EUROPEAN COMMISSION

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Court procedural document

TO THE PRESIDENT AND MEMBERS OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

WRITTEN OBSERVATIONS

submitted by the **EUROPEAN COMMISSION** represented by Mr Leo FLYNN, Legal Adviser, and Mr Jonathan TOMKIN, Member of its Legal Service, acting as Agents, with an address for service at the Legal Service, *Greffe contentieux*, BERL 1/169, 1049 Brussels, and consenting to service by e-Curia, in

Case C-151/17,

The Queen on the Application of

SWEDISH MATCH AB

Claimant

– and –

THE SECRETARY OF STATE FOR HEALTH

Defendant

NEW NICOTINE ALLIANCE

Intervener

Concerning the validity of Articles 1(c) and 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 L 127, 29.4.2014, p. 1).

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1. THE LEGAL FRAMEWORK

1.1. International law

1.1.1. World Health Organisation Framework Convention on Tobacco Control[1]

1. Pursuant to the preamble of the World Health Organisation Framework Convention on Tobacco Control ('the FCTC'), to which the European Union and its Member States are party, the Parties to that convention recognise that "*scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability*" and that "*cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases.*"

2. Pursuant to Article 3, the objective of the Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

3. In accordance with Article 4 of the FCTC, a guiding principle for the attainment of this objective includes the development and support of multisectoral measures and coordinated responses taking into consideration the need to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form.

[1] World Health Organisation Framework Convention on Tobacco Control ('the FCTC'), signed in Geneva on 21 May 2003.

1.2. Union law

1.2.1. The TFEU and the Charter

4. Pursuant to Article 114(3) TFEU, harmonised norms established by the Union legislature under Article 114(1) TFEU are to take as a base a high level of protection of human health and safety.

5. The first paragraph of Article 168(1) TFEU reads as follows:

"*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*"

6. This obligation is repeated in Article 35 of the Charter which provides:

"*Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*"

1.2.2. Council Directive 89/622/EEC as amended by Council Directive 92/41/EEC

7. The Union legislature first introduced the ban on the sale of tobacco for oral use in 1992 through an amendment introduced by Directive 92/41/EEC[2] to Council Directive 89/622/EEC[3].

8. The recitals of Directive 92/41/EEC set out the context in which, and the grounds upon which, the ban was introduced. The eleventh recital of Directive 92/41/EEC reads as follows:

"*It has been proved that smokeless tobacco products are a major risk factor as regards cancer and [...] they should therefore carry a specific warning of that risk.*"

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[2] 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 L 158, 11.6.1992, p. 30).

[3] 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 L 359, 8.12.1989, p. 1).

9. According to the twelfth recital, "*scientific experts are of the opinion that the addiction caused by tobacco consumption constitutes a danger meriting a specific warning on every tobacco product.*"

10. According to the thirteenth recital of Directive 92/41/EEC "[...] *new tobacco products for oral use which have appeared on the market in certain Member States are particularly attractive to young people and [...] the Member States most exposed to this problem have already placed total bans on these new tobacco products or intend so to do.*"

11. The fourteenth recital in that preamble states: "*[...]regarding such products, there are differences between the laws, regulations and administrative provisions of the Member States and [...] these products therefore need to be made subject to common rules.*"

12. According to the fifteenth recital in the preamble: "*[...] there is a real risk that the new products for oral use will be used above all by young people, thus leading to nicotine addiction, unless restrictive measures are taken in time.*"

13. The sixteenth recital in the preamble reads as follows: "*[...]in accordance with the conclusions of the studies conducted by the International Agency for Research on Cancer, tobacco for oral use contains particularly large quantities of carcinogenic substances; [...] these new products cause cancer of the mouth in particular.*"

14. According to the seventeenth recital in the preamble to that directive: "*[...]the sales bans on such tobacco already adopted by three Member States have a direct impact on the establishment and operation of the internal market; [...] it is therefore necessary to approximate Member States' laws, regulations and administrative provisions in this area, taking as a base a high level of health protection; [...]the only appropriate measure is a total ban; [...]however, such a ban should not affect traditional tobacco products for oral use, which will remain subject to the provisions of Directive 89/622/EEC, as amended by this Directive, applicable to smokeless tobacco products.*"

15. Article 1, point 5 of Directive 92/41/EEC inserted a new Article 8a into Council Directive 89/622/EEC, which provided as follows:

"Member States shall prohibit the placing on the market of tobacco for oral use as defined in Article 2(4)."

16. Pursuant to Article 2(4) of Directive 89/622/EEC tobacco for oral use was defined as *"all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms – particularly those presented in sachet portions or porous sachets – or in a form resembling a food product."*

1.2.3. Act of Accession of Austria, Finland and Sweden

17. Article 151(1) of 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, 'the Act of Accession') provides:

"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."

18. Chapter X of Annex XV establishing the list provided for in Article 151 of the Act of Accession, entitled 'Miscellaneous', provides:

"(a) The prohibition in Article 8a of Directive 89/622/EEC, as amended [...], concerning the placing on the market of the product defined in Article 2(4) of [the] Directive [...] shall not apply [in the Kingdom of Sweden ...], with the exception of the prohibition to place this product on the market in a form resembling a food product.

(b) [The Kingdom of Sweden] shall take all measures necessary to ensure that the product referred to in paragraph (a) is not placed on the market in the Member States for which Directives 89/622/EEC and 92/41/EEC are fully applicable."

1.2.4. Directive 2001/37/EC

19. The provisions of Directive 89/662/EC were repealed and subsequently recast in Directive 2001/37/EC.[4] The prohibition on tobacco for oral use was re-enacted in

[4] European Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

Article 8 of that Directive. The provision further specified that the prohibition was without prejudice to the exemption granted to Sweden pursuant to Article 151 of the Act of Accession.

1.2.5. Directive 2014/40/EU

20. Following the repeal of Directive 2001/37/EC, by Directive 2014/40/EU[5], the prohibition on tobacco for oral use was re-enacted, in substantially identical terms, by Directive 2014/40/EU.

21. The thirty-second recital to Directive 2014/40/EU recalled as follows: "*Council Directive 89/622/EEC prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC reaffirmed that prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden 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.*"

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

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

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

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

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[5] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p.1, hereinafter "Directive 2014/40/EU", "the Tobacco Products Directive", or "the Directive").

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

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

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

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

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

23. Article 17 of Directive 2014/40/EU provides for the prohibition by Member States of the placing on the market of tobacco for oral use. It reads as follows:

"*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.*"

1.3. National law

24. In the UK legal order, the prohibition on the marketing of tobacco for oral use imposed by Directive 2014/40/EU is provided for in Regulation 17 of the Tobacco and Related Products Regulations 2016 (the "2016 Regulations"). Regulation 17 provides that "*no person may produce or supply tobacco for oral use*". The 2016 Regulations entered into force on 20 May 2016.

2. THE FACTS AND THE PROCEDURE

25. The claimant, Swedish Match AB ("**Swedish Match**" or "**the claimant**"), is a public limited liability company registered in Sweden that manufactures smokeless tobacco products, including a type of oral tobacco known as 'snus'. Snus is a finely ground or cut tobacco sold loose or in small sachet portions and intended to be consumed by placing between the gum and the lip.

26. By application of 30 June 2016 lodged before the Administrative Court of the High Court of Justice (England and Wales), Swedish Match instituted judicial review proceedings challenging the prohibition on the marketing of snus laid down in

Regulation 17 of the 2016 Regulations. The New Nicotine Alliance was granted permission to intervene on 26 January 2017.

27. As part of its claim, the claimant submits that both Regulation 17 of the 2016 Regulations and Article 17 of the Tobacco Products Directive are incompatible with primary Union law. While acknowledging that the validity of the ban on snus was confirmed by the Court in proceedings it had taken previously (Case C-210/03, *Swedish Match*),[6] the claimant argues that the judgment, which was rendered in December 2004, is no longer applicable by virtue of an altered statutory and evidential position. The claimant maintains that the continuing ban on snus breaches the principle of non-discrimination, as well as the principles of proportionality and subsidiarity. It is further alleged that the ban is insufficiently reasoned and amounts to an unjustified restriction on the free movement of goods. Finally, the claimant argues that the ban is inconsistent with the Charter of Fundamental Rights, in particular the rights conferred by Articles 1, 7 and 35, concerning the right to human dignity, the right to respect for private and family life and the right of access to preventative healthcare.

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

> "*Are Articles 1(c) and 17 of Directive 2014/40/EU 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 EU Charter of Fundamental Rights.*"

[6] Case C-210/03, *Swedish Match*, ECLI:EU:C:2004:802, judgment of 14 December 2004.

3. THE PRELIMINARY REFERENCE

3.1. Introduction

29. At the outset, the Commission recalls that in the context of the claimant's first challenge,[7] the Court has previously had an opportunity to carry out an extensive review of the Union legislature's prohibition on snus and to examine its validity in the light of the *same* Union law norms that are the subject of the first, second, fourth and fifth parts of the question referred. Having examined the prohibition against the principles of non-discrimination, proportionality, the duty to give reasons, the free movement of goods and the protection of fundamental rights, the Court in its judgment of 14 December 2004 confirmed the validity of the ban.[8]

30. In arriving at that conclusion the Court underlined that in an area such as tobacco regulation, which entails complex assessments in the field of political, economic and social policy, the Union legislature is conferred with broad discretion. The Court held that only if the adoption of a measure is manifestly inappropriate in relation to the objective which the competent institutions are seeking to pursue could its lawfulness be affected.[9]

31. The Commission submits that in a context where a measure has already been subject to scrutiny and its validity upheld, an obligation to reverse a lawful ban of a harmful and addictive product could only arise in the event of compelling new grounds or changes in circumstances that would render the continuation of the ban manifestly inappropriate. The requirement for compelling new grounds is heightened in the context of the obligations of the Union and the Member States under the WHO Framework Convention on Tobacco Control ("FCTC"), the objective of which is to work towards the continual *reduction of the prevalence* of all forms of tobacco.

32. The Commission maintains that no such compelling grounds or changes in circumstances have occurred since the Court's previous judgment. While the claimant repeatedly seeks to characterise the adoption of Directive 2014/40/EU as a

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[7] Case C-210/03, *Swedish Match*, ECLI:EU:C:2004:802 (hereinafter "*Swedish Match I*").

[8] The prohibition on tobacco for oral use was also upheld in parallel proceedings in Case C-434/02, *Arnold André*, ECLI:EU:C:2004:800.

[9] See Case C-210/03, *Swedish Match I*, paragraph 48 and cases cited. See also, Case C-434/02, *Arnold André*, ECLI:EU:C:2004:800, paragraph 46.

fundamental alteration of the statutory framework depriving the Court's case-law of its continuing applicability and relevance, it is apparent that differences are overstated and the claim contrived. In fact, there is no significant legislative change with respect to the regulation of oral tobacco. While Directive 2001/37/EC was replaced by Directive 2014/40/EU, the latter Directive re-enacted the ban on oral tobacco in identical terms. Equally, oral tobacco remains a harmful and addictive product.[10] The Commission maintains that the grounds that served as a basis for the prohibition of tobacco for oral use continue to justify the maintenance of that prohibition as part of the adoption of the revised Tobacco Products Directive in 2014.

33. The third and sixth parts of the question requests a review of the validity of the ban on tobacco for oral use against the principle of subsidiarity and the provisions of the Charter that had not been raised in the previous challenge. Nevertheless, the Commission considers that the fact that the Court upheld the validity of the internal market basis of the ban implies that action at a Union level was justified.[11] It is further submitted that arguments according to which a ban on a harmful and addictive substance could infringe the right to human dignity (Article 1), the right to respect for private and family life (Article 7) and the right of access to health care (Article 35) are, to say the very least, entirely without merit or foundation.

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[10] The harmful effects of tobacco for oral use were initially documented in the Explanatory Memorandum to Directive 92/41/EEC (pages 5 to 8). The Memorandum refers, in particular, to studies by the International Agency for Research on Cancer (IARC) in 1985 and the Report of the Surgeon General of the United States (1986) according to which oral tobacco contains significant amounts of carcinogenic substances. Health risks were further highlighted in the 1990 "*Report on a new form of smokeless tobacco: moist snuff*" (European Bureau for Action on Smoking Prevention, December 1990). More recently, in 2008, the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has reiterated health risks associated with the use of smokeless tobacco products, all of which contain nicotine, a toxic and addictive substance. Scientific literature has been summarised in the Impact Assessment to the 2014 Tobacco Products Directive (SWD (2012) 452 final), of 19 December 2012 (Part 1, pages 22 to 24 and pages 64 to 66). In 2014, there has been a further study published by the Norwegian Institute of Public Health "Health Risks of Scandinavian snus consumption". English summary available at: https://www.fhi.no/en/publ/2014/helserisiko-ved-bruk-av-snus/.

[11] Case C-547/14, *Philip Morris et al*, ECLI:EU:C:2016:325, paragraphs 219 to 224.

3.2. The reasons underpinning the initial ban of snus

34. It is recalled that the prohibition on the ban of oral tobacco in 1992 was adopted in a context where the product had just began to appear on the Union market after having grown in popularity in the United States during the nineteen eighties.[12] Two Member States had already banned that product, and a third had adopted provisions that, upon their entry into force, would have the same effect.[13] Moreover, it was expected that similar restrictive measures would be introduced by other Member States.[14] The harmful effects of oral tobacco had been confirmed in numerous studies, including by the International Agency for Research on Cancer (IARC), and restrictive measures had been recommended at international conferences and expert meetings.[15]

35. In its judgment in *Swedish Match I*, the Court recognised that in the absence of the Union measures at issue, the Union legislature could justifiably expect such divergences to increase, as Member States take measures intended to reflect the growing awareness of the dangers to health posed by the consumption of tobacco products.[16] In a context where there existed considerable intra-Union trade in tobacco products, the prohibition at a Union level was intended to prevent the heterogeneous development of that market and to strengthen the internal market by ensuring a level playing field preventing distortion resulting from the fact that tobacco for oral use could be marketed in some Member States but not in others.[17]

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[12] See the Proposal for Directive 92/41/EEC (COM (90)538 final), page 5. See also, Report on a new form of smokeless tobacco: moist snuff" undertaken by the European Bureau for Action on Smoking Prevention at the request of the Union, December 1990, p.12.

[13] See COM (90)538 final, page 5. See also recital 14 of Directive 92/41/EEC and *Swedish Match I*, paragraph 37.

[14] Recital 13 of Directive 92/41/EEC.

[15] See COM (90)538 final, page 6. See in particular, reference to the European Conference on Tobacco or Health (1988) and the meetings of the European Committee on Cancer Experts.

[16] Case C-210/03, *Swedish Match I*, paragraph 49.

[17] Case C-210/03, *Swedish Match I*, paragraph 38.

36. Moreover, it was recognised that in adopting internal market measures, the Union legislature is entitled and even required to take public health into account.[18] As the preamble to Directive 92/41/EEC made clear, the approach adopted by the Union legislature took into account the health risks associated with tobacco for oral use and the risks that the product would lead to nicotine addiction, particularly among young persons.[19]

37. The Commission submits that the considerations that underpinned the initial introduction of the ban in 1992 continued to apply when the Directive was replaced in 2001 and again in 2014.[20] Each of the six elements that form part of the question referred will be considered in turn.

3.3. Question 1(i) – the continued application of the ban is compatible with the general principle of non-discrimination

38. The claimant alleges that the maintenance of the ban on snus is incompatible with the principle of equal treatment on the ground that the Directive does not introduce a similar ban on other tobacco or related products, in particular, (1) chewing and nasal tobacco (2) novel tobacco products (3) cigarettes and other tobacco products for smoking and (4) electronic cigarettes.

39. According to settled case-law, the principle of equal treatment, as a general principle of Union law, requires that comparable situations not be treated differently and that different situations not be treated alike, unless such treatment is objectively justified.[21] However, the situation of the products and categories referred to by the claimant is not comparable.

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[18] Such a requirement derives expressly from Article 114(3) TFEU as well as from Article 168(1) TFEU and Article 35 of the Charter. See Case C-547/14, *Philip Morris et al*, ECLI:EU:C:2016:325, paragraphs 60 to 62 and cases cited.

[19] See recitals 15 and 16 of Directive 92/41/EEC. Indeed, in Norway, which does not apply a ban on snus, a recent study shows that consumption of the product is particularly high among young people in the 16 to 24 year age-group). See, Norwegian Institute of Public Health "*Health Risks of Scandinavian snus consumption*", English summary available at: https://www.fhi.no/en/publ/2014/helserisiko-ved-bruk-av-snus/.

[20] Indeed, this view had been expressed in the Impact Assessment to Directive 2014/40/EU at page 76 (last sentence of the first paragraph).

[21] Case C-210/03, *Swedish Match I*, paragraph 70. See also, Case C-434/02, *Arnold André*, ECLI:EU:C:2004:800, paragraph 68.

(1) On the claim concerning a difference in treatment as regards snus on the one hand and nasal or chewing tobacco on the other

40. At the outset, it is observed that the claim according to which the prohibition on snus is discriminatory because a similar ban was not applied to *nasal or chewing tobacco*, had already been raised, considered and rejected by the Court in the context of the claimant's first challenge.[22]

41. The repetition of the claim in the context of the present proceedings rests on an interpretation of the first *Swedish Match* judgment according to which the decisive criterion that permitted the ban to cover snus – but exclude chewing or nasal tobacco – was the *novelty of snus* compared with those other products. It is alleged that such a criterion can no longer be considered to be relevant in a context where Directive 2014/40/EU provides for the regulation of "novel tobacco products" without providing for their prohibition. Moreover, the claimant contests the relevance of "novelty" as the criterion justifying prohibition in a context where scientific evidence would suggest that adverse health effects associated with the consumption of snus are at the lower end of the risk scale when compared with other smokeless tobacco products.[23]

42. The Commission considers such argumentation to be misconceived in a number of respects. **First**: it mischaracterises the *actual basis* upon which the scope of the ban – and its limitation to snus – was defined and upheld by the Court in *Swedish Match 1*. While the fact that snus was new to the markets of a number of Member States constituted an important factor distinguishing it from products (such as nasal and chewing tobacco) that were already existing in the Member States, the suggestion according to which "novelty" on the Union market was *the sole defining criterion* that determined the scope of the ban rests on an incomplete understanding of the basis for the measure and the judgment of the Court. **Second:** It purports to refute the continuing relevance of the "novelty" criterion for distinguishing between snus, on the one hand, and nasal and chewing tobacco, on the other, by relying on provisions of Directive 2014/40/EU concerning "novel tobacco products" that have

[22] Case C-210/03, *Swedish Match I*, paragraph 71.

[23] Reference for a Preliminary Ruling, paragraphs 33 to 35.

no bearing on the contested measure, and by seeking to apply them outside their regulatory context. **Third:** it erroneously implies that the relative toxicity of snus compared with other smokeless tobacco products must be regarded as the decisive criterion for delimiting the scope of the ban. In doing so, it overlooks the internal market factors that must also be taken into account in the definition of the scope of the measure, in particular, the specific market and regulatory differences which were identified by the Union legislature and confirmed by the Court in *Swedish Match I*. Moreover, the claimant's assessment of relative harm is lacking in that it is based on the relative toxicity of the products without taking into account data relating to market appeal of the products and the extent to which they risked becoming embedded within the populations of the Member States and, in particular, among young persons.

43. As explained at paragraphs 34 to 37 above, the Union-wide prohibition on tobacco for oral use arose in a context where a number of Member States had previously established individual bans in order to prevent a harmful and addictive product from becoming embedded within their populations.[24] The subsequent Union law measure, while taking a high level of health protection as its base, was introduced to counter the fragmentation of the tobacco products market which resulted from divergent regulatory approaches of the Member States. The Court expressly examined and confirmed the internal market basis and justification for the ban at paragraphs 37 to 41 of its judgment in *Swedish Match I.*

44. In that context the Commission underlines that at the time the Union ban was introduced, prohibitions on snus had already been adopted in three Member States.[25]

45. Moreover, the market share of snus was considerably greater than that of nasal and chewing tobacco, in which intra-Union trade was only marginal.[26] While snus was considered a "mainstream" product that was novel and attractive to young people,[27]

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[24] See recital 13 of Directive 92/41/EEC and COM (90)538 final, page 5.

[25] See Case C-210/03, *Swedish Match I,* paragraph 37. See also, recital 14 of Directive 92/41/EEC and the Proposal for that Directive, COM (90)538 final.

[26] The Commission had demonstrated these differences in detail at paragraphs 53 to 59 of its submissions lodged as part of *Swedish Match I.* A copy of these submissions are attached as Annex I.

[27] See, COM (90)538 final, page 6: "*This new produce, which has started to be distributed on the market of certain Member States, is marketed in such a way as to attract young consumers*". At page 7: "*This*

nasal and chewing tobacco were considered traditional "niche" products, typically consumed by older persons. Indeed, consumption was essentially limited to certain socio-professional groups in specific geographic areas.[28] In addition, the production of chewing and nasal tobacco was more costly and less efficient since it entailed considerable manual labour.[29] While, intra-Union trade in nasal and chewing tobacco was minimal and diminishing, market indicators suggested tobacco for oral use had considerable market potential. Indeed, the claimant itself has since referred to the very significant market potential for snus.[30]

46. As a measure adopted under (what is now) Article 114 TFEU, the internal market justification served as the legal basis for the restriction and determined its scope. In those conditions, the Union legislature was perfectly entitled and even obliged to take market and regulatory elements into account, when determining the scope of the ban on snus and whether it was warranted to extend such a ban to other smokeless tobacco products. On the basis of such assessments, the Union legislature considered that the market and regulatory framework that was found to justify the imposition of a ban on snus simply did not apply to "nasal" and "chewing" tobacco.

47. Moreover, even with respect to health considerations which underpinned the selection of harmonised norms, the Union legislature had identified differences with respect to the products, as regards their appeal to young persons and the likelihood that their consumption would become widespread within the territories of the Member States.[31] Given their "niche" status and lack of popular appeal, nasal and chewing tobacco were not perceived as posing a comparable widespread threat to public health. Those factors had not substantially changed when the new Directive

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conviction of the Commission has been reinforced by the fact that, according to all available statistical data, this product has a particular attraction for young people".

[28] See COM (90)538 final, pages 4 and 7. See also the Impact Assessment to Directive 2014/40/EU, page 22 (final paragraph). The social groups identified included seafarers, miners and certain sectors of the army. See also, "*Report on a new form of smokeless tobacco: moist snuff*", undertaken by the European Bureau for Action on Smoking Prevention at the request of the Union, December 1990, pages 9, 10 and 12.

[29] Impact Assessment to Directive 2014/40/EU, pages 24 and 76.

[30] See Impact Assessment to Directive 2014/40/EU, pages 24 and.75: "*The producer has pointed to the huge marketing potential for oral tobacco (snus) outside Sweden and indicated that the current ban is equal to a hypothetical annual loss in export revenues to at least 3 bEUR and in the most optimistic scenario the market could even reach 9 bEUR per year*".

[31] COM (90)538 final, pages 4 and 6 to 8. Impact Assessment to Directive 2014/40/EU, page 24.

was adopted in 2014. Nasal and chewing tobacco remained a niche product with only modest Union-wide sales.[32]

48. The Commission doubts the probative value of scientific studies seeking to claim that the relative impact of snus on health would be lower than that of nasal or chewing tobacco, particularly where no account is taken of the market potential of the products and the extent to which they are attractive to – and risk becoming embedded within – the populations of the Member States and, in particular, among young persons. However, even if that claim were accepted, it would still not constitute a basis for extending the ban to such other products, or reversing the ban on tobacco for oral use. As explained at paragraphs 44 to 46, relative harm of tobacco products was not the defining criterion that determined the scope of the ban and the products remain distinguishable in fundamental respects.

49. Indeed the Union legislature's approach to defining the scope of the ban on oral tobacco was upheld by the Court in its judgment in *Swedish Match I.* In highlighting that the novelty of snus on the Union market (with the exception of Sweden) constituted a relevant factor that distinguished it from products that were already available on the Union market, the Court accepted that *relative harm* of such products could not be considered to be the sole decisive criterion in defining its scope. On the contrary, the Union legislature was entitled to have regard to the specific market and regulatory context, as well as to the risk of a product becoming established in the territory of the Member States. It becomes apparent that references to scientific data about comparative harm constitute an attempt at side-stepping the criteria that the Court held constituted the relevant and valid basis for differentiating between different tobacco products. It follows that, in the Commission's submission, such studies do not constitute new information that would put into question the determination made previously by the Court.

50. Furthermore, the fact that Directive 2014/40/EU contains provisions relating to novel tobacco products has no bearing whatsoever either on the right of Member

[32] The Impact Assessment to Directive 2014/40/EU observes (at page 10) that the "*[Smokeless tobacco product] market is dominated by oral tobacco (snus) and concentrated to Sweden, the only Member State where the marketing of this product is allowed [...] Chewing and nasal tobacco account for less than 0.1% of the total tobacco market and sales are concentrated to about 12 companies, mostly SMEs, who also sell other tobacco products.*" At page 76 it is stated: "*despite some market increase [...] these product have still very small markets in the EU*".

States to prohibit such products on health grounds, or indeed on the right of the Union legislature to take restrictive measures on internal market grounds (for example, in a context where a number of Member States have introduced individual bans resulting in a fragmented market). The establishment of the notification procedure for novel tobacco products by Directive 2014/40/EU is intended to ensure the existence of a framework for the monitoring of future developments in the tobacco market at Union level. However, as recital 34 of the Directive makes clear, it has no bearing on subsequent decisions relating either to the authorisation or the prohibition of such products.[33]

51. The Commission recalls that the comparability between "snus", on the one hand and "nasal" and "chewing tobacco" had been the subject of extensive consideration in the context of the claimant's first challenge. The Court had upheld that the product groups were not comparable and that the "relative harm" criterion was not decisive.

52. Nothing in the arguments disclose new circumstances, either factual or regulatory, that would suggest the continuing application of the ban on snus would be invalid by virtue of the fact that the ban did not extend to nasal or chewing tobacco.

(2) On the claim concerning a difference in treatment as regards snus on the one hand and "novel tobacco products" on the other

53. The Commission submits that the claimant's attempt to draw a comparison between the regulation of "snus" and the Directive's provisions on "novel tobacco products" is erroneous. The argument is based on the incorrect premise that "*snus*" and "*novel tobacco products*" refer to comparable concepts. However, that is manifestly not the case. While tobacco for oral use is a specific identifiable tobacco product category, the concept of "novel tobacco products" refers simply to indeterminate products not yet existing on the market.

54. As explained above,[34] the notification obligation imposed in respect of novel tobacco products was introduced to facilitate the monitoring of future developments

[33] The fact that the regulation of "novel tobacco products" cannot and does not affect the possibility to ban specific categories of tobacco products is considered further under section (2) below and also as part of observations on subsidiarity.

[34] See paragraph 50 of these observations.

in the tobacco market at Union level. However, the fact that a particular novel product may be developed and notified in the future neither exempts it from any existing restrictions provided for by the Directive, nor precludes it from being subject to restrictive measures in the future.

55. As regards existing measures, Article 19(4) of Directive 2014/40/EU expressly affirms that novel products entering the market will be subject to the requirements imposed by the Directive.

56. As regards potential future restrictions, recital 34 of Directive 2014/40/EU underlines that the notification obligation applicable to novel products does not affect the entitlement of Member States to ban such products. In this context, it is recalled that Article 24(3) of Directive 2014/40/EU expressly acknowledges the retained competence of individual Member States to prohibit specific categories of tobacco products on public health grounds. In Case C-547/14, *Philip Morris et al*, the Court underlined that Directive 2014/40/EU is not intended to interfere with the *policies of the Member States* concerning the lawfulness of tobacco products as such.[35] Insofar as a number of Member States exercise their retained competence to ban specific categories of tobacco products on health grounds, it cannot be excluded that such a ban would also be introduced at a Union level insofar as it were considered to address fragmented regulation or otherwise strengthen the functioning of the internal market.

57. Thus, the mere fact that Directive 2014/40/EU introduces a notification obligation applicable to potential future products, has no connection with the question as to whether or not Member States or subsequently the Union may maintain in force a ban that relates to a specific category of tobacco product which has been found to be justified on internal market grounds. It follows that the establishment of a reference by the Tobacco Products Directive to "novel tobacco products" cannot be regarded as constituting a new statutory context that would require the Union legislature to reverse the ban on snus.

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[35] Case C-547/14, *Philip Morris Brands and others*, ECLI:EU:C:2016:325, paragraph 88.

(3) On the claim concerning a difference in treatment as regards snus, on the one hand and "cigarettes and tobacco products for smoking", on the other

58. The Commission recalls that the material scope of the ban laid down in Article 17 of Directive 2014/40/EU was identical to that which was in force at the time of the claimant's first challenge and which has been found to be valid. The fact remains that there were specific internal market circumstances and divergences between Member States which justified the limited ban on oral tobacco and which did not extend to cigarettes or smoking tobacco. Thus, for example, while a number of Member States had banned tobacco for oral use in their domestic legal order, no Member State had introduced an outright ban on cigarettes, and there was no indication that such a ban was likely.

59. The Commission considers there has been no factual or legal change in circumstances since the judgment in *Swedish Match I* which would have required the Union to ban cigarettes and smoking tobacco, failing which, it would be precluded from maintaining the ban on snus that has been in force since 1992.

(4) On the claim concerning a difference in treatment as regards snus and e-cigarettes

60. The Commission submits that the claimant's attempt to draw a comparison between the regulation of snus and the Directive's provisions on e-cigarettes is misplaced.

61. In the first, instance, as this Court has already observed in its ruling in Case C-477/14, *Pillbox 38 (UK)*, e-cigarettes display different objective characteristics from those of tobacco products.[36]

62. At the time of the introduction of the ban on oral tobacco, the risks associated with *tobacco consumption were well established.* By contrast, e-cigarettes *do not contain tobacco*, and the extent of the health risks posed by their consumption had *yet to be determined.* For that reason, the Union legislature considered it appropriate and proportionate to adopt a precautionary approach by establishing, pursuant to Article 20 of Directive 2014/40/EU, a number of substantive technical requirements as well

[36] Case C-477/14, *Pillbox 38 (UK) Ltd*, ECLI:EU:C:2016:324, paragraph 36.

as notification obligations on manufacturers and importers that provided a basis for the technology to be better monitored and understood.

63. The Commission therefore considers that the situation of tobacco for oral use was not identical to that of e-cigarettes. As such the fact that the Union legislature has not banned e-cigarettes does not mean that it must reverse its prohibition on snus.

3.4. Question 1(ii) – the continued application of the ban is compatible with the general principle of proportionality

64. Pursuant to the principle of proportionality, measures implemented through Union provisions are required to be appropriate for attaining the objective pursued and not go beyond what is necessary to achieve it.[37]

65. In that context, the Union legislature has been recognised to have broad discretion in fields that entail political, economic and social choices and that require complex assessments to be made. As such, the lawfulness of a measure in such a field can only be affected if that measure is manifestly inappropriate.[38] That test in law is applicable to the measures impugned by the claimant.

66. The Commission recalls that the proportionality of the establishment of the Union prohibition on snus has already been considered and upheld by the Court in the context of the claimant's first challenge to that prohibition.[39] It follows that the maintenance of the ban could only be regarded as disproportionate, insofar as, in the intervening period, new legal or factual circumstances have come to light that would render its continuing application manifestly inappropriate.

67. It is submitted that there has been no such change. Snus remains a harmful and addictive product.[40] With respect to such a product, prohibition operates at a stage before dependence on such products is established and any less preventive measure would be less effective since it is manifestly much more difficult to diminish or

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[37] Case C-210/03, *Swedish Match I*, paragraph 47.

[38] Case C-210/03, *Swedish Match I*, paragraphs 46 to 48.

[39] Case C-210/03, *Swedish Match I*, paragraph 48 and cases cited.

[40] See the reports and studies referred to in footnote 10.

cease addiction after dependence has been formed.[41] The addictive nature of tobacco products underscores the entitlement to take timely preventive action in a context where the risk for future widespread use and dependence is particularly acute.

68. The claimant appears to ground its proportionality claim on the basis that a similar ban does not extend to other smokeless tobacco products with comparable public health impacts. However, as observed with respect to the first part of the question referred, the scope of the Union measure was determined on the basis of a combination of considerations, including the market and regulatory context of snus, its novelty to the market of Member States and its attractiveness to young persons, in accordance with the internal market legal basis upon which the measure was adopted. Moreover, even with respect to health considerations which underpinned the selection of harmonised norms, the Union legislature was entitled to consider differences with respect to the products, as regards their potential appeal to young persons and the likelihood that their consumption would become widespread within the territories of the Member States. In accordance with settled case-law, the proportionality of a measure falls to be assessed in the light of the objectives the measure is intended to pursue. However, for reasons considered extensively above,[42] neither the internal market objectives pursued, nor the health considerations that informed the selection of harmonised norms, required a ban on other categories of smokeless tobacco products.

69. Finally the Commission would reiterate that these specific arguments challenging proportionality on the basis that the ban does not extend to comparable products, are not based on any new factual or legal circumstances that would have arisen since the Court's judgment in *Swedish Match I.* The scope of the prohibition under Article 17 of Directive 2014/40/EU is identical to the ban that the provision replaces and which was held to be proportionate. It follows that suggestions that the introduction of the new Directive constitute a material change in the statutory context that would call into question the Court's previous ruling confirming the proportionality of the restriction are unfounded.

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[41] See, Case C-210/03, *Swedish Match I,* paragraph 57. The need to take preventative action was extensively considered in the Explanatory Memorandum to the Proposal of Directive 92/41/EEC, see COM (90)538 final, page 7.

[42] See observations in relation to the first part of the question, at paragraphs 40 to 52.

70. The claimant's argumentation does not disclose any compelling grounds that would suggest that the continuation of the ban on tobacco for oral use would be incompatible with the principle of proportionality.

3.5. Question 1(iii) – the continued application of the ban is compatible with Article 5(3) TEU and the EU principle of subsidiarity

71. The Commission submits that as the Court has previously upheld the validity of the internal market basis of the ban on oral tobacco, it is implicit that action at a Union level was justified.[43]

72. However, in the present proceedings, the claimant appears to argue that the fact that Directive 2014/40/EU authorises individual Member States to ban specific categories of tobacco products, illustrates that such action can take place at a national level, without the requirement for Union-wide measures.

73. Such an interpretation results from a misconception of the nature and scope of Article 24(3) of the Directive and erroneously conflates the distinct justification for bans established at a Member State level on the one hand, and those imposed at a Union level on the other.

74. In its judgment in Case C-547/14, *Philip Morris et al*, the Court has underlined that Article 24(3) of the Directive does not constitute the source of the right of Member States to ban a tobacco product, but rather clarifies the retained competence of Member States to determine the lawfulness of a particular tobacco product.[44] Indeed, it is clear from Article 24(3) that restrictive measures may be taken on public health grounds, which is primarily a matter of national competence. However, once a number of individual Member States adopt national restrictions, diverse regulation is liable to impede the effective functioning of the internal market, at which stage action at Union level may be justified. Thus the fact that individual Member States may ban tobacco products on health grounds, does not preclude or obviate the need for subsequent action at a Union level on internal market grounds.

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[43] Case C-547/14, *Philip Morris et al*, ECLI:EU:C:2016:325, paragraphs 219 to 224.

[44] Case C-547/14, *Philip Morris Brands and others*, ECLI:EU:C:2016:325, paragraph 88.

75. It is clear that the inclusion of a provision in the Directive acknowledging retained Member State competence in the field of public health does not constitute an altered statutory framework that would render continuing Union action in breach of the principle of subsidiarity. Rather it confirms the continuing scope for both Member State and Union action, each within their respective spheres of competence. It follows that the claimant has advanced no grounds that would suggest that the continuation of the ban on snus as part of the adoption of Directive 2014/40/EU breaches the principle of subsidiarity.

3.6. Question 1(iv) – the continued application of the ban is compatible with Article 296(2) TFEU

76. The fourth part of the first question concerns the claim by Swedish Match that the Union legislature supposedly failed to sufficiently give reasons for the grounds for the ban imposed by Article 17 of Directive 2014/40/EU.

77. While that claim concerns a new legislative act, both the arguments and the provisions at issue are in substance identical to that raised by and impugned by the claimant in its first challenge, and those arguments were considered and rejected by the Court.

78. In the context of the claimant's first action, the Court recalled that the question whether a statement of reasons satisfies the requirements of what is now Article 296(2) TFEU must be assessed with reference not only to the wording of the measure but also to its context and to the whole body of legal rules governing the matter in question. 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 each of the technical choices made by the institution.[45]

79. The Court further observed that the preamble to Directive 92/41/EEC set out clearly the reasons for which a measure prohibiting the marketing of tobacco products for oral use was to be introduced in Directive 89/622/EEC. In particular, it recalled that scientific experts were of the opinion that all tobacco products entail dangers to health and that it had been proven that smokeless tobacco products were a major risk factor as regards cancer. The recitals proceeded to state that new tobacco

[45] *Swedish Match I*, paragraph 64.

products for oral use appearing on the market in certain Member States were particularly attractive to young people, with the risk of their developing an addiction to nicotine if restrictive measures were not taken in time. It was also observed that the Member States most exposed to that problem had already placed total bans on those new products or intended to do so.[46]

80. The Court ruled that in circumstances where Article 8 of Directive 2001/37/EC merely confirmed the continuation of the ban adopted in 1992, the Union legislature was not required to restate all the grounds upon which the initial ban was imposed.[47] The Court found that the reference in the recitals to the original act which contained the initial prohibition, as well as the explanation according to which Sweden was exempt from the prohibition by virtue of Article 151 of the Act of Accession, satisfied the duty to give reasons.

81. Like Article 8 of Directive 2001/37/EC, Article 17 of Directive 2014/40/EU merely confirms the continuation of the ban adopted in 1992. Recital 32 of the 2014 Directive similarly refers to the initial introduction of the ban in Directive 89/622/EEC. The recital further reiterates the purpose of the restriction, namely, to prevent the substance from becoming established within the territory of the Member States. Furthermore, the Commission in the Impact Assessment set out in detail the reasons for which the maintenance of the ban on tobacco for oral use was considered necessary.[48] It is manifest that insofar as the Union legislature was considered to have complied with its obligations to give reasons for the continuation of the ban in the context of the adoption of Directive 2001/37/EC, the same conclusion applies in respect of Directive 2014/40/EU.

82. In those conditions, the Commission submits that arguments according to which the Union legislature is said to have failed to give sufficient reasons for the maintenance of the ban on oral tobacco are unfounded.

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[46] *Swedish Match I*, paragraph 65.

[47] *Swedish Match I*, paragraph 66.

[48] See Impact Assessment to Directive 2014/40/EU, page 75.

3.7. Question 1(v) – the continued application of the ban is compatible with Articles 34 and 35 TFEU

83. The claimant has previously sought and obtained a review of the compatibility of the Union prohibition on snus with the Treaty's provisions on the free movement of goods.

84. In its judgment in *Swedish Match I*, the Court recalled that the free movement of goods is not an absolute right, but could be subject to limitations, including on grounds of public health. The Court ruled that the ban on snus in particular was justified on public health grounds.[49]

85. In the context of the present proceedings, the claimant submits that even if protection of human health may constitute grounds for restricting the free movement of goods, the restriction remains subject to the general principles of non-discrimination, proportionality and the duty to state reasons. It is alleged that in circumstances where these principles are not respected, the ban cannot be considered to be objectively justified or proportionate.

86. The Commission submits that the arguments raised by the claimant, once again, disclose nothing new that would put into question the Court's previous finding according to which the ban on snus was compatible with the Treaty's free movement provisions. Oral tobacco remains a harmful and addictive substance that represents a serious health hazard to the Union's population and particularly to its young people.[50] As such, the restriction continues to be justified.

87. Moreover, the Commission disputes claims according to which the restriction on free movement would not be objectively justified or proportionate because it would breach the principles of non-discrimination, proportionality and the duty to state reasons. In this regard, the Commission refers to its observations addressing each of the claims made in the context of the first four parts of the question referred.

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[49] *Swedish Match I*, paragraphs 60 and 61.

[50] See the reports and studies referred to in footnote 10.

3.8. Question 1(vi) – the continued application of the ban is compatible with Articles 1, 7 and 35 of the EU Charter of Fundamental Rights

88. It appears from the order for reference that the sixth part of the question arises from observations submitted by the intervener, New Nicotine Alliance, questioning the compatibility of the ban on snus with Article 1 (the right to human dignity), Article 7 (the right to respect of personal and family life) and Article 35 of the Charter (Access to healthcare),

89. While the referring court provides limited information as regards the basis upon which it is considered that Article 17 of Directive 2014/40/EU would breach Articles 7 and 35 of the Charter, it provides no details as regards the basis for the alleged breach of the right to human dignity enshrined in Article 1 of the Charter. In accordance with settled case-law, requests for preliminary rulings made pursuant to Article 267 TFEU, are required to include at least some explanation of the reasons for which a ruling on the referred Union law provisions is requested.[51] In the absence of such reasons as regards Article 1 of the Charter, the Commission has doubts concerning the admissibility of the request insofar as it concerns that provision.

90. In any event, as a general observation, the Commission expresses doubts that measures restricting access to a harmful and addictive product could seriously be suggested to breach the right to human dignity (Article 1) or indeed to the right of access to healthcare (Article 35).

91. Concerning Article 1 of the Charter, it is not disputed that the contested measure has the effect of restricting the availability of – and therefore limiting the choice to purchase – an addictive product that is harmful to human health. However, the right enshrined in Article 1 of the Charter does not negate the right of the Union legislature to adopt harmonised norms – even if the norms selected have the effect of limiting the purchasing opportunities of consumers. The Commission rejects arguments according to which the limitation of access to a harmful and addictive tobacco product would undermine the inalienable value or status of a human being, within the meaning of Article 1 of the Charter.

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[51] Case C-370/12, *Pringle*, ECLI:EU:C:2012:756, paragraphs 84 and 85.

92. Neither is it immediately clear how a ban on tobacco for oral use would be considered to affect the right to private and family life enshrined in Article 7. On the contrary, by seeking to restrict a source of premature illness and death, the contested measure ought to be regarded as contributing to the enjoyment of the right to private and family life. However, even it is were considered to engage Article 7, the Commission recalls that pursuant to Article 52(1) of the Charter, limitations may be imposed on the exercise of rights such as those enshrined in Article 7 of the Charter, as long as the limitations are provided for by law, respect the essence of those rights and freedoms, and, subject to the principle of proportionality, are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

93. Article 17 of Directive 2014/40/EU fully complies with those requirements. As the Court has already recognised on several occasions, the protection of public health constitutes, as follows also from Article 9 TFEU and the second sentence of Article 35 of the Charter, an objective of general interest justifying, where appropriate, a restriction of a fundamental freedom.[52] Moreover, the measure is laid down in law and complies fully with the principle of proportionality.[53]

94. As regards Article 35, the Commission utterly rejects arguments according to which the ban on a harmful and addictive product could be considered inconsistent with the Union's obligations to ensure a high level of health protection in the definition and implementation of its policies and activities. On the contrary, the Commission submits that the measure positively contributes to the objective of ensuring a high level of public health in the Union.

95. The Commission rejects arguments according to which tobacco for oral use ought to be regarded as a substance that promotes public health on the ground that it is to be considered a "less harmful" alternative to smoking tobacco. First, the mere fact that oral tobacco may be *less harmful* than smoking tobacco does not make it either safe or harmless. Indeed, to the Commission's knowledge, even the claimant does not

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[52] See, for example, Case C-544/10, *Deutsches Weintor eG*, ECLI:EU:C:2012:526, paragraph 49.

[53] See observations on proportionality at, paragraphs 64 to 70.

characterise its product as benign.[54] Second, there is no consensus according to which oral tobacco is to be regarded as an aid to smoking cessation. On the contrary, considerable doubt has been raised in opposition to such claims.[55] In any event, numerous cessation aids exist which are free of tobacco and which have been assessed in terms of their quality, safety and efficacy in facilitating the cessation of smoking tobacco without entailing the risks that are inherent in the consumption of tobacco for oral use.[56] However, most fundamentally, even if it were accepted (*quod non*) that tobacco for oral use could play a role in smoking reduction, it could not be considered to promote public health, insofar as it could stimulate the initiation of tobacco consumption amongst individuals who did not previously consume such products.[57] In this context, the Commission recalls that tobacco for oral use has been marketed as a product attractive to young people, rather than as an aid to smoking cessation.[58]

96. The Commission therefore maintains that Articles 1, 7 and 35 of the Charter do not preclude the prohibition on tobacco for oral use provided for in Article 17 of the Directive.

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[54] See Impact Assessment to Directive 2014/40/EU, page 75: "*Although industry emphasises that oral tobacco is less harmful than [factory manufactured cigarettes], they do not claim that it is harmless*".

[55] An analysis of research on substitution and doubts expressed in relation to such claims are set out in the Impact Assessment to Directive 2014/40/EU, pages 66 to 69 (in the context of assessing policy option 1). In particular, it is noted that the correlation between smoking and smokeless tobacco consumption varies in different studies. In particular at page 67 it is observed that: "*SCENIHR has concluded that it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco from countries where oral tobacco is available to EU countries where oral tobacco is not currently available*".

[56] An analysis of research on cessation aids is out in the Impact Assessment to Directive 2014/40/EU, pages 66 to 69. Indeed, a number of nicotine containing cessation aids have undergone assessments as to quality, safety and efficacy, permitting them to be authorised as medicinal products. An illustrative list of such products are accessible at the MRI product index: https://mri.cts-mrp.eu/Human/Product/FullTextSearch?searchTerm=nicotine&includeProductDetails=false&includeSPCResults=true&includeSPCResults=false&includePARResults=true&includePARResults=false&includePARSUMResults=true&includePARSUMResults=false&includeFPLResults=false&includeFLBResults=false&includeFPIResults=false

[57] Impact Assessment to Directive 2014/40/EU, pages 67 and 75.

[58] See COM (90)538 final, pages 5 to 7. At page 6: "*This new product, which has started to be distributed on the market of certain Member States, is marketed in such a way as to attract young consumers*". At page 7: "*This conviction of the Commission has been reinforced by the fact that, according to all available statistical data, this product has a particular attraction for young people*". See also, Impact Assessment to Directive 2014/40/EU, pages 68 and 75. Indeed it is noted that "*Norway has [...] pointed to difficulties from a communication point of view of advocating non-use of oral tobacco (snus) among young people and at the same time advocating the use of the same product as a smoking cessation tool for another group.*"

4. CONCLUSION

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

Examination of the question referred has disclosed nothing capable of affecting the validity of Articles 1(c) and 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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