OPINION OF ADVOCATE GENERAL
SAUGMANDSGAARD ØE
delivered on 12 April 2018 (1)

Case C-151/17

Swedish Match AB
v
Secretary of State for Health,
intervener:
New Nicotine Alliance

(Request for a preliminary ruling from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) (United Kingdom))

(Reference for a preliminary ruling — Approximation of laws — Manufacture, presentation and sale of tobacco products — Directive 2014/40/EU — Article 1(c) — Article 17 — Prohibition on the placing on the market of tobacco for oral use — Request for an assessment of validity — Principle of proportionality — Precautionary principle)

I. Introduction

1. By its request for a preliminary ruling, the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) (United Kingdom) asks the Court to rule on the validity of Article 1(c) and Article 17 of Directive 2014/40/EU. (2) This request was made in the course of proceedings between Swedish Match AB and the Secretary of State for Health (United Kingdom), with the intervention of the New Nicotine Alliance ('the NNA'), concerning the validity of a national legislation transposing those provisions.

2. Under Article 1(c) and Article 17 of Directive 2014/40, Member States are to prohibit the placing on the market of tobacco for oral use. Those provisions therefore maintain an obligation which has been binding upon the Member States since 1992 (3) and had already been renewed in Article 8 of Directive 2001/37/EC, (4) the instrument which preceded Directive 2014/40. However, the Kingdom of Sweden is exempt from that obligation, under a provision in the Act of Accession of that country to the European Union, (5) on account of the traditional use in Sweden of a tobacco product for oral use known as 'snus'.

3. In the judgments in *Swedish Match* (6) and *Arnold André*, (7) the Court has already examined the validity of Article 8 of Directive 2001/37 and found that there was no factor of such a kind as to affect that validity. In the context of the present case, the Court is, in essence, asked to determine whether the validity

of provisions of similar scope laid down in Directive 2014/40 must now be called into question in the light of developments in scientific knowledge and the regulatory framework applicable to tobacco and related products since then.

4. The question referred by the national court raises a number of causes of possible invalidity of Article 1(c) and Article 17 of Directive 2014/40. As requested by the Court, this Opinion will, however, be limited to the analysis of that question in so far as it seeks to ascertain whether those provisions are contrary to the principle of proportionality. Some of the considerations put forward in this connection will, nevertheless, also be relevant for the purposes of examining that question in so far as it concerns the compatibility of those provisions with the principle of non-discrimination.

5. I must state from the outset that this analysis will not reveal any factor of such a kind as to render the provisions at issue invalid.

II. Legal framework

6. On 19 December 2012, the European Commission adopted a proposal for a directive to revise Directive 2001/37 ('the Commission proposal'), (8) accompanied by an impact assessment summarising the results of a detailed study carried out by the Commission services following a public consultation of interested parties ('the impact assessment'). (9) In that impact assessment, the Commission examined the various options available to the legislature regarding, inter alia, the regulation of tobacco for oral use and assessed the potential health and socio-economic impacts of those options. To that end, it took account of scientific studies available at that time and, in particular, advice provided by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2008 at the request of the Commission ('the SCENIHR opinion'). (10)

7. The Commission proposal and the impact assessment served as a basis for the adoption of Directive 2014/40, recital 32 of which is worded as follows:

'Council Directive 89/622/EEC [(11)] prohibited the sale in the Member States of certain types of tobacco for oral use. Directive [2001/37] reaffirmed that prohibition. Article 151 of the Act of Accession ... grants Sweden a derogation from the prohibition. The prohibition of the sale of tobacco for oral use should be maintained in order to prevent the introduction in the Union (apart from Sweden) of a product that is addictive and has adverse health effects. For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use.'

8. Article 1(c) of that directive provides:

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

...

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

...'

9. In accordance with Article 2(8) of that directive, 'tobacco for oral use' designates 'all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets'.

10. Under Article 17 of the same directive, ‘Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the [Act of Accession]’.

11. Under Article 151(1) of the Act of Accession, ‘the Acts listed in Annex XV to this Act shall apply in respect of the new Member States under the conditions laid down in that Annex’. That annex provides, inter alia, that the prohibition on the placing on the market of tobacco for oral use does not apply to the Kingdom of Sweden, with the exception of the prohibition on marketing that product in a form resembling a food product.

12. In the United Kingdom, Article 1(c) and Article 17 of Directive 2014/40 have been implemented by Regulation 17 of the Tobacco and Related Products Regulations 2016 (‘the Tobacco Regulations’), which provides that ‘no person may produce or supply tobacco for oral use’.

III. The dispute in the main proceedings, the question referred for a preliminary ruling and the procedure before the Court

13. Swedish Match is a public limited liability company established in Sweden which primarily markets smokeless tobacco products and, in particular, snus. Snus is consumed orally and is made from pasteurised ground tobacco and food-approved additives. In Sweden, the production of snus is subject to the regulations which apply to food products. The maximum levels of undesirable substances in that product have been strictly specified by the Swedish National Food Agency.

14. Swedish Match has brought an action before the referring court challenging Regulation 17 of the Tobacco Regulations. The Secretary of State for Health is the defendant in those proceedings. The NNA, an association whose social objective is to promote public health by reducing the harmful effects of tobacco, was granted leave to intervene in those proceedings.

15. In the context of its action, Swedish Match claims that the total prohibition on the placing on the market of tobacco for oral use in the United Kingdom, imposed by Regulation 17 of the Tobacco Regulations, is not compatible with EU law. According to Swedish Match, the provisions which Regulation 17 aims to transpose, namely Article 1(c) and Article 17 of Directive 2014/40, are themselves contrary to higher-ranking EU law.

16. Swedish Match submits that the reasoning adopted by the Court in the judgment in *Swedish Match*, (12) in which it found no factor which could cast doubt on the validity of the prohibition on the placing on the market of tobacco for oral use provided for in Article 8 of Directive 2001/37, is no longer valid given the developments since then regarding the applicable legislation, the scientific data available and the characteristics of the market in tobacco products.

17. That company submits, more specifically, that Article 1(c) and Article 17 of Directive 2014/40 are not compatible with the principles of non-discrimination, proportionality and subsidiarity, the obligation to state reasons provided for in Article 296 TFEU and the free movement of goods guaranteed by Articles 34 and 35 TFEU.

18. The NNA contends, in the course of its intervention, that the prohibition on the placing on the market of tobacco for oral use is not only disproportionate, but also contrary to the rights to respect for human dignity and private and family life, enshrined in Articles 1 and 7 of the Charter of Fundamental Rights of the European Union (‘the Charter’) respectively, and the right of access to medical treatment provided for in Article 35 of the Charter.

19. In those circumstances, the referring court decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

‘Are [Article 1(c) and Article 17] of Directive [2014/40] invalid by reason of:

i. breach of the EU general principle of non-discrimination;

ii. breach of the EU general principle of proportionality;

iii. breach of Article 5(3) TEU and the EU principle of subsidiarity;

iv. breach of Article 296(2) of the Treaty [on] the Functioning of the European Union ('TFEU');

v. breach of Articles 34 and 35 TFEU; and

vi. breach of Articles 1, 7 and 35 of the [Charter]?'

20. Swedish Match, the NNA, the Hungarian and Finnish Governments, the European Parliament, the Council of the European Union and the Commission lodged written observations before the Court.

21. Swedish Match, the NNA, the United Kingdom and Norwegian Governments, the Parliament, the Council and the Commission appeared at the hearing held on 25 January 2018.

IV. Analysis

A. Preliminary remarks

22. Like other provisions of that directive, the prohibition on the placing on the market of tobacco for oral use laid down in Article 1(c) and Article 17 of Directive 2014/40 has a twofold objective of facilitating the smooth functioning of the internal market while taking as a base a high level of protection of human health, especially for young people. (13)

23. That prohibition was maintained in that directive in order to avoid reintroducing the fragmentation of the internal market that existed before such a measure was introduced at EU level in 1992. (14) A number of Member States had therefore prohibited the placing on the market of tobacco for oral use or were in the process of doing so, with the result that a harmonisation of national laws was considered necessary to prevent obstacles to trade which were likely to result from a heterogeneous development of those laws. (15)

24. The legislature considered, as it had already in 1992 and in 2001, that, in order to also achieve the abovementioned health protection objective, such harmonisation had to be carried out by prohibiting that product. As is stated in recital 32 of Directive 2014/40, the aim of that prohibition is to prevent access to addictive and harmful tobacco products that are produced for the mass market.

25. That recital, read in the light of the Commission proposal and the impact assessment, indicates that the legislature emphasised the *intrinsic harmfulness* of tobacco for oral use and the need to avoid a new form of nicotine addiction developing in the European Union, particularly among young people (*initiation effect*). Maintaining the prohibition on the placing on the market of tobacco for oral use was deemed even more necessary since that addiction might increase the risk of subsequent use of tobacco for smoking (*gateway effect*). Moreover, lifting that prohibition might hinder the efforts of smokers to stop by allowing them to consume tobacco unnoticed in smoke-free environments. Those smokers whose cessation efforts have not been successful therefore risk a *dual use* of tobacco for smoking and tobacco for oral use. By contrast, it is not established that tobacco for oral use, as an alternative to tobacco for smoking, is an effective cessation aid (*substitution effect*). The legislature concluded that, overall, maintaining that prohibition is beneficial for public health. (16)

26. As is apparent from the order for reference, Swedish Match and the NNA dispute whether the prohibition at issue is compatible with the principle of proportionality, noting that the *relative harm* of tobacco for oral use is lower compared with other tobacco products. According to those parties, lifting that prohibition would allow tobacco products for smoking to be replaced by other less harmful tobacco

products (*substitution effect*). A large number of passive smokers would be spared as a result. Moreover, there is no evidence that the consumption of tobacco for oral use has a *gateway effect* to the consumption of tobacco for smoking. Therefore, although tobacco for oral use is not entirely without harmful effects, that prohibition would be detrimental to public health overall. In addition, Swedish Match and the NNA submit that the prohibition on the placing on the market of tobacco for oral use is not consistent with the treatment of other products covered by Directive 2014/40.

27. These different approaches reflect two distinct strands of tobacco control. Whereas the prohibition on the placing on the market of tobacco for oral use is part of a strategy to *reduce the supply and consumption* of tobacco products, the lifting of that prohibition advocated by Swedish Match and the NNA forms part of a strategy to *reduce the harmful effects* of tobacco.

28. In the present case, however, the Court is not required to verify whether the measure adopted by the legislature was 'the only one or the best one possible', but only whether it was 'manifestly inappropriate'. (17) The EU legislature has a broad discretion in areas which involve political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. The Court has already held that those areas include the regulation of tobacco products, (18) including tobacco for oral use. (19)

29. The judicial review of compliance with the principle of proportionality is thus attenuated with regard to its three constituent elements. In this regard, I would point out that, according to settled case-law, that principle requires, in the first place, that acts of the EU institutions be appropriate for attaining the legitimate objectives they pursue ('suitability test'). In the second place, those acts cannot exceed the limits of what is necessary for that purpose: when there is a choice between several appropriate measures, the least onerous must be favoured ('necessity test'). In the third place, the disadvantages caused must not be disproportionate to the aims pursued ('test of proportionality in the strict sense'). (20)

B. Suitability test

30. From the perspective of the suitability test, an act adopted in a field in which the EU legislature has a broad legislative power may be declared invalid only where it is manifestly inappropriate for attaining the objectives pursued. However, even where it has such a power, the legislature remains obliged to base its choice on objective criteria appropriate to the aims pursued, taking into account all the facts and the technical and scientific data available at the time of adoption of the act in question. (21)

31. In the judgments in *Swedish Match* (22) and *Arnold André*, (23) the Court has already held that the prohibition on the placing on the market of tobacco for oral use provided for in Article 8 of Directive 2001/37 was not manifestly inappropriate to pursue its twofold objective.

32. In that regard, the Court emphasised the *intrinsic harmfulness* of tobacco for oral use. In the first place, tobacco for oral use contains nicotine, which causes addiction and whose toxicity is not disputed. In the second place, the Court noted that the consumption of tobacco for oral use is accompanied by harmful effects such as an increased risk of oral cancer, whilst acknowledging that scientific controversy still existed on that point. In addition, it had not been shown, at the time of adoption of Directive 2001/37, that the harmful effects were less than those associated with the consumption of other tobacco products. (24)

33. The Court also examined the effects that lifting the prohibition in question might have on *consumption patterns*. It noted that that prohibition had been introduced to cope with the real danger that tobacco for oral use would be used by young people. Moreover, the possible existence of a substitution effect has not been established, and is still the subject of debate within the scientific community. (25)

34. In my view, neither the developments in scientific knowledge nor the changes in the legal framework applicable to tobacco and related products since those judgments were delivered call for a different conclusion with regard to the suitability of Article 1(c) and Article 17 of Directive 2014/40 to achieve their twofold objective.

1. The argument alleging the existence of scientific developments

(a) Preliminary clarifications regarding the application of the precautionary principle

35. Like Directive 2001/37, Directive 2014/40 was adopted against a background of great uncertainty and controversy surrounding the nature and the extent of both the harmful effects of tobacco for oral use and the effects that its placing on the market throughout the European Union would have on consumption patterns.

36. The Commission acknowledged in the impact assessment that, although certain harmful effects linked to the consumption of tobacco for oral use were considered to be established, the existence and the extent of other harmful effects remained uncertain. Likewise, because they will happen in the future, the most likely effects that lifting the prohibition on the placing on the market of tobacco for oral use would have on consumer behaviour in Member States other than Sweden could not be predicted with certainty. (26)

37. Moreover, the assessments made in the impact assessment, on the basis of various scientific works, and in particular the SCENIHR opinion, regarding those potential effects, were not unanimous. Swedish Match and the NNA have drawn different conclusions from some parts of that opinion and from some of the articles cited therein. Those parts refer to a scientific report in particular, annexed to the written observations of Swedish Match, produced on behalf of Swedish Match in order to critically evaluate the scientific basis for Directive 2014/40. They also mention a number of studies which postdate the impact assessment, or even the adoption of that directive, which, they contend, contradict the assessments made in the impact assessment.

38. In those circumstances, the suitability of Article 1(c) and Article 17 of Directive 2014/40 to protect human health must be examined in the light of the precautionary principle, as enshrined in Article 191(2) TFEU and clarified in the case-law. Under that principle, ‘where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent’. (27) As will be made clear hereinafter, the uncertainties justifying the application of that principle may concern both the harmful effects of a product and the effects the placing on the market of that product may have on consumption patterns. (28)

39. The validity of precautionary measures is dependent on a risk assessment which is as complete as possible being conducted beforehand. Thus, purely hypothetical considerations relating to the existence of a risk, founded on mere suppositions which are not scientifically verified, do not justify the adoption of such measures. (29) This is permitted only ‘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 should the risk materialise’. (30)

40. Observance of the obligation to base every precautionary measure on a risk assessment of that kind must be determined in the light of the broad discretion which the EU legislature enjoys in areas which involve, on its part, complex assessments. (31) That discretion extends not only to the nature and scope of the measures to be taken but also to the assessment of scientific facts carried out with a view to determining those measures. (32) That is the case since ‘the [EU] judicature cannot substitute its assessment of the scientific and technical facts for that of the legislature on which the Treaty has placed that task’. (33)

41. Where the risk assessment still leaves scientific uncertainties, it is then for the EU legislature to determine the level of the risk deemed unacceptable for the population and to draw up appropriate precautionary measures. This task of risk management, after those risks have been assessed, also presupposes a wide discretion to adopt political choices concerning the level of protection to be achieved and the measures implemented to that end. (34)

42. It is necessary to examine, in the light of those considerations, whether the legislature adopted Article 1(c) and Article 17 of Directive 2014/40 without exceeding the limits of its discretion with regard to the assessment of the risks related to the consumption of tobacco for oral use and the consequent choice regarding the nature and scope of the measure at issue.

(b) The finding that tobacco for oral use is addictive and harmful

43. According to recital 32 of Directive 2014/40, tobacco for oral use 'is addictive and has adverse health effects'. That finding is based on the assessment, in the impact assessment, that the consumption of tobacco for oral use leads to *established* risks of nicotine addiction and certain adverse effects, such as pregnancy complications, and, moreover, is accompanied by the *unknown* risks of other harmful effects. (35) In that regard, that assessment notes the scientific uncertainties concerning the increased risk of pancreatic, oral and oesophageal cancer and of death from myocardial infarction. (36)

44. Swedish Match and the NNA submit, in the first place, that the risks of harmful effects linked to the consumption of tobacco for oral use are lower than those associated with the consumption of tobacco for smoking.

45. In that connection, I note that the impact assessment does acknowledge that tobacco for oral use is less harmful than tobacco for smoking. (37) However, that consideration does not call into question the conclusion underlying the legislative choice to maintain the prohibition at issue, in accordance with which, in absolute terms, tobacco for oral use is harmful to health.

46. In the second place, Swedish Match and the NNA question the finding, in the impact assessment, that the consumption of tobacco for oral use may increase, inter alia, the risk of developing certain cancers. They take the view that a number of studies, including systematic reviews and meta-analyses of individual studies which enable a more reliable understanding of those risks than the works included in the impact assessment, (38) contradict that finding.

47. In my view, that line of argument does not establish that the legislature exceeded the bounds of its discretion in finding that scientific uncertainties remained as to the existence and the extent of those risks and that those uncertainties did not prevent the legislature from taking action with a view to preventing those risks. (39) The risks in question have been evaluated on the basis of an overall assessment of the scientific data available. In the light of that evaluation, the legislature, in the exercise of its discretion, considered that, although they were surrounded by scientific uncertainties, those risks were sufficiently documented.

48. As the Commission stated in the impact assessment, the fact that some of the data on the basis of which it concluded that tobacco for oral use is harmful are challenged by studies indicating the contrary is not sufficient to call into question that overall conclusion. (40) The discretion enjoyed by the legislature to evaluate the risks extends, in my view, to the evaluation of the reliability and the relevance of the available studies, the interpretation of the results of those studies and the determination of the relative weight to be assigned to each relevant study.

49. Moreover, where Swedish Match and the NNA invoke a number of studies postdating the adoption of Directive 2014/40 which, they contend, rule out any association between the consumption of tobacco for oral use and the increased risks of oral and pancreatic cancers, I do not think that there is any need to establish whether and, if so, to what extent, those studies must be taken into consideration when examining the validity of the provisions at issue. (41) It is sufficient to state that, in any event, on the one hand, it has not been established that the conclusions that Swedish Match and the NNA draw from those studies would achieve a consensus within the scientific community and that the uncertainties taken into account by the legislature would therefore be resolved. On the other hand, it is on account of not only those individual risks, but all of the risks linked to the effects of tobacco for oral use on health and consumption patterns that the legislature chose to maintain the prohibition regarding those products.

50. In the light of those considerations, the legislature did not exceed the limits of its discretion in finding that tobacco for oral use is addictive and harmful to health in so far as it increases the risks of certain harmful effects and may, moreover, increase the risks of other harmful effects.

(c) The assessment of the effects that lifting the prohibition at issue might have on consumption patterns

51. In the impact assessment, the Commission noted that, although there would be an improvement in the health of individuals who replace tobacco for smoking entirely with tobacco for oral use, the overall impact on public health caused by lifting the prohibition on the placing on the market of tobacco for oral use would depend on how consumers would react to that lifting at EU level. Only by observing those reactions on the market could it be ascertained whether a possible substitution effect would prevail over the possible effects of initiation, a gateway and dual use, or vice versa, given that all of those effects may occur simultaneously. (42)

52. The Commission nevertheless examined in turn, and in detail, the arguments regarding the likelihood of each of those effects on the basis of an overall assessment of the scientific data collected in the countries where tobacco for oral use may be marketed. (43) It concluded, in essence, that those data did not allow reliable conclusions to be drawn as to the effectiveness of tobacco for oral use in smoking cessation. Moreover, those data substantiated the non-negligible risks of the effects of initiation and of dual use and were unable to affirm or exclude the gateway effect risk. (44) On the basis of that assessment, the Commission and, subsequently, the legislature considered that lifting the prohibition at issue could have negative effects on consumption patterns which would not be outweighed by a possible substitution effect.

53. Swedish Match and the NNA dispute that assessment in relation to the likelihood of substitution and gateway effects as well as the overall impact that lifting the prohibition would have on public health. (45) In essence, Swedish Match and the NNA focus on the data and arguments which advocate the effectiveness of tobacco for oral use as a cessation aid and the absence of any gateway effect. However, they do not deny that other data and arguments, put forward by the Commission on the basis of the SCENIHR opinion in particular, support the opposite conclusions.

54. It is not for the Court to rule on the correctness of those separate arguments and thereby to substitute its assessment of the relevant factual data for that of the legislature. It is sufficient to state that the arguments put forward by Swedish Match and the NNA demonstrate, at most, that scientific uncertainties remain with regard to the nature and extent of the effects that lifting the prohibition on the placing on the market of tobacco for oral use throughout the European Union would have on consumer behaviour.

55. Since the risks which might result from lifting the prohibition on account of its effects on consumption patterns were duly identified and assessed prior to the adoption of Directive 2014/40, such uncertainties did not prevent the legislature from adopting precautionary measures even though the reality and seriousness of those risks had not been fully demonstrated. (46)

56. In that regard, I draw on the judgment in *Pillbox 38*, (47) in which the Court found that there were no conclusive scientific data concerning, in particular, the effectiveness of electronic cigarettes as a method for ceasing smoking and the existence of a 'gateway' effect to smoking linked to the use of that product. (48) In those circumstances, the Court considered that the EU legislature had to act in conformity with the requirements stemming from the precautionary principle. Therefore, the provision of Directive 2014/40 concerning the conditions restricting the placing of electronic cigarettes on the market (49) was not contrary to the principle of proportionality. (50)

57. Accordingly, the EU legislature did not exceed the limits of its discretion in concluding, on the basis of the impact assessment, that lifting the prohibition on the placing on the market of tobacco for oral use could result in an overall increase in the harmful effects of tobacco within the European Union on account of its effects on consumption patterns.

(d) The choice regarding the nature and scope of the measure at issue

58. In the light of its assessment of the risks to public health which might result from lifting the prohibition at issue, the legislature decided to maintain that prohibition in Directive 2014/40. In my view, that choice is not manifestly inappropriate in pursuit of the twofold objective of that directive.

59. As I pointed out above, in the absence of certainty as to the nature and the extent of the health risks of certain products, determining the level of risk deemed unacceptable for the population is part of a political, economic and social choice which is within the discretion of the legislature, guided by the precautionary principle. (51)

60. The legislature was required to exercise that discretion, taking account of the need, as required by a number of provisions of primary law, (52) to ensure a high level of health protection. In that regard, the Court added that Directive 2014/40 is aimed at ensuring such a level of health protection for the population as a whole, and therefore its ability to guarantee that aim cannot be assessed solely in relation to a single category of consumers. (53)

61. In the present case, the legislature has weighed up the — admittedly uncertain — risk that lifting the prohibition at issue would have an overall negative effect on public health, on the one hand, and the — also uncertain — risk that maintaining that prohibition would prevent current smokers from benefiting from an alternative which is less harmful than tobacco for smoking, on the other.

62. Having taken the view that the first of those risks outweighed the second, the legislature considered that preference had to be given to one intermediate objective (of avoiding the creation of a new source of nicotine addiction, particularly among young people, which might also have encouraged a subsequent shift towards the consumption of tobacco for smoking) over another (of making a potential cessation aid available) with a view to achieving the ultimate objective of protecting public health.

63. There is little doubt in my mind that the legislature therefore acted in a manner consistent with the precautionary principle. The discretion it has for the purposes of determining the level of the risk deemed unacceptable for the population extends, if necessary, to a weighing up of the prevention of a number of health risks where those risks cannot be avoided simultaneously. (54)

64. The line of argument put forward by Swedish Match, that the legislature infringed the principle of proportionality by making the lifting of the prohibition on the placing on the market of tobacco for oral use conditional upon demonstrating that the product was harmless, although such a standard is not required for any other product falling within the scope of Directive 2014/40, must also be rejected.

65. That line of argument is divided into two parts. First, Swedish Match complains that the EU legislature maintained that prohibition on the ground that ‘zero risk’ had not been established with regard to the consumption of tobacco for oral use, although a criterion of that kind is disproportionate in accordance with the case-law. Secondly, Swedish Match submits, in essence, that the legislature did not pursue the objective of that directive in a consistent and systematic way. I am not convinced by either of these lines of argument.

66. The first, in my view, is based on a misunderstanding of both the case-law and the grounds on which the EU legislature relied.

67. The legislature is entitled to adopt measures that are intended to prevent health risks provided that those risks have been sufficiently documented following a scientific assessment. (55) However, the case-law does not require that the results of an assessment of that kind make it possible to estimate the actual nature of the risks with a minimum predefined threshold of certainty. (56) Nor has the Court set such a threshold regarding the degree of probability of the risks becoming a reality or the gravity of that reality that must be reached in order to adopt a precautionary measure. (57)

68. However, I have already established that the aim of Article 1(c) and Article 17 of Directive 2014/40 is to prevent specific, established health risks as well as other risks — linked to both its direct impact on health and the consequences that lifting that prohibition might have on consumption patterns — which are not purely hypothetical. Those provisions were therefore adopted not on the ground that the harmless nature of tobacco for oral use had not been proven, but that the consumption of that product entails risks of harmful effects which have been demonstrated or, at least, duly assessed.

69. The second line of argument invoked by Swedish Match overlaps the argument which is the subject of the following section.

2. The argument alleging the existence of changes in the legislative context

70. By their arguments seeking to establish that the prohibition on the placing on the market of tobacco for oral use provided for in Directive 2014/40 is manifestly inappropriate in the light of changes in the legal framework since the judgments in *Swedish Match* (58) and *Arnold André*, (59) Swedish Match and the NNA essentially challenge the appropriateness of that measure to attain the objective it pursues in a consistent and systematic way.

71. They submit that Directive 2014/40 does not prohibit the placing on the market of any other tobacco product (60) and that, in particular, tobacco for smoking and chewing tobacco or nasal tobacco are more harmful than tobacco for oral use. Moreover, that directive introduced new provisions which govern novel tobacco products and electronic cigarettes specifically, but, nevertheless, do not prohibit them. However, recital 34 of that directive acknowledges that all tobacco products are harmful and the Court has demonstrated the potential health risks of electronic cigarettes in the judgment in *Pillbox 38*. (61) That line of argument is largely interwoven with the argument put forward by Swedish Match and the NNA disputing whether the prohibition at issue is compatible with the principle of non-discrimination.

72. In this regard, I would point out that an EU measure is appropriate for the purpose of attaining the desired objective only if it genuinely reflects a concern to attain it in a consistent and systematic manner. (62) Moreover, that requirement corresponds with the requirement that the criteria on which the EU legislature relies must be objective. (63) In the present case, Article 1(c) and Article 17 of Directive 2014/40 satisfy that condition. Neither the other tobacco products nor electronic cigarettes are in a comparable situation to tobacco for oral use; the difference in treatment therefore follows from objective and non-discriminatory criteria.

73. As regards, in the first place, the difference in treatment between tobacco for oral use and *other smokeless tobacco products*, such as chewing tobacco or nasal tobacco, the Court has already held that that difference, as introduced in 1992 and maintained by Directive 2001/37, was not discriminatory. It was the result of objective circumstances relating to the novelty on the internal market at the time of the products affected by the prohibition, their attraction for young people, and the existence of national prohibitive measures in certain Member States. (64) There is nothing in the file to suggest that that is now no longer the case. Moreover, in the impact assessment, the Commission noted that, unlike tobacco for oral use, other smokeless tobacco products represent only niche markets which have limited potential for expansion on account of, inter alia, their costly, and in part artisanal, production methods. (65) As can be seen from recital 32 of Directive 2014/40, the EU legislature did not, therefore, deem it necessary to prohibit the placing on the market of those products.

74. In the second place, with regard to the alleged inconsistency with the treatment of *tobacco for smoking*, I note that, unlike tobacco for smoking, tobacco for oral use was relatively new to the markets of the Member States (with the exception of Sweden) at the time when the prohibition on the placing on the market of that product was introduced. Therefore, that prohibition made it possible to avoid the creation of a new source of addiction, in view of the particular appeal that tobacco for oral use might have had for young people. The impact assessment states that those considerations remained relevant at the time when Directive 2014/40 was adopted. Furthermore, in the impact assessment, the Commission took the view that

the prohibition on tobacco for smoking would most likely lead to the emergence of a black market since the proportion of smokers in the European Union at that time stood at 28%. (66)

75. In the third place, I do not see any inconsistency between the rules applicable to tobacco for oral use and those applicable to the category, introduced by Article 2(14) of Directive 2014/40, of *novel tobacco products*. That category covers all of the products which do not fall under the other categories laid down in that directive and which might be introduced to the EU market after its entry into force. (67) By definition, their effects could not be observed nor, a fortiori, studied at that time. For that reason, that directive requires Member States to introduce a system for notification, by the manufacturers and importers concerned, prior to the placing of novel tobacco products on the market. That notification must be accompanied by, inter alia, studies of their effects on health and on consumption patterns. (68) That system facilitates the assessment of those effects which may, where necessary, lead to the future adoption of prohibitions or restrictions on the marketing of such products. By contrast, although all of the effects of tobacco for oral use could not be assessed and quantified with certainty, those effects were sufficiently identified and substantiated scientifically to justify the prohibition on their being placed on the market.

76. The claim by Swedish Match and the NNA that tobacco for oral use is also a 'novel' product in accordance with recital 34 of Directive 2014/40 and the case-law of the Court is unsuccessful. (69) In my view, tobacco for oral use has been classed as 'novel' only in so far as, had the prohibition not been imposed, it would be a new entrant to the markets of the Member States (with the exception of Sweden). However, unlike 'novel tobacco products' within the meaning of Article 2(14) of that directive, tobacco for oral use is a known and particular product since it has been available in Sweden for a long time and its effects have been the subject of a number of scientific studies.

77. In the fourth place, the argument that the prohibition on the placing on the market of tobacco for oral use is not consistent with the regulation of *electronic cigarettes* must be refuted on the basis of the judgment in *Pillbox 38*. (70) In that judgment, the Court held that, unlike tobacco products, electronic cigarettes, first, do not contain tobacco, secondly, function without combustion and, thirdly, are relatively new products whose risks to human health still need to be clarified. Although the second of those observations supports only the fact that electronic cigarettes and tobacco products for smoking are not comparable, the first and third observations demonstrate the different objective characteristics of electronic cigarettes and all tobacco products, including tobacco for oral use.

78. More generally, I share the view held by Advocate General Geelhoed in his Opinion in *Arnold André*, (71) in accordance with which the EU legislature may, if a number of dangerous products are present on the markets of the Member States, decide which of those products must be prohibited on the basis of an overall assessment — without prejudice to the possibility of prohibiting others if circumstances change. (72)

79. Taking those considerations into account, it may be concluded that the principle of non-discrimination has not been infringed in so far as the tobacco for oral use receives different treatment from that of the other abovementioned products, and that the principle of proportionality been not been infringed by a failure of Directive 2014 to pursue its objectives in a coherent and systematic way.

C. Necessity test

80. The application of the necessity test to an EU legislative act adopted in a field, such as that at issue in the present case, in which the legislature has a broad discretion, involves establishing whether such an act does not manifestly exceed the limits of what is necessary to achieve its objectives. (73)

81. The necessity of the prohibition on the placing on the market of tobacco for oral use provided for in Article 8 of Directive 2001/37 in order to attain its objectives has been confirmed in the judgments in *Swedish Match* (74) and *Arnold André*. (75) According to the Court, all the other measures aimed at making manufacturers subject to technical standards to reduce the harmfulness of the product or at regulating the labelling on the packaging of that product and the conditions of sale, in particular to minors,

would not have the same effect in terms of health protection, inasmuch as they would let a product which is in any event harmful gain a place in the market. (76)

82. That conclusion remains valid in that that prohibition is maintained by Directive 2014/40. As the Commission noted, the addictiveness of tobacco for oral use justifies the adoption of preventive measures in a timely fashion on account of the effects on public health, which are difficult to reverse, and which may arise if that product were to penetrate the market throughout the European Union.

83. That conclusion is all the more compelling since, as is clear from the impact assessment, the other possible measures would not prevent the significant commercial potential of tobacco for oral use, in particular given the introduction of smoke-free environments. (77) Moreover, reversing that prohibition would give an ambiguous message as to the harmful effects of tobacco for oral use. (78) As the Finnish Government observed, since the same prohibition has already been in place since 1992, lifting that prohibition would suggest that those products are harmless, which might increase their attractiveness to young people.

D. Test of proportionality in the strict sense

84. The third element of the proportionality test consists, in the fields in which the EU legislature has a broad discretion, in establishing whether the measure at issue does not lead to disadvantages which are manifestly disproportionate to the aims pursued. (79) The legislature must nevertheless take full account of the interests involved, beyond the main objective pursued, including the interests of individuals negatively affected by that measure. It falls to the legislature to examine whether the objectives pursued are such as to justify even substantial negative economic consequences for certain operators. (80)

85. In my opinion, the EU legislature complied with those requirements in adopting Article 1(c) and Article 17 of Directive 2014/40.

86. In that regard, the Court has already acknowledged that the objective of health protection takes precedence over economic interests. (81) The fundamental nature of that objective in the European Union legal order may, therefore, justify even substantial negative economic consequences for certain economic operators. (82)

87. In my view, it is from that perspective that, in the judgments in *Swedish Match* (83) and *Arnold André*, (84) the Court did not expressly weigh up the interests of economic operators and of public health. (85) It implicitly held that, provided that it passes the first two elements of the proportionality test, a measure which is intended to protect public health must necessarily comply with its third element in so far as the private interests of economic operators must take a back seat in matters concerning the general interest of public health.

88. Following that analysis, I consider that the provisions at issue are not manifestly inappropriate to pursue their twofold objective, do not go manifestly beyond what is necessary in order to attain the objective and do not lead to disadvantages which are manifestly disproportionate to the advantages sought.

V. Conclusion

89. In the light of all the foregoing considerations, I propose that the Court answer point (ii) of the question referred for a preliminary ruling from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court), United Kingdom as follows:

Consideration of point (ii) of the question referred for a preliminary ruling has not revealed any factor capable of affecting the validity of Article 1(c) and Article 17 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and

administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

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1 Original language: French.

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2 Directive 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).

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3 Article 1(1), (2) and (5) of Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products (OJ 1992 L 158, p. 30).

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

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5 Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1, 'the Act of Accession').

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6 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802).

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7 Judgment of 14 December 2004 (C−434/02, EU:C:2004:800).

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8 Proposal for a Directive of the European Parliament and of the Council of 19 December 2012 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).

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9 Commission Staff Working Document, Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products [COM(2012 788 final], 19 December 2012 (SWD(2012) 452 final).

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10 Opinion adopted on 6 February 2008 entitled 'Health Effects of Smokeless Tobacco Products'. See recital 2 of Directive 2014/40.

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11 Directive of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use (OJ 1989 L 359, p. 1).

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12 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802).

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13 See recitals 8 and 21 of Directive 2014/40 and judgments of 4 May 2016, *Philip Morris Brands and Others* (C−547/14, EU:C:2016:325, paragraph 171), and of 4 May 2016, *Poland* v *Parliament and Council* (C−358/14, EU:C:2016:323, paragraph 80).

14 See Commission proposal, p. 9 and impact assessment, p. 62.

15 See, in that regard, judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraphs 37 to 42), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraphs 38 to 43).

16 Commission proposal, p. 9 and impact assessment, pp. 64 to 69.

17 See, inter alia, judgments of 12 July 2001, *Jippes and Others* (C−189/01, EU:C:2001:420, paragraph 83); of 8 June 2010, *Vodafone and Others* (C−58/08, EU:C:2010:321, paragraph 52); and of 7 February 2018, *American Express* (C−304/16, EU:C:2018:66, paragraph 86).

18 Judgments of 10 December 2002, *British American Tobacco (Investments) and Imperial Tobacco* (C−491/01, EU:C:2002:741, paragraph 123); of 4 May 2016, *Poland* v *Parliament and Council* (C−358/14, EU:C:2016:323, paragraph 79); and of 4 May 2016, *Pillbox 38* (C−477/14, EU:C:2016:324, paragraph 49).

19 Judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraph 48), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraph 46). That discretion was not called into question by the argument, raised by the NNA at the hearing, that the prohibition on the placing on the market of tobacco for oral use restricts the right to health enshrined in Article 35 of the Charter. The NNA argues that that fundamental right includes the right to buy, as an alternative to tobacco for smoking, products containing nicotine which are less harmful. I note, in that regard, that the aim of that prohibition is to implement, rather than limit, the right to health, which requires complex assessments in the interests of not only smokers, but also the population as a whole (see, to that effect, inter alia, judgment of 4 May 2016, *Philip Morris Brands and Others* (C−547/14, EU:C:2016:325, paragraph 176)).

20 See, inter alia, judgment of 4 May 2016, *Pillbox 38* (C−477/14, EU:C:2016:324, paragraph 48 and the case-law cited).

21 Judgment of 16 December 2008, *Arcelor Atlantique et Lorraine and Others* (C−127/07, EU:C:2008:728, paragraph 58 and the case-law cited). See, also, to that effect, judgments of 7 September 2006, *Spain* v *Council* (C−310/04, EU:C:2006:521, paragraph 122), and of 8 July 2010, *Afton Chemical* (C−343/09, EU:C:2010:419, paragraph 34).

22 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802).

23 Judgment of 14 December 2004 (C−434/02, EU:C:2004:800).

24 Judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraphs 51 to 53), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraphs 49 to 51).

25 Judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraphs 49 and 51), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraphs 47 and 49).

26 Impact assessment, pp. 64 to 68.

27 See, inter alia, judgments of 5 May 1998, *United Kingdom* v *Commission*, (C−180/96, EU:C:1998:192, paragraph 99); of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C−236/01, EU:C:2003:431, paragraph 111); and of 9 June 2016, *Pesce and Others* (C−78/16 and C−79/16, EU:C:2016:428, paragraph 47).

28 See point 56 of this Opinion.

29 See, inter alia, judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C−236/01, EU:C:2003:431, paragraph 106); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C−77/09, EU:C:2010:803, paragraph 78); and of 13 September 2017, *Fidenato and Others* (C−111/16, EU:C:2017:676, paragraph 51).

30 See, inter alia, judgments of 10 April 2014, *Acino* v *Commission* (C−269/13 P, EU:C:2014:255, paragraph 58); of 17 December 2015, *Neptune Distribution* (C−157/14, EU:C:2015:823, paragraph 82); and of 4 May 2016, *Pillbox 38* (C−477/14, EU:C:2016:324, paragraph 55).

31 See, to that effect, judgments of 5 May 1998, *United Kingdom* v *Commission* (C−180/96, EU:C:1998:192, paragraph 60), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C−77/09, EU:C:2010:803, paragraph 55).

32 See, inter alia, judgment of 7 September 2006, *Spain* v *Council* (C−310/04, EU:C:2006:521, paragraph 121 and the case-law cited).

33 See, inter alia, judgment of 8 July 2010, *Afton Chemical* (C−343/09, EU:C:2010:419, paragraphs 28 and 33 and the case-law cited).

34 Judgments of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C−77/09, EU:C:2010:803, paragraphs 60 and 82); of 11 July 2013, *France* v *Commission* (C−601/11 P, EU:C:2013:465, paragraph 143); and of 9 June 2016, *Pesce and Others* (C−78/16 and C−79/16, EU:C:2016:428, paragraph 49). See, also, Opinion of Advocate General Poiares Maduro in *Commission* v *Netherlands* (C−41/02, EU:C:2004:520, point 32).

35 See point 36 of this Opinion. In that context, the Commission examined specifically the harmful effects of Swedish snus. It considered that, although it now contains a particularly low level of the main carcinogenic substances present in tobacco for oral use, that product is not harmless. It added that the snus in that composition

has not been on the market for long enough to reach a convincing conclusion that the cancer risk is reduced, in the light of the evidence available (impact assessment, p. 64).

36 Impact assessment, pp. 64 and 65.

37 Impact assessment, pp. 23, 50 and 63. Therefore, the finding in the judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraph 53), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraph 51), in accordance with which it had not been shown that tobacco for oral use was less harmful than cigarettes, is no longer up to date.

38 Swedish Match and the NNA submitted that the meta-analyses combine the individual results from a number of scientific studies using statistical methods, making it possible to evaluate the coherence of those results and to reduce the influence of random variations.

39 See points 38 to 40 of this Opinion.

40 Impact assessment, p. 66.

41 In that regard, I would point out that, according to settled case-law, the validity of a European Union measure must be assessed on the basis of the facts and the law as they stood at the time when the measure was adopted (see, inter alia, judgment of 17 October 2013, *Schaible* (C−101/12, EU:C:2013:661, paragraph 50 and the case-law cited)). However, in the judgments of 12 January 2006, *Agrarproduktion Staebelow* (C−504/04, EU:C:2006:30, paragraph 40), and of 9 June 2016, *Pesce and Others* (C−78/16 and C−79/16, EU:C:2016:428, paragraph 51), the Court added that, when new elements change the perception of a risk or show that that risk can be contained by measures less restrictive than the measures in force, it is for the EU institutions to bring about an amendment to the rules in the light of the new information.

42 Impact assessment, p. 64. See also Opinion of Advocate General Geelhoed in *Arnold André* (C−434/02, EU:C:2004:487, points 53 and 54).

43 Impact assessment, pp. 66 to 69.

44 In that regard, the Commission noted that some evidence from the United States indicates that the use of oral tobacco may lead to the subsequent use of tobacco for smoking, whereas some Swedish data do not support that hypothesis. The Commission also made reference to a study which associated oral tobacco use in early adolescence with an increased likelihood of occasional smoking in late adolescence (impact assessment, p. 68).

45 By contrast, Swedish Match and the NNA do not call into question the risks of the initiation effect and of dual use as such. However, Swedish Match submits that the available studies have not identified specific or more pronounced adverse effects among dual users of tobacco for oral use and tobacco for smoking.

46 See points 38 to 40 of this Opinion.

47 Judgment of 4 May 2016 (C−477/14, EU:C:2016:324, paragraphs 50 to 55 and 60).

48 See recital 43 of Directive 2014/40.

49 See Article 20 of Directive 2014/40.

50 See, also, Opinion of Advocate General Kokott in *Philip Morris Brands and Others* (C−547/14, EU:C:2015:853, points 155 to 159).

51 See point 41 of this Opinion.

52 Article 9, Article 114(3) and Article 168(1) TFEU and the second sentence of Article 35 of the Charter.

53 See, to that effect, judgments of 4 May 2016, *Philip Morris Brands and Others* (C−547/14, EU:C:2016:325, paragraph 176), and of 4 May 2016, *Poland* v *Parliament and Council* (C−358/14, EU:C:2016:323, paragraph 86).

54 See, to that effect, judgment of 4 May 2016, *Pillbox 38* (C−477/14, EU:C:2016:324, paragraph 96).

55 See point 39 of this Opinion. This is how the case-law of the General Court, cited by Swedish Match at the hearing, should be understood, in accordance with which the withdrawal or the relaxation of a preventive measure cannot be made subject to 'proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice', with the result that 'a preventive measure may be taken only if the risk, although the reality and extent thereof have not been "fully" demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken' (judgment of 9 September 2011, *France* v *Commission* (T−257/07, EU:T:2011:444, paragraph 76)).

56 In particular, the Court has held, with regard to a refusal or withdrawal of the marketing authorisation for a medicinal product, that the validity of such precautionary measures requires only that there be a risk which 'need not be specific, but only potential' (judgments of 10 April 2014, *Acino* v *Commission* (C−269/13 P, EU:C:2014:255, paragraphs 59 and 73), and of 3 December 2015, *PP Nature-Balance Lizenz* v *Commission* (C−82/15 P, not published, EU:C:2015:796, paragraph 23)).

57 See point 41 of this Opinion.

58 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802).

59 Judgment of 14 December 2004 (C−434/02, EU:C:2004:800).

60 At the hearing, the Government of the United Kingdom and the Parliament rightly pointed out that Article 7 of Directive 2014/40 also prohibits the placing on the market of flavoured tobacco products, subject to

the transitional period provided for in paragraph 14 of that article.

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61 Judgment of 4 May 2016 (C−477/14, EU:C:2016:324, paragraphs 51 and 52).

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62 In the judgment of 5 July 2017, *Fries* (C−190/16, EU:C:2017:513, paragraph 48), the Court applied to an EU measure the settled case-law concerning the appropriateness of a national measure which restricts the freedoms of movement guaranteed by the TFEU to attain its objective in a consistent and systematic way (see, inter alia, judgment of 23 December 2015, *Scotch Whisky Association and Others* (C−333/14, EU:C:2015:845, paragraph 37 and the case-law cited)).

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63 See point 30 of this Opinion.

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64 See judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraphs 66, 67 and 71) and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraphs 64, 65 and 69).

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65 Impact assessment, p. 76.

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66 Impact assessment, pp. 49 and 50. See also Opinion of Advocate General Geelhoed in *British American Tobacco (Investments) and Imperial Tobacco* (C−491/01, EU:C:2002:476, point 231), and in *Arnold André* (C−434/02, EU:C:2004:487, points 60 to 62).

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67 According to Article 2(14) of Directive 2014/40, a novel tobacco product is ‘a tobacco product which: (a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and (b) is placed on the market after 19 May 2014’.

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68 See Article 19 of Directive 2014/40.

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69 See judgments of 14 December 2004, *Swedish Match* (C−210/03, EU:C:2004:802, paragraph 66), and of 14 December 2004, *Arnold André* (C−434/02, EU:C:2004:800, paragraph 64).

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70 Judgment of 4 May 2016 (C−477/14, EU:C:2016:324, paragraphs 36 to 42).

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71 C−434/02, EU:C:2004:487, point 125.

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72 In that connection, the Court has also held that, where the legislature of the European Union is called on to regulate a complex system, it is entitled to have recourse to a step-by-step approach, provided that its choice is based on objective criteria appropriate to the aims pursued by the legislation in question (see, inter alia, judgment of 17 October 2013, *Schaible* (C−101/12, EU:C:2013:661, paragraph 91 and the case-law cited)).

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73 See, inter alia, judgment of 16 June 2015, *Gauweiler and Others* (C−62/14, EU:C:2015:400, paragraph 81).

74 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802, paragraph 57).

75 Judgment of 14 December 2004 (C−434/02, EU:C:2004:800, paragraph 55).

76 See also, by analogy, judgments of 4 May 2016, *Philip Morris Brands and Others* (C−547/14, EU:C:2016:325, paragraph 160), and of 4 May 2016, *Poland* v *Parliament and Council* (C−358/14, EU:C:2016:323, paragraph 95).

77 Impact assessment, p. 75.

78 Impact assessment, p. 68.

79 See, inter alia, judgment of 16 June 2015, *Gauweiler and Others* (C−62/14, EU:C:2015:400, paragraph 91).

80 See, inter alia, judgments of 16 December 2008, *Arcelor Atlantique et Lorraine and Others* (C−127/07, EU:C:2008:728, paragraph 59); of 12 July 2012, *Association Kokopelli* (C−59/11, EU:C:2012:447, paragraph 40); and of 4 May 2016, *Philip Morris Brands and Others* (C−547/14, EU:C:2016:325, paragraph 185).

81 See order of 12 July 1996, *United Kingdom* v *Commission* (C−180/96 R, EU:C:1996:308, paragraph 93); judgments of 19 April 2012, *Artegodan* v *Commission* (C−221/10 P, EU:C:2012:216, paragraph 99 and the case-law cited), and of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, EU:C:2016:325, paragraph 156). In her Opinion in *Philip Morris Brands and Others* (C−547/14, EU:C:2015:853, point 179), Advocate General Kokott stated that the protection of human health has ‘considerably greater’ importance in the value system under EU law than the economic interests of operators. See, also, Opinion of Advocate General Geelhoed in *British American Tobacco (Investments) and Imperial Tobacco* (C−491/01, EU:C:2002:476, points 226 and 229).

82 See, by analogy, judgments of 8 June 2010, *Vodafone and Others* (C−58/08, EU:C:2010:321, paragraph 69), and of 23 October 2012, *Nelson and Others* (C−581/10 and C−629/10, EU:C:2012:657, paragraph 81).

83 Judgment of 14 December 2004 (C−210/03, EU:C:2004:802).

84 Judgment of 14 December 2004 (C-434/02, EU:C:2004:800).

85 See, also, with regard to the examination of the proportionality of national measures which restrict the freedoms of movement guaranteed by the TFEU, judgment of 23 December 2015, *Scotch Whisky Association and Others* (C-333/14, EU:C:2015:845, paragraphs 56 and 59).