be addressed by the authorities which have greater proximity and expertise in respect of the action to be taken.

153. Third, it must be examined whether the problem to be resolved has a purely local or regional dimension or whether, on the contrary, it has cross-border dimensions which, by their nature, cannot be effectively addressed at national, regional or local level. The existence of cross-border problems is one of the most important indicators that the negative component of the subsidiarity test is satisfied. [85]

154. The removal of obstacles to cross-border trade in the European internal market, which is the focus of interest in Article 114 TFEU, is a prime example of action which cannot, as a rule, be sufficiently realised at national level. [86] Apart from the highly unlikely case where all the Member States concerned adopt parallel legislation with essentially identical content within a reasonable period of time, action at national, regional or local level very often leads to a patchwork quilt of disparate rules which do not eliminate obstacles to trade, but possibly compound them. [87]

155. In the present case, Poland nevertheless attempts to deny the existence of a problem with a cross-border dimension by referring to the different consumption patterns and different economic structures in the 28 EU Member States. In the view of Poland, as menthol cigarettes achieve comparatively high market shares in just three Member States — Poland, Slovakia and Finland — health-related action in respect of the use of menthol as a characterising flavour in tobacco products can be taken at national level.

156. That argument is not valid for two reasons.

157. First, Poland misunderstands the actual objective of the action taken. Neither the Directive in general nor the contested prohibition on menthol cigarettes in particular is purely health-related. Rather, the aim is to remove obstacles to trade for tobacco products whilst at the same time ensuring a high level of health protection. As has already been mentioned, [88] 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. However, where a directive simultaneously pursues two objectives which are interdependent, as is the case here, those objectives cannot be considered separately in the subsidiarity test, but must be assessed together. [89]

85 — See, to that effect, the 'Overall approach to the application by the Council of the subsidiarity principle', adopted by the European Council at its meeting in Edinburgh on 11 and 12 December 1992 (see the Conclusions of the Presidency, Part A, Annex 1, Section II, point ii, published in Bull. EC No 12-1992), which refers to 'transnational aspects'.

86 — Judgment in *Netherlands* v *Parliament and Council* (C-377/98, EU:C:2001:523, paragraph 32).

87 — See also, to that effect, judgments in *British American Tobacco* (*Investments*) *and Imperial Tobacco* (C-491/01, EU:C:2002:741, paragraphs 182 and 183) and *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraphs 106 and 107).

88 — See above, point 40 of this Opinion.

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

158. Second, 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. In very rare cases, the market situation before the adoption of an internal market harmonisation measure will be the same in all the Member States. This is also immaterial. 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.

159. In the present case it is clear that the market for tobacco products is characterised by lively cross-border trade,[90] 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.[91]

160. Under these circumstances, the Union legislature cannot be accused of having committed a manifest error of assessment 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.[92]

ii) Positive component of the subsidiarity test: action which can, by reason of its scale and effects, be better achieved at Union level

161. With regard to the positive component of the subsidiarity test, it must be examined whether the objectives of the measures to be taken in respect of the manufacture, presentation and sale of tobacco products could, by reason of the scale or effects of the proposed action, be better achieved at Union level.

162. This second stage of the subsidiarity test thus considers the question whether action by the EU institutions offers *added value* in the sense that the general interests of the European Union can be better served by action at that level than by action taken at national level.[93]

163. Ultimately, the EU's political institutions are required, before adopting any measure not falling within the exclusive competence of the Union, to limit their action to regulating important matters in the common European interest.

164. There is a strong presumption of added value for action at Union level where the EU measure in question has the aim of resolving problems with a cross-border dimension, in particular eliminating obstacles to trade and thus improving the functioning of the European internal market (Article 26(1) TFEU). However, an internal market dimension cannot automatically lead to the conclusion that the positive component of the subsidiarity test must be considered to be satisfied. Otherwise the principle of subsidiarity in internal market matters would be deprived of much of its practical effectiveness.

165. Rather, it is necessary to assess both quantitatively and qualitatively whether action by the EU institutions has added value in the abovementioned sense, in particular in internal market matters. From a quantitative point of view, the added value of intervention at Union level is all the more evident the more Union citizens or market operators are affected and the larger the relevant trade volumes in question. From a qualitative point of view, the economic, social and political importance of the subject to be regulated must be assessed in the light of the Union's objectives as laid down in

90 — 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).

91 — See above, points 59 and 62 of this Opinion.

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

93 — Judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraph 54).

Article 3 TEU and taking into account the fundamental values on which the Union is founded under Article 2 TEU. In addition, the novelty of a product for which, in the absence of uniform legal conditions, there is not yet any market whatsoever, may militate in favour of intervention at Union level. [94]

166. All these considerations must always be applied with a view to the general interest of the European Union; the situation of any particular Member State taken individually is normally not relevant, contrary to the view taken by Poland. [95] An exception may apply where the action envisaged by the EU institutions affects the national identity of a Member State (Article 4(2) TEU) or its fundamental interests. There is no evidence of this in the present case, however. It would also be extremely surprising if the problems relating to the manufacture, sale and consumption of menthol cigarettes were seriously to be regarded as a matter of national interest.

167. Aside from this, it cannot be denied that the manufacture, presentation and sale of tobacco and related products concern a market with a substantial trade volume and affects the lives of millions of Union citizens every day. Furthermore, from a qualitative point of view the trade in tobacco products is an important issue going beyond national boundaries, not least because of the health risks associated with smoking, with the result that a common European interest undoubtedly exists.

168. Under these circumstances, the Union legislature cannot be accused of having committed a manifest error of assessment 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. [96]

169. This impression is reinforced if consideration is also given to the WHO Framework Convention on Tobacco Control. As a Party to that Convention, the Union was required, within the scope of its competences, to contribute to the implementation of that Convention, taking into account the recommendations made in the Guidelines on Implementation of Articles 9 and 10 of that Convention. [97] Such an international obligation must be borne in mind in connection with the question whether and in what manner the EU institutions exercise the competences conferred on them.

170. For the sake of completeness, it should also be mentioned that even where a common European interest and certain international obligations exist, not all aspects of the manufacture, presentation and sale of tobacco or related products necessarily require regulation in EU law at the present time. For example, the implementation of the adopted rules, the monitoring of compliance with those rules on the ground and the imposition of any penalties are matters which the Union can, as a rule, consider to be resolved better by the national authorities in the light of specific national, regional and local features. Accordingly, the contested directive leaves such duties as far as possible to the Member States.

94 — See, in this regard, my Opinion in *Inuit Tapiriit Kanatami and Others* v *Commission* (C-398/13 P, EU:C:2015:190, point 52).

95 — See again judgment in *Estonia* v *Parliament and Council* (C-508/13, EU:C:2015:403, paragraphs 53 and 54).

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

97 — See above, points 78 and 79 of this Opinion.

171. In summary, as in the case of its predecessor, no substantive infringement of the principle of subsidiarity can therefore be established in respect of the Directive.[98] This conclusion is not called into question by the fact that during the legislative procedure a number of national parliaments filed reasoned opinions in accordance with Article 6 of Protocol No 2.[99] First of all, there were an insufficient number of objections regarding subsidiarity in those opinions to trigger the 'yellow card' procedure under Article 7(2) of Protocol No 2 and, second, such objections are based less on a legal assessment than on a political assessment of the draft legislation submitted by the Commission.

b) Adequate statement of reasons for the Directive in the light of the principle of subsidiarity

172. Second, Poland alleges that insufficient account was taken of subsidiarity requirements in the preamble to the Directive. Ultimately, Poland thus claims that the Directive is vitiated by a defective statement of reasons.

173. 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.[100]

174. 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.

175. Poland complains in this regard that the preamble to the Directive includes just one recital relating to the principle of subsidiarity, namely recital 60, which indeed just adopts a standard wording.

176. Recital 60 does indeed merely contain 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'.

177. 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.

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

99 — On the basis of the Commission's draft directive reasoned opinions were filed by the Parliaments of Bulgaria, the Czech Republic, Denmark, Greece, Italy, Portugal, Romania and Sweden. However, hardly any of the reasoned opinions contained substantive statements regarding the contested prohibition on menthol cigarettes.

100 — 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).

178. 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.

179. However, an empty formula like that in the present case contained in recital 60 of the Directive does not necessarily lead to the annulment 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. [101]

180. 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 of 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. As has already been mentioned, [102] 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.

181. 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 body of legal rules governing the matter in question. [103] 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. [104]

182. 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 [105] and, second, on the comprehensive preparatory work by the Commission staff in connection with the impact assessment [106] 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.

183. 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.

101 — 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).

102 — See above, point 143 of this Opinion.

103 — 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).

104 — See, to this 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).

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

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

184. In addition, it cannot be inferred from Article 5 of Protocol No 2 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.

185. 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.

186. 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.

c) Interim conclusion

187. All in all, an infringement of the principle of subsidiarity cannot therefore be established from either a substantive or a procedural point of view. Consequently, Poland's third plea in law is also unsuccessful.

188. 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.

C – *Summary*

189. As none of the pleas in law raised by Poland — in some cases supported by Romania — is well founded, the action must be dismissed in its entirety, in part as inadmissible[107] and in part as unfounded.

V – **Costs**

190. Under Article 138(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since, according to my proposed solution, Poland has been unsuccessful and the Parliament and the Council have applied for costs, Poland must be ordered to pay the costs of the proceedings.

191. On the other hand, Ireland, France, Romania, the United Kingdom and the Commission, as interveners, must each bear their own costs in accordance with Article 140(1) of the Rules of Procedure.

107 — With regard to the inadmissible parts of this action, see above, points 24 to 30 and 34 of this Opinion.

VI – **Conclusion**

192. In the light of the foregoing observations, I propose that the Court should:

(1) dismiss the action;

(2) order Ireland, the French Republic, Romania, the United Kingdom of Great Britain and Northern Ireland and the European Commission each to bear their own costs, and that the Republic of Poland pay the remainder of the costs of the proceedings.