JUDGMENT OF THE COURT (Second Chamber)

26 June 2025 (*)

(Reference for a preliminary ruling – Public health – Directive 2014/40/EU – Article 7(12) – Article 11(6) – Delegated Directive (EU) 2022/2100 – Validity – Manufacture, presentation and sale of tobacco products – Delegation of power to the European Commission – Novel tobacco products – Heated tobacco products – Power to withdraw exemptions from prohibitions of flavourings and labelling requirements – Substantial change of circumstances)

In Case C-759/23,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court (Ireland), made by decision of 29 November 2023, received at the Court on 7 December 2023, in the proceedings

PJ Carroll & Company Ltd,

Nicoventures Trading Ltd

v

The Minister for Health,

Ireland,

The Attorney General,

interested parties:

Philip Morris Ltd,

Philip Morris Products SA,

Philip Morris Manufacturing & Technology Bologna SpA,

THE COURT (Second Chamber),

composed of K. Jürimäe (Rapporteur), President of the Chamber, K. Lenaerts, President of the Court, acting as Judge of the Second Chamber, M. Gavalec, Z. Csehi and F. Schalin, Judges,

Advocate General: N. Emiliou,

Registrar: R. Stefanova-Kamisheva, Administrator,

having regard to the written procedure and further to the hearing on 28 November 2024,

after considering the observations submitted on behalf of:

– PJ Carroll & Company Ltd and Nicoventures Trading Ltd, by C. Barrett, K. O'Connor, N. Skelton, Solicitors, M. Schonberg and L. Van den Hende, advocaten,

– The Minister for Health, Ireland and The Attorney General, by M. Browne, Chief State Solicitor, A. Burke, A. Joyce, S. Sheehy, acting as Agents, and by E. Barrington, Senior Counsel, and L. Mooney, Barrister-at-Law,

– Philip Morris Ltd, Philip Morris Products SA and Philip Morris Manufacturing & Technology Bologna SpA, by N. Buckley, Barrister-at-Law, M. Byrne, H. Kelly, R. McKittrick, R. Walsh, Solicitors, E. McCullough, Senior Counsel, and H. Saugmandsgaard Øe, advokat,

– the French Government, by B. Fodda, M. de Lisi and B. Travard, acting as Agents,

– the Italian Government, by S. Fiorentino and F. Meloncelli, acting as Agents,

– the European Commission, by E. Schmidt and F. van Schaik, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 January 2025,

gives the following

Judgment

1 This reference for a preliminary ruling concerns 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 (OJ 2022 L 283, p. 4).

2 The request has been made in proceedings between PJ Carroll & Company Ltd and Nicoventures Trading Ltd, on the one hand, and The Minister for Health (Ireland), Ireland and The Attorney General (Ireland), on the other, concerning the validity of the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023 ('the 2023 Regulations'), which transpose Delegated Directive 2022/2100 into Irish law.

Legal context

European Union law

Directive 2014/40/EU

3 Recitals 19, 26 and 34 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1), state:

‘(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.

…

(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. The labelling of these other tobacco products should follow rules that are specific to them. The visibility of health warnings on smokeless tobacco products should be ensured. Health warnings should, therefore, be placed on the two main surfaces of the packaging of smokeless tobacco products. As regards waterpipe tobacco, which is often perceived as less harmful than traditional tobacco products for smoking, the full labelling regime should apply in order to avoid consumers being misled.

…

(34) All tobacco products have the potential to cause mortality, morbidity and disability. Accordingly, their manufacture, distribution and consumption should be regulated. It is, therefore, important to monitor developments as regards novel tobacco products. Manufacturers and importers should be obliged to submit a notification of novel tobacco products, without prejudice to the power of the Member States to ban or to authorise such novel products.’

4 Under Article 2 of that directive, headed ‘Definitions’:

‘For the purposes of this Directive, the following definitions shall apply:

…

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

…

(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;

…’

5 Article 5 of that directive, headed ‘Reporting of ingredients and emissions’, provides, in paragraphs 5 and 6 thereof:

‘5. The [European] Commission shall, by means of implementing acts, lay down and, if necessary, update the format for the submission and the making available of information referred to in paragraphs 1 and 6 of this Article and Article 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

6. … 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.’

6 Prior to its amendment by Delegated Directive 2022/2100, Article 7 of that directive, entitled ‘Regulation of ingredients’, read as follows:

‘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. Filters, papers and capsules shall not contain tobacco or nicotine.

…

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.

…’

7 Article 9 of Directive 2014/40 concerns the general warning and information message that must appear on unit packets and outside packaging of tobacco products for smoking. Article 10 of that directive lays down the obligations relating to the health warnings that must be indicated on each unit packet or any outside packaging of those products.

8 Prior to its amendment by Delegated Directive 2022/2100, Article 11 of Directive 2014/40, which was

then headed ‘Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco’, provided:

‘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.’

9 Under Article 19 of Directive 2014/40, headed ‘Notification of novel tobacco products’:

‘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. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with Article 5. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the competent authorities with:

…

2. Member States shall require manufacturers and importers of novel tobacco products to transmit to their competent authorities any new or updated information on the studies, research and other information referred to in points (a) to (c) of paragraph 1. Member States may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information. 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. Member States may charge manufacturers and importers proportionate fees for that authorisation.

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.’

10 Article 28 of that directive, headed ‘Report’, is worded as follows:

‘1. No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council [of the European Union], 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:

…

(b) market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19;

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

…

The Member States shall assist the Commission and provide all available information for carrying out the assessment and preparing the report.

3. The report shall be followed-up by proposals for amending this Directive, which the Commission deem[s] 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.'

Delegated Directive 2022/2100

11 According to Article 1 of Delegated Directive 2022/2100:

'Directive [2014/40] is amended as follows:

(1) Article 7(12) is replaced by the following:

"12. Tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products 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.

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.";

(2) Article 11 is amended as follows:

(a) the heading is replaced by the following:

"*Article 11*

Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products";

(b) in paragraph 1, the first subparagraph is replaced by the following:

"Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products as defined in Article 7(12), second subparagraph, from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. In that event, and in addition to the general warning provided for Article 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Annex I. The general warning specified in Article 9(1) shall include a reference to the cessation services referred to in Article 10(1), point (b).".'

Implementing Decision (EU) 2015/2186

12 Article 2(1) of Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products (OJ 2015 L 312, p. 5) provides:

'Member States shall ensure that manufacturers and importers of tobacco products submit information on ingredients, emissions and sales volumes referred to in Article 5 of Directive [2014/40], including modifications and withdrawal from the market, in accordance with the format provided for in the Annex.'

Irish law

13 The 2023 Regulations transpose Delegated Directive 2022/2100 into Irish law. The notice relating to the adoption of the 2023 Regulations was published in the *Iris Oifigiúil* (Irish State Gazette) of 30 June 2023. Those regulations entered into force on 23 October 2023.

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

14 PJ Carroll & Company and Nicoventures Trading (together, 'PJ Carroll') and Philip Morris, Philip Morris Products and Philip Morris Manufacturing & Technology Bologna (together, 'Philip Morris') market or intend to market, throughout the European Union, heated tobacco products that contain 'characterising flavours' or flavourings in their components.

15 PJ Carroll is of the view that the Commission was not empowered to adopt Delegated Directive 2022/2100. It therefore submits that that delegated directive is invalid and that, consequently, the 2023 Regulations, which transpose it into Irish law, are unlawful.

16 On 11 January 2023, the High Court (Ireland), which is the referring court, granted PJ Carroll leave to initiate judicial review proceedings seeking, inter alia, a declaration that the 2023 Regulations are invalid. That court notes that it does not have jurisdiction to declare an EU act invalid and that it is therefore necessary first to refer a question to the Court of Justice. That court submits that PJ Carroll has put forward arguments to show that, by adopting Delegated Directive 2022/2100, the Commission impermissibly encroached on the EU's exclusive sphere of legislating, contrary to Article 290 TFEU. Furthermore, the Commission did not validly assess whether there had been a 'substantial change of circumstances', within the meaning of Article 2(28) of Directive 2014/40.

17 As regards the validity of Delegated Directive 2022/2100, the referring court notes, in essence, that, by defining, in that delegated directive, a new category of tobacco products, namely heated tobacco products, and by deciding that it was appropriate to withdraw, for that new category of products, the benefit of the exemptions provided for in Article 7(12) and Article 11(6) of Directive 2014/40, the Commission unlawfully made a political choice. According to that court, prohibiting, on the basis of the sales volume, a category of tobacco products that was not in existence on the date of adoption of that directive and that was not the subject of separate policy and health assessments by the EU legislature falls within the sole competence of that legislature and not of the Commission.

18 In the referring court's view, it is apparent from the scheme of Directive 2014/40 that the EU legislature regulates the placing on the market of novel tobacco products in the light of scientific and technical developments. The outright prohibition of such products is to be addressed by basic legislation, depending on the political choices made by that legislature as to how best to regulate those new products. That would be the case, in particular, where those new products cannot be readily categorised as smokeless tobacco products or tobacco products for smoking and where such products may have the same level of tobacco content as existing products.

19 It is therefore possible to argue that defining a new category of products, which covers both smokeless tobacco products and tobacco products for smoking, for the purposes of immediately prohibiting a flavoured version of those new products, infringes the second subparagraph of Article 290(1) TFEU. By adopting such a definition, the Commission legislated for an 'essential element' of Directive 2014/40 since the scope, content and objective of such a definition were not explicitly defined in that directive. In order for Delegated Directive 2022/2100 to be valid, the Commission should have had the delegated power to withdraw the exemptions provided for in Article 7(12) and Article 11(6) of Directive 2014/40 for all flavoured novel tobacco products that satisfy the sales volume conditions provided for in Article 2(28) of that directive, irrespective of their tobacco content or their health impact relative to existing products.

20 As regards the determination of the 'substantial change of circumstances', within the meaning of Article 2(28) of Directive 2014/40, the referring court considers that, in its quantitative sales-volume analysis, the Commission did not compare like with like when it assessed whether the level of market penetration of heated tobacco products was such as to warrant a prohibition of such flavoured products.

21 In that court's view, one of the core objectives of Directive 2014/40 is the protection of health given the harmful effects of tobacco. Accordingly, the tobacco content of tobacco products is a key concern driving the regulatory measures provided for in that directive. An approach that focused on the overall tobacco content of products and assessed the sales volume on that basis would thus have been more consistent with that objective. The Commission did not attempt, in developing its methodology, to harmonise the metrics as between heated tobacco products and cigarettes and other tobacco products as regards tobacco content. However, such harmonisation would have been necessary to ensure that like was compared with like.

22 In those circumstances, the High Court decided to stay 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]?'

Consideration of the questions referred

The first question

23 By its first question, the referring court asks whether Delegated Directive 2022/2100 is invalid on the ground that the Commission exceeded the powers conferred on it by Article 7(12) and Article 11(6) of Directive 2014/40, read in the light of Article 290 TFEU and Article 2(14) and Articles 19 and 28 of that directive.

24 Article 7(12) and Article 11(6) of Directive 2014/40 empower the Commission to adopt delegated acts, in the event of a substantial change of circumstances, in order to withdraw the exemptions for certain tobacco products referred to in those provisions. Those exemptions concern, first, the prohibition of the use of characterising flavours in those products and the prohibition of flavourings in their components and, secondly, the obligation to affix an information message and combined health warnings on unit packets or outside packaging of those products.

25 PJ Carroll and Philip Morris maintain, in essence, that that delegation of power is limited to 'particular product categories' specified by that directive. That delegation of power does not therefore concern 'novel tobacco products', within the meaning of Article 2(14) of that directive. It follows that, by creating and defining a new category of products by adopting Delegated Directive 2022/2100, the Commission exceeded the powers delegated to it by Article 7(12) and Article 11(6) of Directive 2014/40.

26 In that regard, it must be borne in mind that it is clear from Article 290(1) TFEU that a legislative act may delegate to the Commission the power to adopt non-legislative acts of general scope which supplement or amend certain non-essential elements of that legislative act. In accordance with the second subparagraph of that provision, the objectives, content, scope and duration of the delegation of power must be explicitly defined in the legislative act granting such a delegation. According to settled case-law, that requirement implies that the purpose of granting a delegated power is to achieve the adoption of rules coming within the regulatory framework as defined by the basic legislative act (see, to that effect, judgments of 18 March 2014, *Commission* v *Parliament and Council*, C-427/12, EU:C:2014:170, paragraph 38; of 17 March 2016, *Parliament* v *Commission*, C-286/14, EU:C:2016:183, paragraph 30; and of 26 July 2017, *Czech Republic* v *Commission*, C-696/15 P, EU:C:2017:595, paragraph 49).

27 Furthermore, it is also settled case-law that the essential elements of a legislative act are those the adoption of which requires political choices falling within the responsibilities of the EU legislature, in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments, or if it means that the fundamental rights of the persons concerned may be interfered with to such an extent that the involvement of the EU legislature is required (see, to that effect, judgments of 5 September 2012, *Parliament* v *Council*, C-355/10, EU:C:2012:516, paragraphs 65, 76 and 77, and of 26 July 2017, *Czech Republic* v *Commission*, C-696/15 P, EU:C:2017:595, paragraph 78).

28 As regards Directive 2014/40, the regulatory framework into which the powers delegated to the Commission in Article 7(12) and Article 11(6) of Directive 2014/40 must be incorporated is based on the political choices expressed by the EU legislature in Article 7(1) and (7), Articles 9 and 10 and Article 19(4) of that directive.

29 By those provisions, the EU legislature, first, chose to establish a general regime for the use of flavourings and labelling obligations by prohibiting the use of characterising flavours in tobacco products and the use of flavourings in their components and by requiring the affixing of an information message and combined health warnings on unit packets or outside packaging of tobacco products for smoking.

30 Secondly, that legislature took the view that certain tobacco products, which are mainly consumed by older consumers and small groups of the population, are exempt from that general regime. However, that legislature decided that those exemptions had to be withdrawn, by the Commission, in the event that a 'substantial change of circumstances', as defined in Article 2(28) of Directive 2014/40, read in the light of recitals 19 and 26 thereof, were to be found at the level of the sales volume of one of the tobacco products concerned or of young people's consumption patterns in relation to that product.

31 Thirdly, the EU legislature chose to make 'novel tobacco products' subject to the requirements laid down by Directive 2014/40, the conditions for recognising a 'novel tobacco product' being set out in Article 2(14) of that directive.

32 It must be held that, by adopting Delegated Directive 2022/2100 in order to withdraw, for novel tobacco products that are heated tobacco products, the benefit of the exemptions provided for in Article 7(12) and Article 11(6) of Directive 2014/40, the Commission acted in compliance with the regulatory framework summarised in paragraphs 28 to 31 above and did not make any political choice falling within the EU legislature's own responsibilities.

33 First, the finding that those products exist and that there has been a change in their consumption is based on the objective criteria set out in Article 2(14) and (28) of Directive 2014/40.

34 Secondly, on the basis of those findings, the Commission applied to those products the provisions of that directive that give legal expression to the political choices made by the EU legislature, namely, on the one hand, to prohibit the use of characterising flavours in tobacco products and flavourings in their components, and, on the other, to require the affixing of an information message and combined health warnings on unit packets or outside packaging.

35 None of the arguments relied on before the Court is capable of calling into question the validity of Delegated Directive 2022/2100.

36 It is true that the Commission inserted the definition of heated tobacco products outside the list of definitions set out in Article 2 of Directive 2014/40. However, Article 7(12) and Article 11(6) of that directive do not refer to the categories of products set out in Article 2(14) of that directive as regards the withdrawal of the benefit of those exemptions. Moreover, the Commission had no choice but to define the 'novel tobacco product' covered by Delegated Directive 2022/2100, in so far as the category of 'novel tobacco products' is necessarily open and to be clarified in relation to the appearance and development of such new products on the market.

37 Furthermore, as the Advocate General explained in points 87 and 91 of his Opinion, the exercise of the Commission's delegated power in respect of 'novel tobacco products' meets the twofold objective pursued by Directive 2014/40, which is to facilitate the smooth functioning of the internal market for tobacco products and related products, while ensuring a high level of protection of human health, especially for young people (see, to that effect, judgments of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraphs 143 and 220, and of 22 November 2018, *Swedish Match*, C-151/17, EU:C:2018:938, paragraph 67).

38 In that regard, PJ Carroll's argument – in so far as it relies, in support of the claim that Delegated Directive 2022/2100 is invalid, on Article 168(5) TFEU, under which the EU legislature is prevented from harmonising health policy on tobacco and from which it follows that the power to authorise the sale of certain novel tobacco products, in particular those that present reduced health risks compared with other tobacco products, is reserved to the Member States – cannot be accepted.

39 It is true that, although, under that provision, the EU legislature may adopt, inter alia, measures that have as their direct objective the protection of public health regarding tobacco, it is, however, to the exclusion of any harmonisation of the laws and regulations of the Member States.

40 That being said, it should be noted that Directive 2014/40 is not based on that provision, but on Article 114 TFEU, which allows for the approximation of provisions which have as their object the establishment and functioning of the internal market. It is settled case-law that, where the conditions for recourse to that article as a legal basis are satisfied, 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 (judgments of 10 December 2002, *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 62; of 12 December 2006, *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 39; and of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 60).

41 The point should also be made that the first subparagraph of Article 168(1) TFEU provides that a high level of human health protection is to be ensured in the definition and implementation of all EU policies and activities, and that Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed (judgments of 10 December 2002, *British American Tobacco (Investments) and Imperial Tobacco*, C-491/01, EU:C:2002:741, paragraph 62; of 12 December 2006, *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraph 40; and of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 61).

42 The situation cannot be different as regards Delegated Directive 2022/2100, since that delegated directive was adopted by the Commission on the basis of a delegation of power by the EU legislature, provided for in Article 7(12) and Article 11(6) of Directive 2014/40, in accordance with Article 290 TFEU.

43 It therefore follows from the interdependence of the two objectives pursued by Directive 2014/40 that the Commission could legitimately exercise its delegated power in order for 'heated tobacco products' to be subject to the general regime on the use of flavourings and the labelling obligations imposed by Directive 2014/40 (see, by analogy, judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 222).

44 Furthermore, by making heated tobacco products subject, in Delegated Directive 2022/2100, to the

prohibition of flavourings and to the labelling obligations imposed by Directive 2014/40, the Commission does not in any way encroach on the power of the Member States, as defined in Article 19(1) to (3) of Directive 2014/40, with regard to 'novel tobacco products'. In particular, the Member States remain free to make those products subject to a system of prior authorisation.

45 Last, as regards the obligation to submit an assessment report laid down in Article 28 of Directive 2014/40, it is true that the Commission must, under points (b) and (c) of the first subparagraph of Article 28(2) of that directive, pay special attention, inter alia, to market developments concerning novel tobacco products and to market developments which constitute a substantial change of circumstances.

46 However, that provision is not inconsistent with Article 19(4) of that directive, which provides that novel tobacco products placed on the market must already, and therefore independently of any proposal from the Commission following an assessment report, respect the requirements of that directive. In those circumstances, Article 28 of Directive 2014/40 cannot be interpreted as being a rule that limits the exercise of the power delegated to the Commission in Article 7(12) and Article 11(6) of that directive.

47 It follows from all the foregoing reasons that the examination of the first question has not revealed any factor of such a kind as to affect the validity of Delegated Directive 2022/2100.

The second question

48 By its second question, the referring court asks, in essence, whether Delegated Directive 2022/2100 is invalid on the ground that the Commission should have relied on the overall tobacco content of heated tobacco products in order to conclude that there was a 'substantial change of circumstances', within the meaning of Article 7(12) and Article 11(6) of Directive 2014/40, read in conjunction with Article 2(28) of that directive, rather than on the number of units sold.

49 The existence of a 'substantial change of circumstances' is a requirement for triggering the Commission's delegated power imposed both in Article 7(12) and in Article 11(6) of Directive 2014/40.

50 That concept is defined in Article 2(28) of that directive by reference to the sales volumes of the category of tobacco products concerned. That provision makes no mention of the weight of tobacco or, more generally, the quantity of tobacco present in a given product category. By contrast, that provision refers to sales data submitted in accordance with Article 5(6) of that directive. It follows from the wording of the latter provision that Member States must require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, on a yearly basis.

51 In that regard, as the Advocate General explained in point 111 of his Opinion, Implementing Decision 2015/2186, which specifies the characteristics of the information to be submitted by the Member States, also refers to the sales volume of tobacco products per unit or by weight in the mandatory format to which that implementing decision refers in Article 2 thereof.

52 In those circumstances, there is nothing to prevent the Commission from determining whether there is a 'substantial change of circumstances' of a specific category of tobacco products by calculating the sales volume of that category on the basis of either the number of units of the product concerned sold or the quantity of tobacco present in that product by weight.

53 In any event, measuring the ‘substantial change of circumstances’ with regard to the sales volume calculated per unit of product is consistent with the specific objective underlying the exemptions provided for in Article 7(12) and Article 11(6) of Directive 2014/40, while ensuring a high level of protection of human health.

54 First, it is apparent from recitals 19 and 26 of that directive that, in so far as it focuses on young people, those exemptions should no longer apply if a substantial change of circumstances were to be found in terms of sales or consumption patterns of that category of the population. Secondly, it follows from a combined reading of recital 34 of that directive and the definition of ‘tobacco products’ in Article 2(4) of that directive that, in the view of the EU legislature, any product that consists, even partly, of tobacco has the potential to cause mortality, morbidity and disability.

55 From that point of view, it cannot be considered that referring to the weight of the tobacco contained in a product in order to assess changes in consumption patterns of young people is the only permissible methodology. It follows that the Commission did not necessarily have to rely on the overall tobacco content of heated tobacco products in order to conclude that there was a ‘substantial change of circumstances’ within the meaning of Article 7(12) and Article 11(6) of Directive 2014/40.

56 It follows from all the foregoing reasons that the examination of the second question has not revealed any factor of such a kind as to affect the validity of Delegated Directive 2022/2100.

Costs

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

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

The examination of the questions referred by the High Court (Ireland) has not revealed any factor of such a kind as to affect 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.

Jürimäe Lenaerts Gavalec

Csehi Schalin

Delivered in open court in Luxembourg on 26 June 2025.

A. Calot Escobar K. Jürimäe

Registrar President of the Chamber

---

* Language of the case: English.