Reports of Cases

OPINION OF ADVOCATE GENERAL
EMILIOU
delivered on 30 January 2025 [1]

Case C-759/23

PJ Carroll & Company Ltd,
Nicoventures Trading Ltd
v
The Minister for Health,
Ireland,
Attorney General,
joined parties:
Philip Morris Ltd,
Philip Morris Products SA,
Philip Morris Manufacturing & Technology Bologna SpA

(Request for a preliminary ruling from the High Court (Ireland))

(Reference for a preliminary ruling – Internal market – Public health – Directive 2014/40/EU – Manufacture, presentation and sale of tobacco and related products – Articles 7 and 12 – Validity of Delegated Directive (EU) 2022/2100 – Article 290(1) TFEU – Delegated powers of the European Commission – Essential elements – Novel tobacco products – Heated tobacco products – Ingredients – Labelling)

I. Introduction

1. The present case concerns the interpretation of certain provisions of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. [2]

2. Directive 2014/40 aims to improve the functioning of the internal market for those products, whilst assuring a high level of public health protection, especially for young people. To that end, it provides, inter alia, that (i) Member States should prohibit the placing on the market of tobacco products with a characterising flavour ('the flavouring ban') and (ii) each unit packet and any outside packaging of tobacco products should carry certain health warnings and information messages ('the labelling obligation') (together, 'the obligations at issue').

[1] Original language: English.
[2] OJ 2014 L 127, p. 1.

3. At the same time, it provides for certain *exemptions* from the obligations at issue, in particular, for tobacco products which are mainly consumed by older consumers and small groups of the population. However, the directive also authorises the European Commission to adopt *delegated acts* withdrawing the exemptions at issue for a particular product category ('the withdrawal of exemptions'), if there is a substantial change of circumstances, meaning a significant increase in either the sales volumes of that product category or the level of prevalence of use by young consumers.

4. The present case raises the issue as to whether the Commission could, through Delegated Directive (EU) 2022/2100,[3] validly withdraw the exemptions in respect of a newly created product category, namely heated tobacco products. In order to answer that question, it should be ascertained whether, in doing so, the Commission has exceeded the powers delegated to it by the EU legislature through Directive 2014/40.

5. That is, naturally, an issue of constitutional significance since the principle of institutional balance, a key characteristic of the institutional structure of the European Union, requires that each of the institutions exercise its powers with due regard for the powers of the other institutions.[4] It is, thus, important that, when doubts such as those raised by the referring court emerge, the Court can verify whether, when exercising powers delegated to it under Article 290 TFEU, the Commission has respected the limits of the delegation of powers, as 'explicitly defined' in the main act.[5]

II. Legal framework

A. European Union law

1. Directive 2014/40

6. Recitals 8, 15, 19, 22 to 24, 26, 34, 35, 51 and 52 of Directive 2014/40 read:

'(8) In accordance with Article 114(3) [TFEU], a high level of health protection should be taken as a base for legislative proposals … Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people.

…

(15) The lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. … Without harmonisation, the obstacles to the smooth functioning of the internal market are expected to increase in the coming years, taking into account the implementation of the [World Trade Organization's Framework

[3] Delegated Directive of 29 June 2022 amending Directive 2014/40 as regards the withdrawal of certain exemptions in respect of heated tobacco products (OJ 2022 L 283, p. 4).

[4] See, for example, judgment of 22 November 2022, *Commission* v *Council (Accession to the Geneva Act)* (C-24/20, EU:C:2022:911, paragraph 83).

[5] See, for example, judgment of 26 July 2017, *Czech Republic* v *Commission* (C-696/15 P, EU:C:2017:595, paragraphs 49 and 51).

Convention on Tobacco Control ('FCTC')] and the relevant FCTC guidelines[6] throughout the Union and in the light of experience gained in other jurisdictions outside the Union. The FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

…

(19) Considering this Directive's focus on young people, tobacco products other than cigarettes and roll-your-own tobacco, should be granted an exemption from certain requirements relating to ingredients as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people.

…

(22) Disparities still exist between national provisions regarding the labelling of tobacco products …

(23) Such disparities are liable to constitute a barrier to trade and to impede the smooth functioning of the internal market in tobacco products, and should, therefore, be eliminated. …

(24) Adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. …

…

(26) For tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers and small groups of the population, it should be possible to continue to grant an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people. …

…

(34) All tobacco products have the potential to cause mortality, morbidity and disability. … It is, therefore, important to monitor developments as regards novel tobacco products. …

(35) In order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive.

…

[6] WHO Framework Convention on Tobacco Control, Guidelines for implementation, Article 5.3, Article 8, Articles 9 and 10, Article 11, Article 12, Article 13, Article 14.

(51) In order to ensure that this Directive is fully operational and to adapt it to technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of … withdrawing certain exemptions granted to tobacco products other than cigarettes and roll-your-own tobacco …

(52) The Commission should monitor the developments as regards the implementation and impact of this Directive and submit a report by 21 May 2021, and when necessary thereafter, in order to assess whether amendments to this Directive are necessary. The report should include information on … market developments concerning novel tobacco products, market developments that amount to a substantial change of circumstances …'

7. Article 2 of Directive 2014/40 includes the following definitions:

'(4) "tobacco products" means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

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

…

(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;

…

(28) "substantial change of circumstances" means an increase of the sales volumes by product category by at least 10% in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed [2.5]% of total sales of tobacco products at Union level'.

8. Article 5(6) of Directive 2014/40, concerning reporting of ingredients and emissions, provides:

'6. Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups,

including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Member States shall also require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015. Member States shall provide any other sales volume data that is available to them.'

9. Article 7 of Directive 2014/40, entitled 'Regulation of ingredients', before being amended by Delegated Directive 2022/2100, provided:

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

…

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

…

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

…'

10. Articles 9 and 10 of Directive 2014/40 lay down, respectively, the 'general warnings and information messages on tobacco products for smoking' and the 'combined health warnings for tobacco products for smoking' that unit packets and outside packaging of tobacco are to carry.

11. Article 11 of Directive 2014/40 (entitled 'Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco'), before being amended by Delegated Directive 2022/2100, stated:

'1. Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. …

…

6. The Commission shall adopt delegated acts in accordance with Article 27, to withdraw the possibility of granting exemptions for any of the particular product categories referred to in paragraph 1 if there is a substantial change of circumstances as established in a Commission report for the product category concerned.'

12. Article 19 (entitled 'Notification of novel tobacco products') of Directive 2014/40 reads:

'1. 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. …

…

2. … Member States shall make all information received pursuant to this Article available to the Commission.

3. Member States may introduce a system for the authorisation of novel tobacco products. …

4. Novel tobacco products placed on the market shall respect the requirements of this Directive. Which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking.'

13. Article 28 (entitled 'Report') of Directive 2014/40 provides:

'1. No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

…

2. In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:

…

(c) market developments which constitute a substantial change of circumstances;

…

3. The report shall be followed-up by proposals for amending this Directive, which the Commission deem necessary to adapt it – to the extent necessary for the smooth functioning of the internal market – to developments in the field of tobacco and related products, and to take into account new developments based on scientific facts and developments concerning internationally agreed standards for tobacco and related products.'

2. Delegated Directive 2022/2100

14. Article 1 of Delegated Directive 2022/2100 amends Article 7(12) and Article 11 of Directive 2014/40 as follows.

15. As regards Article 7(12) of Directive 2014/40, 'heated tobacco products' was added to the list of categories (namely, cigarettes and roll-your-own tobacco) that, under the first subparagraph of that provision, are not exempted from the prohibitions laid down in paragraphs 1 and 7 of Article 7. In addition, a second subparagraph was added to the provision, stating:

'For the purposes of the first subparagraph, "heated tobacco product" means a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking'.

16. In turn, Article 11 has been amended in two respects. First, the title of the provision was replaced by the following: 'Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products'. Second, in the first subparagraph of paragraph 1 thereof, 'heated tobacco products as defined in Article 7(12), second subparagraph' were added to the list of categories (namely, cigarettes, roll-your-own tobacco and waterpipe tobacco) that may not be exempted from the obligations to carry the information message and warnings provided for in Article 9(2) and Article 10 of the directive.

B. Irish law

17. Ireland transposed Delegated Directive 2022/2100 with the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023 ('the 2023 Regulations').

III. Facts, national proceedings and the questions referred for a preliminary ruling

18. In January 2023, PJ Carroll & Company Limited and Nicoventures Trading Limited, and Philip Morris Limited, Philip Morris Products SA and Philip Morris Manufacturing & Technology Bologna SpA (together, 'the applicants in the main proceedings'), brought proceedings before the High Court (Ireland) seeking, inter alia, a declaration that the 2023 Regulations which transpose Delegated Directive 2022/2100 into Irish law are invalid. The applicants took the view that Delegated Directive 2022/2100 was invalid since the Commission had exceeded the powers delegated to it under Directive 2014/40. In particular, they argue that the Commission was not empowered to create a new product category from those which fall within the definition of 'novel tobacco products', and that it could not withdraw the exemptions in respect of that new category of products. In their view, the provisions of Directive 2014/40 which authorise the Commission to do so do not apply to novel tobacco products.

19. Harbouring doubts as to the proper interpretation of the relevant provisions of EU law, the High Court decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is [Delegated Directive 2022/2100] invalid on the basis that it goes beyond the powers granted by [Article] 7(12) and [Article] 11(6) of Directive [2014/40], in [the] light of Article 290 TFEU, and taking into account Article 2(14), [Article] 19 and [Article] 28 of Directive [2014/40]?

(2) Is [Delegated Directive 2022/2100] invalid on the basis that the Commission was not entitled to conclude that there was a substantial change of circumstances within the meaning of Article 7(12) and/or [Article] 11(6) and/or [Article] 2(28) of Directive [2014/40]?'

20. Written observations in the present proceedings have been submitted by the applicants in the main proceedings, Ireland, the French and Italian Governments and the Commission. Those parties also presented oral argument at the hearing held on 28 November 2024.

IV. Analysis

21. By its two questions, the referring court seeks from the Court of Justice a review of the validity of Delegated Directive 2022/2100, withdrawing the exemptions regarding the flavouring ban and the labelling obligation ('the exemptions') for heated tobacco products, a new category of products created by the Commission.

22. The referring court raises two issues in that regard. The first issue is of an institutional and substantive nature: with the delegated directive, has the Commission exceeded the powers delegated to it under the main act? The second one is more procedural and circumstantial in nature: was the condition relating to a 'substantial change of circumstances' satisfied?

23. For the sake of clarity, I shall emphasise, from the outset, that it is undisputed that heated tobacco products constitute 'novel tobacco products' for the purposes of Directive 2014/40. Indeed, they do not fall into any of the specific categories defined in Article 2 thereof and were first placed on the market after 19 May 2014.

24. It is also quite obvious that, in principle, the provisions of that directive which concern the *obligations at issue* apply to novel tobacco products. Indeed, pursuant to Article 7(1) of Directive 2014/40, the flavouring ban applies to 'tobacco products', which obviously encompasses novel tobacco products. Similarly, according to Article 9(2) and Article 10 of Directive 2014/40, the labelling obligations apply to 'tobacco products for smoking', which also includes novel tobacco products, if they are products for smoking.

25. By the same token, novel tobacco products were (or could be) *exempted* from the obligations at issue since they are 'tobacco products other than cigarettes and roll-your-own tobacco' (under Article 7(12) of Directive 2014/40) and, if for smoking, also 'tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco' (under Article 11(1) of Directive 2014/40).

26. What is in dispute is, in essence, the Commission's authority to withdraw, by means of a delegated act, the exemptions in respect of novel tobacco products.

A. First question

27. By its first question, the referring court essentially asks whether, by creating a new category of product (heated tobacco products) and withdrawing the exemptions for that category, the Commission has exceeded the powers delegated to it by the EU legislature in Article 7(12) and Article 11(6) of Directive 2014/40.

28. The applicants in the main proceedings and the Italian Government argue that, with Delegated Directive 2022/2100, the Commission has gone beyond the delegation of power set out in Directive 2014/40 and amended some essential elements thereof. By contrast, Ireland, the French Government and the Commission take the opposite view, arguing that the provisions on the withdrawal of exemptions also apply to novel tobacco products.

29. In the following sections, I shall explain why, despite the arguments put forward by the applicants in the main proceedings and the Italian Government having some force, I am nonetheless bound to conclude that, by adopting Delegated Directive 2022/2100, the Commission did not exceed the powers delegated to it by the EU legislature.

1. Article 290(1) TFEU and the 'essential elements' of the main act

30. At the outset, I should say that, in the present proceedings, the parties who submitted observations discussed at length whether or not Delegated Directive 2022/2100 has amended some 'essential elements' of the main act (Directive 2014/40) within the meaning of Article 290(1) TFEU. That provision states:

'A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.

The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.'

31. According to settled case-law, the 'essential elements' of a legislative act, within the meaning of Article 290(1) TFEU, are those which, in order to be adopted, 'require *political choices* falling within the responsibilities of the EU legislature'.[7] That concept cannot be given an overly broad scope, since it must be reserved for 'provisions which are intended to give concrete shape to the fundamental guidelines of [the relevant EU] policy'.[8] That is the case, in particular, when the element in question 'requires the conflicting interests at issue to be weighed up on the basis of a number of assessments, or [when] the fundamental rights of the persons concerned may be interfered with to such an extent that the involvement of the EU legislature is required'.[9]

32. In the light of the above, I am of the view that Delegated Directive 2022/2100 does *not* amend any essential elements of Directive 2014/40.

33. As far as the provisions which are relevant in the present proceedings are concerned, to my mind, there are essentially three key political choices made by the EU legislature.[10] First, in principle, flavouring ingredients should be removed from the products,[11] and unit packets and outside packaging of products should carry health warnings and information messages.[12] Second, some exemptions in respect of those obligations should (or may be) granted to products which are 'mainly consumed by older consumers and small groups of the population'.[13] Third, those exemptions should be withdrawn when there is a 'substantial change of circumstances' in terms of sales volumes or consumption patterns of young people.[14]

7 See, for example, judgment of 11 May 2017, *Dyson* v *Commission* (C-44/16 P, EU:C:2017:357, paragraph 61 and the case-law cited). Emphasis added.

8 See judgment of 27 October 1992, *Germany* v *Commission* (C-240/90, EU:C:1992:408, paragraph 37).

9 See, inter alia, judgment of 26 July 2017, *Czech Republic* v *Commission* (C-696/15 P, EU:C:2017:595, paragraph 78).

10 On this matter, similarly, see Opinion of Advocate General Kokott in *Philip Morris Brands and Others* (C-547/14, EU:C:2015:853, points 253 and 254).

11 See, in particular, recital 15 of Directive 2014/40.

12 Recitals 22 to 25 of Directive 2014/40.

13 Recitals 19 and 26 of Directive 2014/40.

14 Ibid. See also recitals 51 and 52 of Directive 2014/40.

34. It seems to me that none of those key choices is affected by Delegated Directive 2022/2100, which constitutes a mere implementation of those choices in respect of a new type of product. The decision to withdraw the exemptions is, in fact, a rather technical exercise in which the Commission enjoys fettered technical discretion to verify whether the conditions for the withdrawal (set out in Article 2(28) of Directive 2014/40) are satisfied, and no policy discretion (under Article 7(12) and Article 11(6) of Directive 2014/40[15] with regard to whether the exemptions should be withdrawn.[16]

35. In addition, the argument that how novel tobacco products should be regulated under Directive 2014/40 requires major policy choices is no more convincing.[17] Indeed, the EU legislature has already (i) taken the view that 'all tobacco products have the potential to cause mortality, morbidity and disability [and a]ccordingly, their manufacture, distribution and consumption should be regulated' (recital 34 of Directive 2014/40); (ii) made clear that 'novel tobacco products … are tobacco products as defined in [Directive 2014/40]' (recital 35 thereof); and (iii) decided that novel tobacco products 'should comply with the requirements of [Directive 2014/40]' (also recital 35 thereof).

36. It is, therefore, clear that the Commission did not exceed its delegated power by touching upon an essential element of the main act, in infringement of Article 290(1) TFEU. I shall now turn to the question of whether, when adopting Delegated Directive 2022/2100, the Commission complied with the 'objectives, content, scope and duration of the delegation of power' included in Article 7(12) and Article 11(6) of Directive 2014/40. Indeed, aside from the issue of whether the delegated directive respects the limits set out in Article 290(1) TFEU (which apply to all delegated acts), there is also the issue of whether it respects the limits placed by the EU legislature in the relevant provisions of Directive 2014/40.

37. To that end, I shall now discuss the meaning and scope of Article 7(12) and Article 11(6) of Directive 2014/40. It is – I must say – not an easy task. Indeed, the wording of certain provisions of Directive 2014/40 is to some extent ambiguous and, whichever interpretative approach is taken in respect of those provisions, their interaction is not always clear.

38. In the following sections, I shall explain why I take the view that, on balance, the arguments confirming the Commission's authority to withdraw the exemptions at issue for novel tobacco products are more persuasive than those contesting it.

2. A literal interpretation of Article 7(12) and Article 11(6)

39. It seems to me to be logical to start my analysis by examining the wording of Article 7(12) and Article 11(6) of Directive 2014/40.

[15] In particular, both provisions state that the Commission '*shall* adopt delegated acts … if there is a substantial change of circumstances' (emphasis added).

[16] For the distinction between technical discretion and policy discretion, see my Opinion in *ECB* v *Crédit lyonnais* (C-389/21 P, EU:C:2022:844, points 47 to 53).

[17] In this context, I wish to point out that, above, I used the term 'key' or 'major' policy choices since it follows from the case-law referred to in point 31 above that Article 290(1) TFEU does not preclude the EU legislature from delegating powers which, for the exercise thereof, require the Commission to make some (strictly framed) discretionary choices. See, to that effect, judgment of 26 July 2017, *Czech Republic* v *Commission* (C-696/15 P, EU:C:2017:595, paragraph 52).

40. Article 7(12) of Directive 2014/40, I recall, provides that 'tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7' and that 'the Commission shall adopt delegated acts … to withdraw that exemption for a particular product category, if there is a substantial change of circumstances …'. Similarly, Article 11(6) of Directive 2014/40 provides that 'the Commission shall adopt delegated acts … to withdraw the possibility of granting exemptions for any of the particular product categories referred to in paragraph 1 if there is a substantial change of circumstances …'.

41. Two textual elements seem to me to be of particular significance in this context.

42. First, both provisions establish a clear link between the categories of products which *benefit* (or may benefit) from exemptions and those for which the exemptions may be *withdrawn*. The link in Article 7(12) of Directive 2014/40 is structural: the same paragraph of that provision (i) lays down an exemption and (ii) introduces the possibility to withdraw that exemption. The link in Article 11(6) of Directive 2014/40 is even more explicit, being made through a *renvoi* to the categories of products concerned (same categories for exemption and withdrawal of the exemption). To my mind, the existence of this link is an element which, quite obviously, supports the interpretation of those provisions put forward by Ireland, the French Government and the Commission.

43. Second, both provisions refer to '*particular* product categories'.[18] The applicants in the main proceedings and the Italian Government argue that that expression should be understood as referring to the tobacco products which belong to the various categories defined in Article 2 of Directive 2014/40. They contend that the Commission is, consequently, not empowered to create new categories of tobacco products by isolating a group of products (*in casu*, heated tobacco products) from those falling within the definition of 'novel tobacco products'.

44. I am not convinced by those arguments.

45. The term 'particular' is not defined in Directive 2014/40. Nevertheless, in the light of the overall scheme of the directive, it seems to me to be reasonable to understand it as a synonym of the terms 'given', 'specific' or 'certain'.[19] In essence, what the two provisions signify is, in my view, that any withdrawal of exemptions should concern only the category of products in relation to which a significant change of circumstances has occurred. The withdrawal cannot extend to other – similar or related – products. The withdrawal of exemptions is, as explained, a rather mechanical exercise in which the Commission enjoys limited leeway.

46. I do not see any textual or contextual element in Directive 2014/40 to suggest that the term 'particular' should be read as meaning 'pre-existing' or 'already defined'. Nor does that follow from the ordinary meaning of the term.

[18] Emphasis added.

[19] In fact, the term 'certain category' appears in Article 24(3) of Directive 2014/40. That provision allows Member States to 'prohibit a certain category of tobacco or related products [which comply with the directives], on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health'. Asked at the hearing whether that provision is applicable to novel tobacco products, the applicants in the main proceedings did not take a firm position (first, they answered in the negative and subsequently admitted that perhaps it could be applicable), whereas the Italian Government took the view that it does apply. For my part, I find no ground on the basis of which Article 24(3) of Directive 2014/40 could be considered to be inapplicable to novel tobacco products.

47. By the same token, nowhere in the directive do I find any indication that the term 'product categories' in Article 7(12) and Article 11(6) of Directive 2014/40 refers to those defined in Article 2 thereof.

48. In that respect, it should not be overlooked that, in order to first define the products which fall within its scope, but also to determine what sets of rules apply to which products, Directive 2014/40 employs a variety of definitions to categorise the relevant products. The products concerned are, in fact, combined into various groups, subgroups and categories. With some simplification, those are as follows: (i) the directive applies to 'tobacco products' and certain tobacco-related (that is to say, non-tobacco) products;[20] (ii) tobacco products may be divided into 'smokeless tobacco products' and 'tobacco products for smoking'; (iii) tobacco products belonging to those two groups are then divided into specific categories; and (iv) products that do not fall into the existing specific categories and that enter the market after the date of transposition of the directive are considered 'novel tobacco products'.[21]

49. The complexity of this scheme is compounded by two additional elements. First, Directive 2014/40 acknowledges that there are products which may, because of their characteristics or intended use, fall into two or more specific categories.[22] Second, the directive indicates that 'novel tobacco products' may fall under the definition of smokeless tobacco products or of tobacco products for smoking.[23]

50. Against that backdrop, I agree with the applicants in the main proceedings that the Commission is not empowered to alter the groups and categories set out in Directive 2014/40, or vary the substantive provisions applicable to them. However, it does not follow from the above that the list of 'particular' categories is closed and exhaustive. If that were the case, Article 2(14)(a) of Directive 2014/40 – according to which novel tobacco products are those that, inter alia, '[do] 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'[24] – would be oddly formulated since those categories essentially exhaust those set out in Article 2. In fact, the wording suggests that, potentially at least, there may well be *other* categories of tobacco products. Furthermore, if the listed categories correspond to those which – according to the applicants in the main proceedings and the Italian Government – form the 'particular categories' referred to in Article 7(12) and Article 11(6) of Directive 2014/40, why has that expression not also been used in Article 2(14)(a) thereof?

51. The judgment of the Court in *Planta Tabak*[25] – referred to by the applicants in the main proceedings – does not call that into question. In that judgment, the Court merely confirmed that (i) certain product categories defined in Article 2 of Directive 2014/40 are indeed 'product categories' within the meaning of Article 7 thereof; and (ii) the concept of 'product categories' should be interpreted consistently throughout the directive. I fail to see any passage of that judgment which supports the view that product categories can only be those defined in Article 2 of the directive.

[20] Products such as 'herbal products for smoking', 'electronic cigarettes' and 'refill containers'.

[21] Article 2(14) of Directive 2014/40.

[22] See recital 9 and Article 2(13) of Directive 2014/40.

[23] Article 19(4) of Directive 2014/40.

[24] Emphasis added.

[25] Judgment of 30 January 2019 (C-220/17, EU:C:2019:76, paragraphs 60 to 67).

52. In fact, it is true – as emphasised by the applicants in the main proceedings – that no provision expressly allows the Commission to create new product categories. However, it is equally true that no provision expressly prohibits it from doing so. Thus, whether the Commission can validly do so depends, I would say, on whether that may be considered *necessary* to ensure the correct execution of the powers delegated to it under Article 7(12) and Article 11(6) of Directive 2014/40.

53. If those provisions are also applicable to novel tobacco products, then the Commission *must* be able to create a new category of products. Indeed, as explained, those provisions empower the Commission to take action only with regard to particular categories of products and it would be absurd to think of 'novel tobacco products' as one of those categories. Otherwise, it would mean that a significant rise in the sales of a new product would require the Commission to withdraw the exemptions in respect of *all* novel tobacco products, including those which (in terms of composition, mode of consumption, organoleptic features, and so forth) have little in common with the former and which, moreover, may also have very limited sales. That would be an absurd reading of the directive.

54. In the light of the foregoing, the crucial question is, in my view, whether there are other elements in Directive 2014/40 which, in addition to what I have noted in point 42 above, indicate that the delegation of powers to the Commission to withdraw the exemptions also covers novel tobacco products.

55. I think there are such elements.

3. A contextual interpretation of Article 7(12) and Article 11(6) – first part

56. First, I am of the view that, on the whole, a contextual interpretation of Article 7(12) and Article 11(6) of Directive 2014/40 suggests that the Commission may also withdraw the exemptions in respect of some novel tobacco products. Indeed, although there are elements which may suggest another interpretation of those provisions, those pointing to more room for manoeuvre for the Commission in implementing the obligations at issue are more persuasive than those doing the opposite

57. It is, first of all, uncontested that the rules set out in Directive 2014/40 *generally* apply to novel tobacco products. In that regard, Article 19(4) of the directive provides that 'novel tobacco products placed on the market shall respect the requirements of this Directive', and that the specific provisions of the directive which apply to novel tobacco products '[depend] on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking'. That rule is echoed by recital 35 of the directive, according to which 'in order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive'.

58. In the light of that, and considering that (i) the rules on the obligations at issue and on the exemptions at issue are clearly applicable to novel tobacco products;[26] and (ii) the rules on withdrawal do not expressly exclude 'novel tobacco products',[27] it appears reasonable to assume that novel tobacco products must also fall within the scope of the rules on the *withdrawal* of the exemptions.

[26] See above, points 24 and 25 of this Opinion.

[27] See above, points 40 and 42 of this Opinion.

59. After all, had the EU legislature wished to make the obligations at issue inapplicable vis-à-vis novel tobacco products, it would have been more straightforward to directly exclude those products from the scope of the relevant provisions, rather than going through the combination of an obligation in principle and a non-withdrawable exemption from that obligation.

60. That view seems to be corroborated by the fact that, in respect of the obligations at issue, Directive 2014/40 includes some special rules for certain groups or categories of products such as, for example, 'products with characterising flavour with a higher sales volume', [28] or 'electronic cigarettes [and] refill containers'. [29] More generally, where certain products are subject to specific rules, thereby derogating from the general or sectorial regime, the provisions of the directive do so explicitly. [30]

61. Furthermore, my findings also appear to be more consistent with the legal framework laid down in the FCTC and its guidelines. The framework convention is, as stated in recital 7 of Directive 2014/40, binding on the Union and its Members States and should, therefore, be implemented when laying down rules on matters such as those governed by Directive 2014/40. As regards the FCTC guidelines, although they do not have binding force, they are nonetheless intended, in accordance with Articles 7 and 9 of the FCTC, to assist the contracting parties in implementing the provisions of that convention. [31] For that reason, the EU legislature has decided duly to take them into account in Directive 2014/40. [32]

62. Although the FCTC guidelines refer, in various points, to novel tobacco products, [33] they do not suggest any more lenient treatment of those products in comparison to existing products, in particular with regard to measures concerning ingredients and labelling. [34] The same holds true for the FCTC: no provision in that convention suggests that those products may be temporarily exempted from the general rules while their impact on the market and public health is being assessed. [35]

63. Accordingly, I find nothing in the relevant elements of context that contradicts the finding that the Commission may very well decide to withdraw the exemptions as regards some novel tobacco products. That said, the applicants in the main proceedings and the Italian Government point to other elements of context which, in their view, support their position. I shall assess those arguments below.

4. A contextual (and historical) interpretation of Article 7(12) and Article 11(6) – second part

64. To begin with, the applicants in the main proceedings argue that a 'broad' interpretation of Article 7(12) and Article 11(6) of Directive 2014/40, which would make them applicable to novel tobacco products also, cannot be reconciled with the rules set out in Article 19(1) and Article 28 thereof. Those provisions show – according to those parties – that the EU legislature envisaged a special regime for novel tobacco products.

28 See recital 16 of Directive 2014/40.

29 See recital 47 of Directive 2014/40.

30 See, for instance, Article 6, Article 16(3) and Article 30 of Directive 2014/40.

31 See judgment of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, EU:C:2016:325, paragraph 111).

32 See recitals 15 and 24 of Directive 2014/40.

33 See pages 70, 78 and 85 of the FCTC guidelines.

34 See, in particular, pages 33 to 41, 61 and 62 of the FCTC guidelines.

35 See, in particular, Articles 9 and 11 of the Convention.

65. Article 19(1) establishes a system of notification of novel tobacco products to national authorities prior to them being placed on the market. The information to be supplied should include, inter alia, 'a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions'. Article 28 of the same directive requires the Commission to produce, 'whenever necessary', a report on the application of the directive. In that report, the Commission is to pay special attention to, inter alia, 'market developments concerning novel tobacco products' and 'market developments which constitute a substantial change of circumstances'. That report should be followed by 'proposals for amending [the] Directive, which the Commission deem necessary …'.

66. Admittedly, those two provisions may, at first sight, be read as suggesting that, as regards novel tobacco products, the EU legislature has opted for a 'wait and see' approach, reserving its decision as to how they should be regulated at a future moment in time. [36]

67. In my view, however, on closer examination, those provisions should be read in a different manner.

68. First, a 'wait and see' approach appears to be incompatible with the clear wording of recital 35 and Article 19(4) of Directive 2014/40 – recalled in point 57 above – which requires those products to respect the requirements of the directive. Moreover, if the only relevant requirements were those stemming from Article 19 of the directive, as argued by the applicants in the main proceedings, the second sentence of Article 19(4) ('which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking') would be deprived of any meaning. Indeed, it is clear that the notification obligations set out in Article 19(1) and (2) concern both groups of products. The expressions 'which of the provisions of this Directive apply' included in Article 19(4) cannot but refer to the *substantive* provisions of the directive, including those on ingredients and labelling.

69. Second, the *travaux préparatoires* do not indicate that the legislature's choice was to give novel tobacco products the benefit of the doubt, but the opposite: novel tobacco products should remain fully subject to the *general rules* of the directive while their effects on health and consumption practices are being studied. Stricter rules could then be adopted in the future, if appropriate.

70. This is borne out by the Commission's impact assessment, published in 2012. The Commission's preferred regulatory option for novel tobacco products has been the following: 'A notification obligation is introduced for novel tobacco products … and a report on the market development in these products will be issued by the Commission five years after the transposition of [the new tobacco directive]. Novel tobacco products placed on the market must respect the rules on labelling (health warnings on both sides) and ingredients regulation (ban on products with characterising flavours).' Interestingly, none of the regulatory options evaluated in the impact assessment supports the arguments put forward by the applicants in the main proceedings. [37]

[36] See also recital 34 ('it is … important to monitor developments as regards novel tobacco products') and recital 52 ('the report should include information on … market developments concerning novel tobacco products [and] market developments that amount to a substantial change of circumstances') of Directive 2014/40.

[37] Commission staff working document – Impact assessment – Accompanying the document 'Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products', SWD(2012) 452 final, pp. 50 to 52, 74 to 76 and 117.

71. That approach (co-existence of a notification procedure and default application of the general rules) is fully reflected in the Explanatory Memorandum, accompanying the Commission's proposal for a directive, tabled in 2012. Indeed, in Section 3.6 (entitled 'Novel tobacco products') thereof, the Commission wrote:

'Novel tobacco products … will have to respect requirements of the Directive (e.g. in terms of labelling and ingredients) to ensure a level playing field, and the applicable rules will depend on whether the product involves a combustion process or not.

The proposal *also* foresees a notification obligation for novel tobacco products and a report on the market development in these products will be issued by the Commission five years after the transposition deadline of the Directive. …' [38]

72. Third, the above findings appear to be confirmed by existing case-law. In its judgment in *Philip Morris Brands and Others*, the Court stated that, with Directive 2014/40, the EU legislature 'decided to adopt *uniform rules for all tobacco products* containing a characterising flavour'. [39] That is not called into question by paragraph 32 of the judgment in *Swedish Match*. [40] The applicants in the main proceedings argue that, in that passage, the Court found that novel tobacco products, because their effects on health and consumption practices could not yet be ascertained, were only brought within the scope of Directive 2014/40 in order to make them subject to the notification procedure.

73. I do not agree. In that passage, the Court intended to emphasise that, unlike tobacco for oral use, the sale of novel tobacco products was *not prohibited* because their impact on public health and market dynamics was unknown. That much becomes clear when that passage of the judgment is read in its proper context. What the Court was considering was whether Directive 2014/40 was 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 tobacco products, including novel tobacco products. In that regard, it should not be overlooked that one of the regulatory options envisaged during the process which eventually led to the adoption of Directive 2014/40 was to introduce an outright ban on the sale of novel tobacco products, as was already the case for oral tobacco. [41]

74. Fourth, the reading of Articles 19 and 28 of Directive 2014/40 put forward by the applicants in the main proceedings is not supported by the text and objective of those provisions, which have a broad scope and are not specifically concerned with the obligations at issue.

75. The system of notification set out in Article 19 and Article 28(2)(b) of Directive 2014/40 serves multiple purposes, in particular: (i) to permit Member States to authorise the placing on the market of those products (should they have such a system in place); [42] (ii) to determine which sets of provisions of Directive 2014/40 apply; [43] and (iii) to keep the EU and national authorities abreast of relevant market and scientific developments for possible amendments of the

[38] Emphasis added.

[39] Judgment of 4 May 2016 (C-547/14, EU:C:2016:325, paragraph 108). Emphasis added.

[40] Judgment of 22 November 2018 (C-151/17, EU:C:2018:938).

[41] See the Commission's impact assessment, pp. 50 to 52.

[42] Article 19(3) of Directive 2014/40.

[43] Article 19(4) of Directive 2014/40.

directive.[44] Article 19 of Directive 2014/40 does not link, explicitly or implicitly, the notification in question to the need for the EU legislature to determine whether the obligations at issue should be made applicable, by withdrawing the exemptions.

76. As far as Article 28 of Directive 2014/40 is concerned, it seems to me quite obvious that a piece of legislation which approximates Member States' laws on the manufacture, presentation and sale of tobacco and related products might require regular revisions over time, since the market is constantly evolving (existing products may change, new products are placed on the market and consumers' preferences shift) and new scientific studies become available. It is equally obvious that the EU legislature may want to amend the legal framework – as regards both the general principles and definitions, and the more specific rules on obligations, exemptions and withdrawal of exemptions – in order to adapt those rules to, inter alia, the specificities of tobacco products that have entered the market after the adoption of Directive 2014/40.

77. Naturally, in line with the maxim *a maiori ad minus* (those who can do more can also do less),[45] the EU legislature could, in doing so, also decide on matters in respect of which it has delegated powers to the Commission. Therefore, I do not see the references to novel tobacco products and to the possible change of circumstances included in Article 28 of Directive 2014/40 as precluding the interpretation of Article 7(12) and Article 11(6) thereof defended by Ireland, the French Government and the Commission.

78. Fifth, a 'wait and see' approach would not be in keeping with the precautionary principle – enshrined, notably, in Article 35 of the Charter of Fundamental Rights of the European Union, Article 9 TFEU, Article 114(3) TFEU and Article 168(1) TFEU[46] – which, according to consistent case-law, is applicable where the EU institutions adopt, under the policy on the internal market, measures for the protection of human health.[47] The Court has consistently stated that, where there is uncertainty as to the existence or extent of risks to human health, the EU legislature may, in the light of that principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.[48]

79. After all, the threefold regime set up by Directive 2014/40 with regard to the obligations at issue (main rule/exemption/withdrawal of the exemption) would appear somewhat lopsided if the third leg of it were to be removed in respect of certain products. I shall come back to this point in Section 6 below.

5. A contextual interpretation of Article 7(12) and Article 11(6) – third part

80. In addition, the applicants in the main proceedings point to Article 2(28) of Directive 2014/40, according to which a 'substantial change of circumstances' requires an increase of the sales volumes or of the level of prevalence of use in the under-25-years-of-age consumer group by certain percentages (10% and 5%, respectively). Are not those thresholds too easily met by novel tobacco products – those parties wonder – since those products are likely to realise, when they

[44] Article 28(2)(b) of Directive 2014/40.

[45] See, for example, judgment of 13 May 2003, *Commission* v *Spain* (C-463/00, EU:C:2003:272, paragraph 41).

[46] See, in that regard, judgment of 4 May 2016, *Pillbox 38* (C-477/14, EU:C:2016:324, paragraph 116).

[47] See, inter alia, judgments of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 41 and the case-law cited).

[48] See, for example, judgment of 22 November 2018, *Swedish Match* (C-151/17, EU:C:2018:938, paragraph 38 and the case-law cited).

enter the market, only minimal sales? Essentially, they point to the fact that any meaningful expansion in the market could easily meet the 10% sale increase threshold and thus trigger the withdrawal of the exemptions.

81. The doubts voiced by the applicants in the main proceedings are, to some extent, understandable. However, I do not think that the conditions laid down in Article 2(28) of Directive 2014/40 unfairly penalise novel tobacco products.

82. There is, first, a relatively high requirement that has to be met by a product category (either existing or new) for such a change of circumstances to occur: the sales volume of the category in question must, at retail level, exceed 2.5% of total sales of tobacco products at EU level. If that 2.5% threshold is not met, there can be no withdrawal of exemptions, irrespective of the amount of growth of the sales or increase in use by young persons. In a market that was, in 2020, estimated at approximately 600 million units,[49] the 2.5% threshold ensures – I believe – that only products with a significant presence in the European Union could be subject to the withdrawal of exemptions.

83. Moreover, an increase in the sale or level of prevalence of use by young persons of the products in question must be recorded in at least five Member States. This requirement has, inevitably, the effect of excluding products whose presence in the EU market is mainly local or purely marginal.

84. Last but not least, the sales data used to assess a possible change of circumstances are those transmitted by the manufacturers and importers themselves *on a yearly basis*. This not only ensures the quality of the data, but also that sporadic or transitory increases in sales cannot trigger the withdrawal of exemptions, given that sale increases can only be determined by comparing yearly data. Similarly, as regards the level of prevalence of use in young persons, the directive requires the Commission to base its assessment on 'the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies'. To my mind, 'equivalent' studies means studies that are comparable, in terms of accuracy and detail, to the Special Eurobarometer 385 report of May 2012: a rather in-depth study of the situation in the national markets.[50]

85. Therefore, I do not find the arguments based on Article 2(28) of Directive 2014/40 put forward by the applicants in the main proceedings to be convincing.

6. A teleological interpretation of Article 7(12) and Article 11(6)

86. Second, accepting that the threefold 'main rule/exemption/withdrawal of exemption' regime applies in full to novel tobacco products is consistent with the two main objectives of Directive 2014/40.[51]

87. On the one hand, it strengthens the internal market, given that it leads to more uniform rules for new tobacco products.[52] It is true that the regulation of those products is largely a matter for the Member States. However, the impact of a withdrawal decision in that respect is rather

[49] Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40 (COM(2022) 279 final, p. 4.

[50] Available online, on the Commission's website.

[51] See, in particular, recital 21 and Article 1 of Directive 2014/40.

[52] See also recitals 4 to 6, 22 and 23 of Directive 2014/40.

limited: it simply requires certain novel tobacco products to follow the general rules on ingredients and labelling. That is by no means rendering Member States' competence on the authorisation of those products ineffective, as argued by PJ Carroll.

88. In fact, a decision to increase the level of harmonisation in that respect would be consistent with the legislature's view that the lack of harmonised approach on ingredients and labelling was affecting the smooth functioning of the internal market,[53] and the divergences between national legislation were likely to increase in the future.[54]

89. The above approach is in line with the Court's case-law, according to which, 'although recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade as a result of divergences in national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them'.[55] Case-law is also clear that, provided that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, the EU legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.[56]

90. That is true with regard to both the initial act and any subsequent amendment thereof. Indeed, as the Court has held, the EU legislature cannot be denied the possibility of adapting an act approximating Member States' laws to any change in circumstances or development of knowledge, having regard to its task of safeguarding the general interests recognised by the Treaty. In such a situation, the EU legislature can properly carry out its task of safeguarding the general interests recognised by the Treaty only if it has the freedom to amend the relevant EU legislation so as to take account of such changes.[57] Therefore, PJ Carroll's argument concerning a potential issue under Article 168(5) TFEU – which excludes any harmonisation in the field of human health protection – is clearly unfounded.

91. On the other hand, my suggested reading of Article 7(12) and Article 11(6) of Directive 2014/40 would also render that instrument more effective in its pursuit of a high level of health protection, since consumers would be more effectively protected against the risks from novel tobacco products.[58] It should not be overlooked that, if the withdrawal of exemptions in respect of those products were to be reserved for the EU legislature, a significant period of time would necessarily elapse before that could be implemented. Indeed, the amendment of the directive would need to go through the ordinary legislative procedure, and the directive would have to set a reasonable date for its transposition. By contrast, the procedure for the Commission to adopt a delegated act is, normally, much faster.

92. The above considerations appear to be even more compelling given the focus of the directive on young people.[59] For example, the rationale of the flavouring ban is to prevent the marketing of products that may be particularly attractive to young people and may, accordingly, facilitate

[53] See recital 15 of Directive 2014/40.

[54] See recital 16 of Directive 2014/40.

[55] See judgment of 3 December 2019, *Czech Republic* v *Parliament and Council* (C-482/17, EU:C:2019:1035, paragraph 35 and the case-law cited).

[56] See, for example, judgment of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, EU:C:2016:325, paragraph 60 and the case-law cited).

[57] See judgment of 3 December 2019, *Czech Republic* v *Parliament and Council* (C-482/17, EU:C:2019:1035, paragraphs 38 and 39 and the case-law cited).

[58] See recitals 18, 21, 36, 43, 54, and 59, and Article 1 of Directive 2014/40.

[59] See, in particular, recitals 8, 19, 21, 26, 27 and 47, and Article 1 of Directive 2014/40.

initiation of tobacco consumption.[60] In that context, it seems rather logical that the exemption from that ban which is granted to novel tobacco products may be rapidly withdrawn, should a new tobacco product gain traction within a relatively short period of time. It is not absurd to think that new tobacco products may often be conceived and marketed in order to expand the customer base of tobacco products, rather than to induce existing customers to switch their product of preference.

93. It is true, as the applicants in the main proceedings emphasise, that the category of 'novel tobacco products' is a broad and heterogeneous one which encompasses, inter alia, products containing limited quantities of tobacco. In their view, in so far as those products may be less dangerous for human health, and their actual impact on human health may vary from one type of product to another, it stands to reason that the decision as to whether the exemptions at issue should be withdrawn should be left to the EU legislature.

94. However, it appears that, in that regard, the EU legislature has already taken a clear position. Indeed, as recalled above, recital 34 states that 'all tobacco products have the potential to cause mortality, morbidity and disability. Accordingly, their manufacture, distribution and consumption should be regulated.' Significantly, that recital is followed by recital 35, which states that 'in order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive'.

95. The EU legislature has, thus, considered that (i) *all* tobacco products are dangerous for human health; and (ii) to ensure a *level playing field*, novel tobacco products should generally follow the same rules as those of existing tobacco products.

7. Final considerations

96. Lastly, some of the parties which submitted observations have referred to certain passages of various documents issued by the EU institutions or by some Member States as allegedly supporting their arguments.

97. I did not find any of those references to be particularly persuasive, although, on balance, they rather seem to corroborate my position.

98. In the first place, I note that the Explanatory Memorandum accompanying the Commission's proposal for a directive,[61] already referred to in point 71 above, includes other considerations that, especially when taken together, seem to confirm the interpretation of Article 7(12) and Article 11(6) suggested by Ireland, the French Government and the Commission. In particular, that document (i) in respect of the obligations at issue, appears to give the same scope to the exemptions and the withdrawal thereof;[62] (ii) indicates that new tobacco products have to respect the requirements of the directives and that, in terms of labelling and ingredients, the applicable rules depend (only) on whether the product involves a combustion process or not;[63] and (iii) observes that, with regard to labelling and ingredients, 'the heterogeneous situations in Member States have resulted in a situation where the industry has to produce different product lines for

[60] See recital 16, Article 19(1)(c) and Article 28(2)(g) of Directive 2014/40. See also, to that effect, judgment of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, EU:C:2016:325, paragraphs 114 and 173).

[61] COM(2012) 788 final.

[62] See sections 3.1 and 3.2 of the Explanatory Memorandum.

[63] Section 3.6 of the Explanatory Memorandum.

different markets' and, accordingly, that '*only a harmonised approach* at EU-level in such areas can remove obstacles to cross-border trade and avoid fragmentation, while ensuring a comparable high level of health protection'. [64]

99. That said, to the extent that the Explanatory Memorandum reflects the structure and language of the proposal, its hermeneutic added value should not be overstated.

100. For their part, the applicants in the main proceedings point to the Commission's 2021 report on the application of Directive 2014/40 concerning the manufacture, presentation and sale of tobacco and related products. [65] In that report, the Commission stated that 'without flexibility to *define new product categories*, it is challenging to apply rules developed for existing categories to novel tobacco products, as they do not necessarily respond to the distinct properties of the new products'. [66] In the light of that statement, the applicants claim that the Commission has expressly recognised its lack of authority to create new product categories.

101. This passage of the 2021 report is admittedly ambiguous. However, I doubt that the reading thereof by the applicants in the main proceedings is accurate. In my view, the lack of flexibility which the Commission complains of concerns its inability to create new categories (or sub-categories) in respect of which the application of the directive's substantive rules can be varied or modulated. As I read it, the Commission's statement does not concern the (much narrower in scope) question of whether new categories could be established for the purpose of Article 7(12) and Article 11(6) of Directive 2014/40. In fact, other passages of that report suggest that the Commission considered the withdrawal of exemptions in respect of novel tobacco products to be possible, and refers expressly to heated tobacco products. [67]

102. In any event, I do not think that the Commission's reading of the directive, expressed after the adoption of that legal instrument, should be given undue weight when an issue of interpretation of EU law is raised before the Court. [68] The same holds true, *mutatis mutandis*, for the declarations made by the three Member States that, during the comitology procedure, expressed the view that, by adopting Delegated Directive 2022/2100, the Commission was exceeding the EU legislature's delegation of powers.

103. In fact, when asked at the hearing whether they were aware of any preparatory document, in particular from the Parliament or the Council, which supports their arguments (for example, expressing the view that, unlike what the Commission had proposed, novel tobacco products had to be subject to a special or, at any rate, milder regime), the applicants in the main proceedings essentially answered in the negative.

104. In addition, I am not convinced by the Italian Government's argument that, by creating a new category of products which may include both tobacco products for smoking and smokeless tobacco products, the Commission has created a '*tertium genus*' which does not fit into the scheme of Directive 2014/40 since a tobacco product must *necessarily* be either smokeless or for smoking.

64 Section 3.9.2 of the Explanatory Memorandum. Emphasis added.

65 COM(2021) 249 final.

66 Section 7 (emphasis added).

67 See, in particular, pages 11 and 16 of the report.

68 See, in that regard, my Opinion in Joined Cases *Illumina and Grail* v *Commission* (C-611/22 P and C-625/22 P, EU:C:2024:264, points 74, 77 and 78).

105. As indicated in point 49 above, the directive itself refers to the possibility that certain products may fall within the definitions of two or more categories and, in that case, the stricter rules will apply. No provision of Directive 2014/40 lays down a general and unconditional rule that each and every product within a given category must follow the same rules. I also do not see why, on grounds of principle, a new category of products (*in casu*, heated tobacco products), established only for the purposes of the obligations at issue, could not comprise both tobacco products for smoking and smokeless tobacco products.

106. There is, finally, also no circumvention of the general rules laid down by the EU legislature in the main act since – and that is rather clear to me – the labelling obligations which, pursuant to Articles 9 and 10 of Directive 2014/40, apply only to tobacco products for smoking will not apply to heated tobacco products which do not involve a combustion process.

107. In the light of the above, I conclude that, by creating a new category of product (heated tobacco products) and withdrawing the exemptions for that category, the Commission has not exceeded the powers delegated to it by the EU legislature in Article 7(12) and Article 11(6) of Directive 2014/40. Accordingly, the examination of the first question referred has disclosed nothing capable of affecting the validity of Delegated Directive 2022/2100.

B. Second question

108. By its second question, the referring court essentially asks the Court of Justice whether Delegated Directive 2022/2100 is invalid because the Commission was not entitled to conclude that there was a substantial change of circumstances, within the meaning of Article 2(28), Article 7(12) and Article 11(6) of Directive 2014/40, in relation to heated tobacco products, on the basis of the sales of product units (on a 'per stick' basis). The applicants in the main proceedings argue that the Commission should have, instead, used sales volume on a 'per weight' basis which would take into account the quantity of tobacco involved.

109. I do not agree with the applicants in the main proceedings.

110. In defining what constitutes a 'substantial change of circumstances', Article 2(28) of Directive 2014/40 refers to 'an increase of the *sales volumes* by product category … *based on sales data transmitted* in accordance with Article 5(6) …'.[69] That provision does not, accordingly, prescribe the manner in which the sales volumes have to be determined, but merely refers to the sales data which manufacturers and importers have to report to the Member States. In that regard, Article 5(6) of Directive 2014/40 provides that 'manufacturers and importers [should] report their sales volumes per brand and type, reported *in sticks or kilograms*, and per Member State on a yearly basis …'.[70]

111. The two options (per weight and per stick) are also provided for in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products.[71] In particular, Article 2(1) of that decision requires manufacturers and importers to submit information on, inter alia, sales volumes in accordance with the format provided for in the annex thereto. Section 3 of the annex ('Product

[69] Emphasis added.

[70] Emphasis added.

[71] Decision of 25 November 2015 (OJ 2015 L 312, p. 5).

Information Submission and Description – Part B'), includes the item 'Product_Sales_Volume', which reads as follows: 'Information on annual sales volume of the product per Member State to be reported annually in *product units* or in *kg loose tobacco*'.[72]

112. In fact, I understand that the applicants in the main proceedings themselves have, in previous years, reported their sales of heated tobacco products on a per-stick basis – as is the case for the vast majority of tobacco products marketed in the European Union.[73]

113. Nowhere in the applicable provisions is it envisaged that the Commission should convert the unit data into weight data. In that regard, it also appears relevant – as Ireland points out – that Article 2(28) of Directive 2014/40 requires the Commission to verify that 'the sales volume *of the product category* at retail level [exceeds] [2.5]% of *total sales of tobacco products* at Union level'. It would thus seem that the key data to be examined by the Commission in this context are, according to the EU legislature, those which concern the units of products sold, and not those on the quantity of tobacco used in those products.

114. That approach is, in my view, consistent with one of the main objectives pursued by the directive: to reduce the use of tobacco products by young people, in particular by discouraging them from initiating consumption. It should not be overlooked that, as set out above, the EU legislature has taken the view that tobacco products for the purposes of Directive 2014/40 are all products that consist 'even partly, of tobacco' and that 'all tobacco products have the potential to cause mortality, morbidity and disability'.[74]

115. Accordingly, I conclude that the Commission did not err in evaluating the possible substantial change of circumstances with regard to heated tobacco products on the basis of the units of products sold. Therefore, the examination of the second question referred has also disclosed nothing capable of affecting the validity of Delegated Directive 2022/2100.

V. Conclusion

116. In the light of the foregoing, the examination of the questions referred by the High Court (Ireland) has disclosed nothing capable of affecting the validity of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.

[72] Emphasis added.

[73] I understand that, essentially, only sales data relating to roll-your-own, pipe and chewing tobacco are reported on a per-weight basis.

[74] Article 2(4) and recital 34 of Directive 2014/40.