Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

22 November 2018*

Reference for a preliminary ruling — Approximation of laws — Manufacture, presentation and sale of tobacco products — Directive 2014/40/EU — Article 1(c) and Article 17 — Prohibition on the placing on the market of tobacco products for oral use — Validity)

In Case C-151/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) (United Kingdom), made by decision of 9 March 2017, received at the Court on 24 March 2017, in the proceedings

Swedish Match AB

v

Secretary of State for Health,

intervening party:

New Nicotine Alliance,

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, Vice-President, acting as President of the First Chamber, J.-C. Bonichot, E. Regan, C.G. Fernlund and S. Rodin (Rapporteur), Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 25 January 2018,

after considering the observations submitted on behalf of:

– Swedish Match AB, by P. Tridimas, Barrister, and by M. Johansson, advokat,

– New Nicotine Alliance, by P. Diamond, Barrister,

– the United Kingdom Government, by S. Brandon, acting as Agent, and by I. Rogers QC,

– the Hungarian Government, by M.Z. Fehér, G. Koós and M.M. Tátrai, acting as Agents,

* Language of the case: English.

– the Finnish Government, by H. Leppo, acting as Agent,

– the Norwegian Government, by M. Reinertsen Norum, acting as Agent, and by K. Moen, advocate,

– the European Parliament, by A. Tamás and I. McDowell, acting as Agents,

– the Council of the European Union, by M. Simm, E. Karlsson and A. Norberg, acting as Agents,

– the European Commission, by L. Flynn and J. Tomkin, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 April 2018,

gives the following

Judgment

1 This request for a preliminary ruling concerns 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 (OJ 2014 L 127, p. 1).

2 The request has been made in proceedings between Swedish Match AB and the Secretary of State for Health (United Kingdom) concerning the legality of a prohibition on the production and supply of tobacco for oral use in the United Kingdom.

Legal context

3 Recital 32 of Directive 2014/40 states:

‘Council Directive 89/622/EEC [of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products (OJ 1989 L 359, p. 1)] prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC [of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products — Commission statement (OJ 2001 L 194 p. 26)] reaffirmed that prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden [the 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] 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.

4 Article 1 of Directive 2014/40 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;

...'.

5 Article 2 of that directive provides:

'For the purpose of this Directive, the following definitions shall apply:

...

(5) "smokeless tobacco product" means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

...

(8) "tobacco for oral use" means 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.

(9) "tobacco products for smoking" means tobacco products other than a smokeless tobacco product;

...

(14) "novel tobacco product" means 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;

...'

6 Article 17 of that directive, headed 'Tobacco for oral use', states:

'Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.'

7 Article 19(1) of Directive 2014/40, headed 'Notification of novel tobacco products' reads as follows:

'Member States shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned. ...'

8 Article 24(3) of that directive is worded as follows:

'A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary

discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.'

The dispute in the main proceedings and the question referred for a preliminary ruling

9 Swedish Match is a public limited liability company established in Sweden which primarily markets smokeless tobacco products and, in particular, 'snus'.

10 On 30 June 2016 Swedish Match brought an action before the courts of the United Kingdom in order to challenge the legality of Regulation 17 of the Tobacco and Related Products Regulations 2016, which transposed into United Kingdom law Article 1(c) and Article 17 of Directive 2014/40, and which provides that 'no person may produce or supply tobacco for oral use'.

11 In that action, Swedish Match challenges the validity, having regard to the principle of non-discrimination, of Article 1(c) and Article 17 of Directive 2014/40, by reason of the difference in treatment which those provisions establish between, on the one hand, tobacco products for oral use, whose placing on the market is prohibited, and, on the other hand, other smokeless tobacco products, novel tobacco products, cigarettes and other tobacco products for smoking, and electronic cigarettes, whose consumption is not prohibited. Further, according to Swedish Match, the prohibition of tobacco products for oral use cannot be justified on public health grounds since the current scientific data, not available at the time of adoption of Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622 (OJ 1992 L 158, p. 30), demonstrates that those products are at the lower end of the risk scale in terms of adverse health effects as compared with other smokeless tobacco products. Moreover, Swedish Match claims that there is no evidence to support the idea that the consumption of tobacco products for oral use is a 'gateway' that leads to smoking tobacco. Nor can the prohibition be justified by the novelty of snus, since novel tobacco products are not prohibited by Directive 2014/40, under Article 2(14) thereof, notwithstanding that there is no scientific track record and that those products may have potential adverse health effects. Again, the fact that tobacco products for oral use are produced for the mass market cannot justify the discrimination to which they are subject, since other products falling within the scope of that directive, in particular other smokeless tobacco products, electronic cigarettes and novel tobacco products, are also produced for the mass market.

12 Further, Swedish Match claims that the prohibition on placing on the market tobacco products for oral use is contrary to the principle of proportionality, since neither the recitals of Directive 2014/40, nor the impact assessment of 19 December 2012 carried out by the Commission, which accompanies the 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 (SWD(2012) 452 final, p. 49 et seq.) ('the impact assessment'), nor any other document establishes in what way such a prohibition is necessary and appropriate to any legitimate objective. On that point, the precautionary principle cannot be relied on, since that prohibition is not consistent with permitting the placing on the market of other tobacco products, the toxicity of which, however, according to the current scientific evidence, is higher.

13 Further, the outright prohibition of tobacco products for oral use, since it takes no account of the individual circumstances of each Member State, is not, according to Swedish Match, compatible with the principle of subsidiarity. That is not a necessary approach, as indicated by the fact that Directive 2014/40 itself leaves to the Member States a degree of discretion in the adoption of their legislation in relation to other tobacco products.

14 In addition, Swedish Match claims that neither Directive 2014/40 nor its context explain why tobacco products for oral use are subject to discrimination as compared with other smokeless tobacco products, electronic cigarettes, novel tobacco products and cigarettes. Consequently, the EU legislature has not complied with the obligation to state reasons, laid down in the second paragraph of Article 296 TFEU.

15 The prohibition on placing tobacco products for oral use on the market also constitutes, according to Swedish Match, an unjustified restriction on the free movement of goods, since it is contrary to the principles of non-discrimination and proportionality and in breach of the obligation to state reasons.

16 Moreover, leaving aside the fact that the Court has not yet had occasion to give a ruling on the validity of Article 1(c) and Article 17 of Directive 2014/40, Swedish Match argues that the judgment of 14 December 2004, *Swedish Match* (C-210/03, EU:C:2004:802), is not applicable to the main proceedings, since recent scientific evidence on the allegedly harmful effects of tobacco products for oral use contradicts what is said in that judgment, the rules introduced by Directive 2014/40 are significantly different from those established by Directive 2001/37 and, last, there have been extensive changes in the market for tobacco products since that judgment.

17 In his defence, the Secretary of State for Health considers that a reference to the Court for a preliminary ruling on the validity of Article 1(c) and Article 17 of Directive 2014/40 is appropriate, and states, in particular, that the Court alone has the power to declare that a directive or a part of it is invalid.

18 As a party granted leave to intervene in the main proceedings, the New Nicotine Alliance ('NNA'), a registered charity whose objective is to promote public health by means of tobacco harm reduction, claims before the referring court that the prohibition on the placing of tobacco products for oral use on the market is contrary to the principle of proportionality and is in breach of Articles 1, 7 and 35 of the Charter of Fundamental Rights of the European Union ('the Charter'). Such a prohibition is an unsuitable means of achieving the objective of public health protection, since it deprives consumers who want to avoid the consumption of cigarettes and other tobacco products for smoking of the option of using a less toxic product, as shown by the success of electronic cigarettes and the scientific evidence on the harmful effects of tobacco in Sweden. Snus forms part, together with other tobacco harm reduction products, already available in the United Kingdom, of a coherent tobacco harm reduction strategy.

19 In those circumstances, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court) (United Kingdom), 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 [the second paragraph of Article 296 TFEU];

v. breach of Articles 34 and 35 TFEU; and

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

Consideration of the question referred

20 By the question referred for a preliminary ruling, the referring court raises the issue of the validity of Article 1(c) and Article 17 of Directive 2014/40, having regard to the principles of equal treatment, proportionality and subsidiarity, the obligation to state reasons laid down in the second paragraph of Article 296 TFEU, Articles 34 and 35 TFEU and Articles 1, 7 and 35 of the Charter.

The validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of equal treatment

21 The referring court seeks to ascertain whether Directive 2014/40 is in breach of the principle of equal treatment in that it prohibits the placing on the market of tobacco products for oral use while permitting the marketing of other smokeless tobacco products, cigarettes, electronic cigarettes and novel tobacco products.

22 According to settled case-law, the principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (judgment of 7 March 2017, *RPO*, C-390/15, EU:C:2017:174, paragraph 41).

23 In that regard, it must be recalled that the issue of breach of the principle of equal treatment by reason of a prohibition on placing on the market tobacco products for oral use, imposed by Directive 2001/37, has previously been the subject of the judgments of 14 December 2004, *Swedish Match* (C-210/03, EU:C:2004:802), and of 14 December 2004, *Arnold André* (C-434/02, EU:C:2004:800).

24 In those judgments, the Court held that the particular situation of the tobacco products for oral use referred to in Article 2 of Directive 2001/37 permitted a difference in their treatment, and it could not validly be argued that there was a breach of the principle of non-discrimination. The Court held that those products, although they are not fundamentally different in their composition or indeed their intended use from tobacco products intended to be chewed, were not in the same situation as the latter products by reason of the fact that the tobacco products for oral use which were the subject of the prohibition laid down in Article 8a of Directive 89/622 and repeated in Article 8 of Directive 2001/37 were new to the markets of the Member States subject to that measure (judgments of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 71, and of 14 December 2004, *Arnold André*, C-434/02, EU:C:2004:800, paragraph 69).

25 Following the delivery of those judgments, the EU legislature has not adopted any measure that permits tobacco products for oral use to be placed on the market in Member States subject to Article 17 of Directive 2014/40.

26 Accordingly, if those products were to be introduced onto that market, they would continue to be novel as compared with other smokeless tobacco products and tobacco products for smoking, including cigarettes, and would accordingly be attractive to young people.

27 Further, as the Advocate General stated in point 73 of his Opinion, it is stated in the impact assessment, which is not challenged on that point, that smokeless tobacco products other than those for oral use represent only niche markets which have limited potential for expansion, on account of, inter alia, their costly and in part small-scale production methods. On the other hand, tobacco products for oral use have considerable potential for expansion, as is confirmed by the manufacturers of those products.

28 Consequently, such particular circumstances mean that it is permissible for the treatment of tobacco products for oral use to differ from both that of other smokeless tobacco products and that of cigarettes, and no breach of the principle of equal treatment can validly be claimed.

29 As regards the alleged breach of the principle of equal treatment because of the less favourable treatment of tobacco products for oral use as compared with electronic cigarettes, the Court has previously held that the objective characteristics of the latter differ from those of tobacco products in general and, therefore, that electronic cigarettes are not in the same situation as tobacco products (see, to that effect, judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraphs 36 and 42).

30 It follows that the principle of equal treatment cannot be infringed by reason of the fact that the particular category consisting of tobacco products for oral use is subject to different treatment from that of the other category that consists of electronic cigarettes.

31 As regards the alleged breach of the principle of equal treatment because of the less favourable treatment of tobacco products for oral use as compared with novel tobacco products, it must be observed that Article 2(14) of Directive 2014/40 defines 'novel tobacco product' as being a tobacco product which is placed on the market after 19 May 2014 and which 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.

32 Consequently, and as stated by the Advocate General in point 75 of his Opinion, taking into consideration when they were placed on the market, the effects of novel tobacco products on public health could not, by definition, be observed or studied at the time when Directive 2014/40 was adopted, whereas the effects of tobacco products for oral use were, at that time, sufficiently identified and substantiated scientifically. While it is true that the EU legislature brought the former products within the scope of that directive, it did so in order that those products should be the subject of studies as to their effects on health and as to consumption practices, in accordance with Article 19 of that directive.

33 Accordingly, since tobacco products for oral use had been the subject of a number of scientific studies, they could not, when Directive 2014/40 was adopted, be considered to be novel to the same extent as the novel tobacco products that are referred to in Article 2(14) of that directive.

34 In those circumstances, Article 1(c) and Article 17 of Directive 2014/40 are not in breach of the principle of equal treatment.

The validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of proportionality

35 First, it must be recalled that, according to the Court's settled case-law, the principle of proportionality requires that acts of the EU institutions should be appropriate for attaining the legitimate objectives pursued by the legislation at issue and should not go beyond what is necessary in order to achieve those objectives (judgment of 7 February 2018, *American Express*, C-304/16, EU:C:2018:66, paragraph 85).

36 With regard to judicial review of compliance with those conditions, the Court has accepted that in the exercise of the powers conferred on it the EU legislature must be allowed a broad discretion in areas such as that at issue in which its action involves political, economic and social choices and in which it is called upon to undertake complex assessments and evaluations. Accordingly, the criterion to be applied is not whether a measure adopted in such an area was the only or the best possible measure,

since its legality can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institutions are seeking to pursue (see, to that effect, judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraph 49).

37 As regards the assessments of highly complex scientific and technical facts that are necessary in order to determine whether the prohibition on the placing on the market of tobacco products for oral use is proportionate, it must be recalled that the Courts of the European Union cannot substitute their assessment of that material for that of the legislature on which the FEU Treaty has placed that task. The EU legislature's broad discretion, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts (see, to that effect, judgment of 21 June 2018, *Poland* v *Parliament and Council*, C-5/16, EU:C:2018:483, paragraphs 150 and 151).

38 Further, the EU legislature must take account of the precautionary principle, according to which, 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. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (judgment of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 47 and the case-law cited).

39 Those considerations must guide the Court in its examination of the validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of proportionality.

40 In this case, it must be observed that Directive 2014/40 pursues, according to Article 1 thereof, a twofold objective of facilitating the smooth functioning of the internal market for tobacco and related products while taking as a base a high level of protection of human health, especially for young people (judgment of 4 May 2016, *Poland* v *Parliament and Council*, C-358/14, EU:C:2016:323, paragraph 80).

41 With respect to the objective of ensuring a high level of protection of human health, especially for young people, it is apparent from the impact assessment (p. 62 et seq.) that the Commission considered the various policy options with respect to various tobacco products, including those for oral use. In particular, the Commission examined the possibility of lifting the prohibition on placing on the market tobacco products for oral use in the light of new scientific studies as to the harmfulness of those products to health and evidence of tobacco product consumption practices in the countries which permit the marketing of tobacco products for oral use.

42 In that regard, the Commission stated, first, that, even though scientific studies indicate that smokeless tobacco products are less dangerous to health than those involving combustion, it remains the case that all smokeless tobacco products contain carcinogens, it has not been scientifically established that the levels of those carcinogens in tobacco products for oral use is such as to diminish the risk of cancer, they increase the risk of fatal myocardial infarction, and there are some indications that their use is associated with pregnancy complications.

43 The Commission further observed that the studies which suggest that snus may facilitate the cessation of smoking predominantly rely on empirical data and, therefore, cannot be regarded as being conclusive.

44 Moreover, the Commission also stated that a decision to lift the prohibition on placing on the market tobacco products for oral use would affect the policies for controlling the consumption of tobacco products by encouraging people who are not yet consumers of tobacco products, in particular young people, to become consumers and, therefore, such a decision would entail certain public health risks.

45 Consequently, having thus taken into account all the scientific studies referred to in the impact assessment, the Commission considered that the precautionary principle justified maintaining the prohibition on placing tobacco products for oral use on the market.

46 In order to challenge the validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of proportionality, Swedish Match and the NNA refer, as is stated in the order for reference, to recent scientific studies which, from their perspective, demonstrated that tobacco products for oral use, including snus, are less harmful than other tobacco products, that they are less addictive than the latter and that they facilitate the cessation of smoking. In particular, Swedish Match and the NNA state, relying on observations made in Sweden and in Norway, that the consumption of snus tends to replace, rather than be additional to the consumption of tobacco products for smoking, and that it has no 'gateway effect' to the latter products.

47 In that context, it is clear that the EU legislature was entitled, on the basis of scientific studies, in the exercise of the broad discretion available to it in that regard and in conformity with the precautionary principle, to conclude, in accordance with the case-law cited in paragraphs 36 and 38 of the present judgment, that the effectiveness of tobacco products for oral use as an aid to the cessation of smoking if the prohibition on placing on the market such products were to be lifted was uncertain, and that there were public health risks, such as the risk of a gateway effect, due, in particular, to those products being attractive to young people.

48 As regards the appropriateness of the prohibition on the placing on the market of tobacco products for oral use to attaining the objective of ensuring a high level of protection of public health, it must be recalled that that appropriateness cannot be assessed solely in relation to a single category of consumers (see, to that effect, judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 176).

49 Given that, if the prohibition on placing on the market tobacco products for oral use were to be lifted, the positive effects would be uncertain with respect to the health of consumers seeking to use those products as an aid to the cessation of smoking and, moreover, there would be risks to the health of other consumers, particularly young people, requiring the adoption, in accordance with the precautionary principle, of restrictive measures, Article 1(c) and Article 17 of Directive 2014/40 cannot be regarded as being manifestly inappropriate to the objective of ensuring a high level of public health.

50 Conversely, less restrictive measures, such as those laid down for other tobacco products in Directive 2014/40, in particular the strengthening of health warnings and the prohibition on flavoured tobacco, do not appear to be equally appropriate to achieving the objective pursued.

51 By reason of both the considerable potential for growth in the market for tobacco products for oral use, confirmed by the manufacturers themselves of those products, and the introduction of smoke-free environments, those products are especially liable to encourage people who are not yet consumers of tobacco products, in particular young people, to become consumers.

52 Moreover, tobacco products for oral use are particularly dangerous for minors because of the fact that their consumption is hardly noticeable. The consumption of such a product generally involves placing the product between the gum and upper lip and keeping it in place (see, to that effect, judgment of 14 December 2004, *Arnold André*, C-434/02, EU:C:2004:800, paragraph 19).

53 Consequently, the prohibition on the placing of tobacco products for oral use on the market does not manifestly exceed what is necessary in order to attain the objective of ensuring a high level of protection of public health.

54 Further, in accordance with settled case-law, the objective of protection of health takes precedence over economic considerations (judgment of 19 April 2012, *Artegodan* v *Commission*, C-221/10 P, EU:C:2012:216, paragraph 99 and the case-law cited), the importance of that objective being such as to justify even substantial negative economic consequences (see, to that effect, judgment of 23 October 2012, *Nelson and Others*, C-581/10 and C-629/10, EU:C:2012:657, paragraph 81 and the case-law cited). In this case, even if there is considerable potential for growth in the market for tobacco products for oral use, the economic consequences deriving from the prohibition on the placing on the market of such products remain, in any event, uncertain, since, at the time when Directive 2014/40 was adopted, those products were not present on the market of the Member States subject to Article 17 of Directive 2014/40.

55 With respect to the objective of facilitating the smooth functioning of the internal market of tobacco and related products, it must be stated that the prohibition on the placing on the market of tobacco products for oral use laid down by those provisions is also appropriate to facilitating the smooth functioning of the internal market of tobacco and related products.

56 The Court observed in paragraph 37 of its judgment of 14 December 2004, *Swedish Match* (C-210/03, EU:C:2004:802), that there were differences, at the time of adoption of Directive 92/41, between the laws, regulations and administrative provisions of the Member States intended to stop the expansion in consumption of products harmful to health which were novel to the markets of the Member States and were thought to be especially attractive to young people.

57 Just as the Court stated in that same judgment that the legislative context had not changed at the time of adoption of Directive 2001/37, which had also prohibited the placing on the market of tobacco products for oral use (see, to that effect, judgment of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 40), it must be observed that that context remained the same at the time of adoption of Directive 2014/40.

58 Tobacco products for oral use remain harmful to health, are addictive and are attractive to young people. Further, as stated in paragraph 26 of the present judgment, such products would, if placed on the market, represent novel products for consumers. In that context, it remains likely that Member States may be led to adopt various laws, regulations and administrative provisions designed to bring to an end the expansion in the consumption of tobacco products for oral use.

59 Moreover, as regards more particularly the claim by Swedish Match that the permission given to the marketing of other tobacco and related products demonstrates that the prohibition on the placing on the market of tobacco products for oral use is disproportionate, it must be recalled that an EU measure is appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a consistent and systematic manner (see, to that effect, judgment of 5 July 2017, *Fries*, C-190/16, EU:C:2017:513, paragraph 48).

60 In that regard, it follows from paragraph 34 of the present judgment that Article 1(c) and Article 17 of Directive 2014/40 are not in breach of the principle of equal treatment on the ground that the treatment of tobacco products for oral use differs from the treatment of other tobacco and related products.

61 Accordingly, Article 1(c) and Article 17 of Directive 2014/40 do not lead to disadvantages that are manifestly disproportionate to the aims pursued.

62 It follows from the foregoing that those provisions do not involve restrictions that are disproportionate to the twofold objective pursued by Directive 2014/40, namely to facilitate the smooth functioning of the internal market in tobacco and related products and to ensure a high level of protection of public health.

63 Consequently, it must be held that those provisions are not in breach of the principle of proportionality.

The validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of subsidiarity

64 It is stated in the order for reference that Swedish Match challenges the validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the principle of subsidiarity, because of the fact that the general and absolute prohibition on the placing on the market of tobacco products for oral use deprives Member States of any discretion in their legislation and imposes a uniform body of rules, with no consideration of the individual circumstances of the Member States, with the exception of the Kingdom of Sweden. Further, according to Swedish Match, such an approach was not necessary, as demonstrated by the fact that Article 24(3) of that directive grants to each Member State the option of prohibiting, on grounds relating to its specific situation, this or that category of tobacco or related products.

65 It must be recalled that the principle of subsidiarity is set out in the second paragraph of Article 5(3) TEU, which provides that the Union, in areas which do not fall within its exclusive competence, is to act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Union. Furthermore, Article 5 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality, annexed to the EU Treaty and to the FEU Treaty, lays down guidelines for the purpose of determining whether those conditions are met (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 215).

66 Since the present case concerns an area — the improvement of the functioning of the internal market — which is not among those in respect of which the European Union has exclusive competence, it must be determined whether the objective of Directive 2014/40 could be better achieved at EU level (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 219).

67 In that regard, as stated in paragraph 40 of the present judgment, Directive 2014/40 pursues a twofold objective, in that it seeks to facilitate the smooth functioning of the internal market for tobacco and related products, while ensuring a high level of protection of human health, especially for young people (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 220).

68 Even if the second of those objectives might be better achieved at the level of Member States, the fact remains that pursuing it at that level would be liable to entrench, if not create, situations in which, as stated in paragraph 58 of the present judgment, some Member States permit the placing on the market of tobacco products for oral use, while other Member States prohibit it, thereby running completely counter to the first objective of Directive 2014/40, namely the improvement of the functioning of the internal market for tobacco and related products (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 221).

69 The interdependence of the two objectives pursued by that directive means that the EU legislature could legitimately take the view that it had to establish a set of rules for the placing on the EU market of tobacco products for oral use and that, because of that interdependence, that twofold objective could best be achieved at EU level (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 222).

70 As regards the claim that Article 24(3) of Directive 2014/40 demonstrates that the objectives of that directive could be adequately achieved by the Member States, it must be observed that that provision grants to each Member State the option of prohibiting a certain category of tobacco or related

products on grounds relating to the specific situation of that Member State, provided that those provisions are justified by the need to protect public health, while the Commission retains the power to approve or reject those provisions of national law, after having verified, taking into account the high level of protection of human health achieved by that directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States.

71 In that regard, it must be recalled that the authors of the Treaty intended to confer on the EU legislature a discretion, depending on the general context and the specific circumstances of the matter to be harmonised, as regards the method of approximation most appropriate for achieving the desired result, in particular in fields with complex technical features. It was thus open to the EU legislature, in the exercise of that discretion, to proceed towards harmonisation only in stages and to require only the gradual abolition of unilateral measures adopted by the Member States (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 63).

72 Depending on the circumstances, the measures referred to in Article 114(1) TFEU may consist in requiring all the Member States to authorise the marketing of the product or products concerned, subjecting such an obligation of authorisation to certain conditions, or even provisionally or definitively prohibiting the marketing of a product or products (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 64).

73 In having prohibited the placing on the market of tobacco products for oral use, while permitting the marketing of other tobacco products, the EU legislature must be regarded as having undertaken a harmonisation in stages of tobacco products.

74 Article 24(3) of Directive 2014/40 therefore concerns an aspect which is not covered by the harmonisation measures in that directive (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 90).

75 Consequently, that provision cannot, per se, demonstrate that the objectives of that directive could be adequately achieved by the Member States.

76 It follows that Article 1(c) and Article 17 of Directive 2014/40 are not in breach of the principle of subsidiarity.

The validity of Article 1(c) and Article 17 of Directive 2014/40 having regard to the second paragraph of Article 296 TFEU

77 It is apparent from the order for reference that Swedish Match claims that Directive 2014/40 provides no specific and consistent explanation of the selective prohibition of tobacco products for oral use and adds that nor is such an explanation apparent from the context of that directive.

78 In that regard, it must be recalled that, in accordance with settled case-law, 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 institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the court with jurisdiction to exercise its power of review. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons for a measure meets the requirements of the second paragraph of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (judgment of 17 March 2011, *AJD Tuna*, C-221/09, EU:C:2011:153, paragraph 58).

79 It is also settled case-law that the extent of the requirement to state reasons depends on the nature of the measure in question and that, in the case of measures intended to have general application, the statement of reasons may be limited to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it is intended to achieve, on the other. In that context, the Court has held, in particular, that if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made (see, to that effect, judgment of 17 March 2011, *AJD Tuna*, C-221/09, EU:C:2011:153, paragraph 59).

80 In this case, recital 32 of Directive 2014/40 and the impact assessment contain information that shows clearly and unequivocally the reasoning of the Commission that gave rise to the prohibition on the placing on the market of tobacco products for oral use.

81 In particular, recital 32 of Directive 2014/40 states that the prohibition on 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 effects on human health, and refers to the reasons stated in Directives 89/622 and 2001/37, which clearly set out, as previously held by the Court (see, to that effect, judgment of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 65), the grounds that gave rise to that prohibition.

82 That being the case, since that information ensures that the reasons for the prohibition on the placing on the market of tobacco products for oral use can be ascertained and that the court with jurisdiction can exercise its power of review, Directive 2014/40 satisfies the obligation to state reasons laid down in the second paragraph of Article 296 TFEU.

The validity of Article 1(c) and Article 17 of Directive2014/40 having regard to Articles 34 and 35 TFEU

83 It is apparent from the order for reference that Swedish Match claims that Article 1(c) and Article 17 of Directive 2014/40 are contrary to Articles 34 and 35 TFEU on the ground that those provisions are in breach of the principles of equal treatment and proportionality and of the obligation to state reasons.

84 In that regard, while it is true that the prohibition on the placing on the market of tobacco products for oral use constitutes a restriction, within the meaning of Articles 34 and 35 TFEU, such a restriction is clearly justified, as stated above, on grounds of protection of public health, is not in breach of the principles of equal treatment and proportionality, and satisfies the obligation to state reasons.

85 Consequently, Article 1(c) and Article 17 of Directive 2014/40 are not invalid having regard to Articles 34 and 35 TFEU.

The validity of Article 1(c) and Article 17 of Directive2014/40 having regard to Articles 1, 7 and 35 of the Charter

86 It is apparent from the order for reference that Swedish Match and the NNA claim that Article 1(c) and Article 17 of Directive 2014/40 are in breach of Articles 1, 7 and 35 of the Charter, since the effect of the prohibition on the placing on the market of tobacco products for oral use is that individuals who want to stop smoking cannot use products that would improve their health.

87 In that regard, Article 52(1) of the Charter provides that any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law and must respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

88 In this instance, even if it were the case, as claimed by Swedish Match and the NNA, that Article 1(c) and Article 17 of Directive 2014/40 limit fundamental rights, such a limitation is provided for by law, respects the essence of those rights and is compatible with the principle of proportionality.

89 In that regard, as concerns respecting the essence of fundamental rights, it is clear that the prohibition on placing on the market tobacco products for oral use laid down in Article 1(c) and Article 17 of Directive 2014/40 is intended not to restrict the right to health but, on the contrary, to give expression to that right and, consequently, to ensure a high level of protection of health with respect to all consumers, by not entirely depriving people who want to stop smoking of a choice of products which would help them to achieve that goal.

90 Those provisions, as stated in paragraph 63 of the present judgment, are also not in breach of the principle of proportionality.

91 In those circumstances, it must be held that Article 1(c) and Article 17 of Directive 2014/40 are not invalid having regard to Articles 1, 7 and 35 of the Charter.

92 It follows from all the foregoing that consideration of the question referred has disclosed nothing capable of affecting the validity of Article 1(c) and Article 17 of Directive 2014/40.

Costs

93 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

Consideration of the question referred has disclosed nothing 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.

Silva de Lapuerta Bonichot Regan

Fernlund Rodin

Delivered in open court in Luxembourg on 22 November 2018.

A. Calot Escobar
Registrar

K. Lenaerts
President