Reports of Cases

JUDGMENT OF THE COURT (Grand Chamber)

22 February 2022*

(Reference for a preliminary ruling – Directive 2014/40/EU – Manufacture, presentation and sale of tobacco products – Products not complying with the maximum emission levels – Prohibition on placing on the market – Measurement method – Filter cigarettes with small ventilation holes – Measurement of the emissions on the basis of ISO standards – Standards not published in the *Official Journal of the European Union* – Compliance with the publication requirements laid down in Article 297(1) TFEU read in the light of the principle of legal certainty – Compliance with the principle of transparency)

In Case C-160/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Rechtbank Rotterdam (District Court, Rotterdam, Netherlands), made by decision of 20 March 2020, received at the Court on 24 March 2020, in the proceedings

Stichting Rookpreventie Jeugd,

Stichting Inspire2live,

Rode Kruis Ziekenhuis BV,

Stichting ClaudicatioNet,

Nederlandse Vereniging voor Kindergeneeskunde,

Nederlandse Vereniging voor Verzekeringsgeneeskunde,

Accare, Stichting Universitaire en Algemene Kinder- en Jeugdpsychiatrie Noord-Nederland,

Vereniging Praktijkhoudende Huisartsen,

Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose,

Nederlandse Federatie van Kankerpatiëntenorganisaties,

Nederlandse Vereniging Arbeids- en Bedrijfsgeneeskunde,

Nederlandse Vereniging voor Cardiologie,

* Language of the case: Dutch.

Koepel van Artsen Maatschappij en Gezondheid,

Koninklijke Nederlandse Maatschappij tot bevordering der Tandheelkunde,

College van Burgemeester en Wethouders van Amsterdam

v

Staatssecretaris van Volksgezondheid, Welzijn en Sport,

intervener:

Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten (VSK),

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, A. Arabadjiev, K. Jürimäe, C. Lycourgos, E. Regan, S. Rodin (Rapporteur), I. Jarukaitis and J. Passer, Presidents of Chambers, J.-C. Bonichot, M. Safjan, F. Biltgen, P.G. Xuereb, N. Piçarra, L.S. Rossi and A. Kumin, Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Stichting Rookpreventie Jeugd, Stichting Inspire2live, Rode Kruis Ziekenhuis BV, Stichting ClaudicatioNet, Nederlandse Vereniging voor Kindergeneeskunde, Nederlandse Vereniging voor Verzekeringsgeneeskunde, Accare, Stichting Universitaire en Algemene Kinder- en Jeugdpsychiatrie Noord-Nederland, Vereniging Praktijkhoudende Huisartsen, Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose, Nederlandse Federatie van Kankerpatiëntenorganisaties, Nederlandse Vereniging Arbeids- en Bedrijfsgeneeskunde, Nederlandse Vereniging voor Cardiologie, Koepel van Artsen Maatschappij en Gezondheid, Koninklijke Nederlandse Maatschappij tot bevordering der Tandheelkunde and College van Burgemeester en Wethouders van Amsterdam, by A. van den Biesen, advocaat,

– Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten (VSK), by W. Knibbeler, B. Verheijen and P.D. van den Berg, advocaten,

– the Netherlands Government, by M.K. Bulterman and C.S. Schillemans, acting as Agents,

– the European Parliament, by L. Visaggio, R. van de Westelaken and W.D. Kuzmienko, acting as Agents,

– the Council of the European Union, by S. Emmerechts, Á. de Elera-San Miguel Hurtado and P. Plaza García, acting as Agents,

– the European Commission, by I. Rubene, S. Delaude, F. Thiran and H. Kranenborg, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 15 July 2021,

gives the following

Judgment

1 This request for a preliminary ruling concerns the validity and interpretation of Article 4(1) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1).

2 The request has been made in proceedings between (i) the Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation, Netherlands) and 14 other entities and (ii) the Staatssecretaris van Volksgezondheid, Welzijn en Sport (State Secretary for Health, Welfare and Sport, Netherlands; 'the State Secretary') concerning the method of measuring the levels of tar, nicotine and carbon monoxide emission from cigarettes.

Legal context

International law

3 The World Health Organisation Framework Convention on Tobacco Control ('the FCTC'), concluded in Geneva on 21 May 2003, and to which the European Union and its Member States are party, entered into force on 27 February 2005. Article 5(3) of the FCTC provides:

'In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.'

4 Article 7 of the FCTC provides:

'… The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of [Articles 8 to 13 of the FCTC].'

5 Articles 8 to 13 of the FCTC deal with measures relating to the reduction of demand for tobacco. They concern, respectively: protection from exposure to tobacco smoke; regulation of the contents of tobacco products; regulation of tobacco product disclosures; packaging and labelling of tobacco products; education and public awareness of tobacco control issues; and a comprehensive ban on tobacco advertising, promotion and sponsorship.

6 Article 9 of the FCTC provides:

'The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national

authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.'

European Union law

Regulation (EU) No 216/2013

7 Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ 2013 L 69, p. 1) states, in recitals 5 and 6:

'(5) The Court of Justice of the European Union has held, in [the judgment of 11 December 2007, *Skoma-Lux* (C-161/06, EU:C:2007:773)], that legal acts of the Union are not enforceable against individuals if they have not been properly published in the Official Journal and that making such acts available online does not equate to valid publication in the Official Journal in the absence of any rules in that regard in Union law.

(6) If publication in the Official Journal in electronic form were to constitute valid publication, access to Union law would be faster and more economical. Citizens should, nevertheless, continue to have the possibility to obtain a printed version of the Official Journal from the Publications Office.'

8 Article 1 of Regulation No 216/2013 provides:

'1. The Official Journal shall be published in electronic form, in accordance with this Regulation, in the official languages of the institutions of the European Union.

2. Without prejudice to Article 3, only the Official Journal published in electronic form (hereinafter "the electronic edition of the Official Journal") shall be authentic and shall produce legal effects.'

Directive 2014/40

9 Recitals 7, 8 and 11 of Directive 2014/40 state:

'(7) Legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control ("FCTC") of May 2003, the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.

(8) In accordance with Article 114(3) [TFEU], a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. 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.

…

(11) For measuring the tar, nicotine and carbon monoxide yields of cigarettes …, reference should be made to the relevant, internationally recognised ISO standards. The verification process should be protected from tobacco industry influence by using independent laboratories, including State laboratories. …'

10 Article 1 of Directive 2014/40 provides:

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

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

…

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

11 Article 2 of Directive 2014/40 states:

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

…

(21) "emissions" means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

…'

12 As set out in Article 3(1) of Directive 2014/40:

'The emission levels from cigarettes placed on the market or manufactured in the Member States ("maximum emission levels") shall not be greater than:

(a) 10 mg of tar per cigarette;

(b) 1 mg of nicotine per cigarette;

(c) 10 mg of carbon monoxide per cigarette.’

13 Article 4 of Directive 2014/40 provides:

‘1. The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide.

The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO standard 8243.

2. The measurements referred to in paragraph 1 shall be verified by laboratories which are approved and monitored by the competent authorities of the Member States.

Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

…

3. The [European] Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the methods of measurement of the tar, nicotine and carbon monoxide emissions, where this is necessary, based on scientific and technical developments or internationally agreed standards.

4. Member States shall notify the Commission of any measurement methods they use for emissions from cigarettes other than the emissions referred to in paragraph 3 and for emissions from tobacco products other than cigarettes.

…’

14 Article 24 of Directive 2014/40 provides:

‘1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.

3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of

human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.'

Netherlands law

15 Article 17a(4) of the Tabaks- en rookwarenwet (Law on tobacco products and smoking-related products), which transposed Article 24(3) of Directive 2014/40, enables the State Secretary to prohibit by ministerial regulation, on grounds relating to the protection of public health, certain categories of tobacco products which also meet the requirements laid down by the law or prescribed pursuant to it.

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

16 By letters of 31 July and 2 August 2018, the applicants in the main proceedings requested the Nederlandse Voedsel- en Warenautoriteit (Netherlands Food and Consumer Product Safety Authority; 'the NVWA') to ensure that filter cigarettes offered for sale to consumers in the Netherlands comply, when used as intended, with the maximum emission levels for tar, nicotine and carbon monoxide prescribed in Article 3 of Directive 2014/40. They also requested the NVWA to order manufacturers, importers and distributors of tobacco products, by an administrative enforcement measure, to withdraw from the market filter cigarettes allegedly not complying with those maximum emission levels.

17 That request for an order is based on a study by the Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment, Netherlands; 'the RIVM') of 13 June 2018, which is said to show that, when the 'Canadian Intense' measurement method, and not the method prescribed in Article 4 of Directive 2014/40, is applied, all filter cigarettes sold in the Netherlands exceed appreciably the maximum emission levels for tar, nicotine and carbon monoxide prescribed in Article 3(1) of that directive. The applicants in the main proceedings consider that the measurement method laid down in Article 4 of the directive fails to take account of the way in which a cigarette filter is used, namely that the smoker's fingers and lips block the small holes in the filter. Those small holes allow clean air to be drawn through the filter, with the result that the quantities of tar, nicotine and carbon monoxide are reduced by mixing with it. According to the applicants in the main proceedings, measuring carried out in respect of the various brands of cigarettes with a ventilated filter thus reveals emissions between 2 and more than 20 times lower than what is recorded when the filter is covered. When the cigarettes are used as intended, those small holes are largely blocked by the smoker's fingers and lips, so that he or she inhales quantities of tar, nicotine and carbon monoxide significantly above the maximum emission levels prescribed in Article 3 of Directive 2014/40.

18 On 20 September 2018, the NVWA rejected the request for an order.

19 The applicants in the main proceedings brought before the State Secretary an administrative objection challenging the decision of 20 September 2018. By decision of 31 January 2019, the State Secretary rejected the objection as unfounded in so far as it was brought by the Stichting Rookpreventie Jeugd and as inadmissible in so far as it was brought by the other applicants in the main proceedings.

20 The applicants in the main proceedings then brought an action before the referring court challenging the decision of 31 January 2019. The Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten (VSK) (Netherlands Cigarette and Tobacco Manufacturers' Association) applied for leave to intervene in the proceedings, which was granted.

21 Before the referring court, the applicants in the main proceedings submit that Article 4(1) of Directive 2014/40 does not require recourse to a particular method of measuring emission levels and that the ISO standards, on the basis of which the measuring is to be carried out, do not constitute requirements of general application. They contend that it is clear from several studies, that is to say, the RIVM's study of 13 June 2018 and a study that appeared in the *Journal of the National Cancer Institute* on 22 May 2017 entitled 'Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma', and from letters sent by the State Secretary to the Commission, that the 'Canadian Intense' measurement method is the method that should be applied in order to determine the precise levels of tar, nicotine and carbon monoxide emissions from a filter cigarette used as intended.

22 In the first place, the referring court observes that Article 4(1) of Directive 2014/40 provides that the quantities of tar, nicotine and carbon monoxide emitted by cigarettes are to be measured on the basis of ISO standards which are not freely accessible to the public and can be consulted only in return for payment, although the protection granted to citizens by Article 3(1) of that directive is founded on those standards. It is therefore unsure whether such a method of regulation is compatible with the publication regime applicable to legislative acts of the European Union and with the principle of transparency.

23 In the second place, the referring court states that, in each of the ISO standards mentioned in Article 4 of Directive 2014/40, reference is made, as regards measuring the relevant emission level, to ISO standard 3308. That standard concerns use of a smoking machine. The referring court considers that it appears from that standard itself that the emission levels of tar, nicotine and carbon monoxide are not only to be measured and verified by the prescribed method, but may or must also be measured and verified in a different manner and with different intensities of machine smoking.

24 In the third place, the referring court is uncertain whether the measurement and validation methods laid down in Article 4(1) of Directive 2014/40 are consistent with the directive's objective as resulting from its preamble, and whether the emission levels laid down in Article 3 of the directive can be measured only on the basis of the ISO 3308 method. First, it notes that the applicants in the main proceedings contend, without being contradicted in that regard, that those measurement methods were established with the participation of the tobacco industry. Second, it states that failure to observe the ceiling for emissions from filter cigarettes consumed as intended would seriously undermine the objective set out in recital 8 of the directive, of ensuring a high level of health protection. The referring court therefore raises the question whether Article 4(1) of Directive 2014/40 might be contrary to Article 114(3) TFEU, the FCTC and Articles 24 and 35 of the Charter of Fundamental Rights of the European Union ('the Charter').

25 In the fourth place, the referring court raises the question whether, if Article 4(1) of Directive 2014/40 is contrary inter alia to Article 297(1) TFEU, Regulation No 216/2013 and the principle of transparency, Directive 2014/40 lacks effect in its entirety or only as regards Article 4(1). The referring court is also uncertain what alternative method may or must be used and whether the Court has jurisdiction to prescribe it or, less extensively, to entrust the EU legislature or the

Member States with the task of adopting new legislation governing the matter. Furthermore, the referring court points out that, under the Netherlands law that transposed Article 24(3) of Directive 2014/40, the State Secretary may, on grounds relating to the protection of public health, prohibit by ministerial regulation certain categories of tobacco products which meet the requirements laid down by the law or prescribed pursuant to it.

26 In those circumstances, the Rechtbank Rotterdam (District Court, Rotterdam, Netherlands) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is the form of the measurement method provided for in Article 4(1) of Directive 2014/40, based on ISO standards which are not freely accessible, in accordance with Article 297(1) TFEU (and Regulation (EU) No 216/2013) and with the underlying principle of transparency?

(2) Must the ISO standards 4387, 10315, 8454 and 8243 referred to by Article 4(1) of Directive 2014/40 be interpreted and applied in such a way that, in the interpretation and application of Article 4(1) of that directive, emissions of tar, nicotine and carbon monoxide should not be measured (and verified) only by the prescribed method, but that those emissions may or must also be measured (and verified) in a different manner and with a different intensity?

(3) (a) Is Article 4(1) of Directive 2014/40 contrary to the underlying principles of that directive and to Article 4(2) thereof as well as to Article 5(3) of the [FCTC], given that the tobacco industry played a role in determining the ISO standards referred to in Article 4(1) of that directive?

(b) Is Article 4(1) of Directive 2014/40 contrary to the underlying principles of that directive, to Article 114(3) TFEU, to the spirit of the [FCTC] and to Articles 24 and 35 of the Charter, on the ground that the measurement method prescribed therein does not measure the emissions from filter cigarettes during their intended use since, with that method, no account is taken of the effect of the small ventilation holes in the filter which are largely closed off during their intended use by the smoker's lips and fingers?

(4) (a) Which alternative measurement method (and verification method) may or must be used should the Court of Justice:

– answer Question 1 in the negative;

– answer Question 2 in the affirmative;

– answer Question 3(a) and/or Question 3(b) in the affirmative?

(b) If the Court is unable to give an answer to Question 4(a): Does the temporary unavailability of a measurement method give rise to a situation such as that referred to in Article 24(3) of Directive 2014/40?'

Consideration of the questions referred

Question 2

27 By Question 2, which it is appropriate to examine first, the referring court asks, in essence, whether Article 4(1) of Directive 2014/40 is to be interpreted as providing that the maximum emission levels for tar, nicotine and carbon monoxide from cigarettes intended to be placed on the market or manufactured in the Member States, prescribed in Article 3(1) of that directive, must be measured in accordance with the measurement methods arising from ISO standards 4387, 10315, 8454 and 8243, to which Article 4(1) refers.

28 First of all, it should be noted that Article 3(1) of Directive 2014/40 prescribes the maximum emission levels for tar, nicotine and carbon monoxide from cigarettes placed on the market or manufactured in the Member States. Article 4(1) of that directive provides that emissions of those substances are to be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide, the accuracy of the measurements being determined in accordance with ISO standard 8243.

29 In accordance with settled case-law, in interpreting a provision of EU law, it is necessary to consider not only its wording, by considering the latter's usual meaning in everyday language, but also the context in which the provision occurs and the objectives pursued by the rules of which it is part (judgment of 14 October 2021, *Dyrektor Z. Oddziału Regionalnego Agencji Restrukturyzacji i Modernizacji Rolnictwa*, C-373/20, EU:C:2021:850, paragraph 36).

30 It is clear, first, from the wording of the first subparagraph of Article 4(1) of Directive 2014/40, in particular from the words 'shall be measured' used in it, that that provision refers in mandatory terms to ISO standards 4387, 10315 and 8454 for the purpose of measuring tar, nicotine and carbon monoxide emissions respectively and that it does not mention any other measurement method. It is also in mandatory terms that the second subparagraph of Article 4(1) specifies that the accuracy of those measurements is to be determined in accordance with ISO standard 8243.

31 As regards, next, that provision's context, it should be noted that, under Article 4(4), the Member States are to notify the Commission of any other measurement methods they use for emissions from cigarettes other than tar, nicotine and carbon monoxide emissions and for emissions from tobacco products other than cigarettes. Neither Article 4 nor any other provision of Directive 2014/40 indicates that the Member States have a notification obligation if they use measurement methods for tar, nicotine and carbon monoxide emissions from cigarettes other than those provided for by ISO standards 4387, 10315 and 8454, or methods for verifying the accuracy of the measurements of those substances other than that provided for by ISO standard 8243. Since recital 11 of the directive states that the tar, nicotine and carbon monoxide yields of cigarettes should be measured by referring to those internationally recognised standards, the context in which Article 4(1) of the directive occurs must be regarded as tending to confirm that that provision lays down the exclusive application of those standards as a mandatory requirement.

32 Finally, it should be pointed out that Directive 2014/40 pursues a twofold objective of facilitating the smooth functioning of the internal market for tobacco and related products while taking as a base a high level of protection of human health, especially for young people (judgment of 22 November 2018, *Swedish Match*, C-151/17, EU:C:2018:938, paragraph 40). Without prejudice to the examination of Question 3(b), concerning, in essence, the validity of Article 4(1) of the directive having regard to the requirement – laid down in particular in Article 114(3) TFEU – for

a high level of protection of human health, to have recourse only to the methods provided for by the ISO standards referred to in Article 4(1) of the directive in order to measure the level of tar, nicotine and carbon monoxide emissions from cigarettes is consonant with that objective of smooth functioning of the internal market since it ensures that access of cigarettes to the EU market and their manufacture within the European Union will not be prevented on account of the application of various methods of measuring the levels of those substances in the Member States.

33 In the light of all the foregoing considerations, the answer to Question 2 is that Article 4(1) of Directive 2014/40 is to be interpreted as providing that the maximum emission levels for tar, nicotine and carbon monoxide from cigarettes intended to be placed on the market or manufactured in the Member States, prescribed in Article 3(1) of that directive, must be measured in accordance with the measurement methods arising from ISO standards 4387, 10315, 8454 and 8243, to which Article 4(1) refers.

Question 1

34 By Question 1, the referring court asks, in essence, whether Article 4(1) of Directive 2014/40 is valid having regard to the principle of transparency, to Regulation No 216/2013, and to Article 297(1) TFEU read in the light of the principle of legal certainty.

35 So far as concerns, in the first place, the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency, it should be noted that that principle, which is inextricably linked to the principle of openness, is enshrined in the second paragraph of Article 1 and Article 10(3) TEU, Article 15(1) and Article 298(1) TFEU and Article 42 of the Charter. It enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system (see, to that effect, judgments of 6 March 2003, *Interporc* v *Commission*, C-41/00 P, EU:C:2003:125, paragraph 39; and of 9 November 2010, *Volker und Markus Schecke and Eifert*, C-92/09 and C-93/09, EU:C:2010:662, paragraph 68; and order of 14 May 2019, *Hungary* v *Parliament*, C-650/18, not published, EU:C:2019:438, paragraph 13 and the case-law cited).

36 In particular, Article 15(1) TFEU provides that, in order to promote good governance and ensure the participation of civil society, the European Union's institutions, bodies, offices and agencies are to conduct their work as openly as possible. To that end, a right of access to documents is ensured under the first subparagraph of Article 15(3) TFEU and enshrined in Article 42 of the Charter, a right which has been implemented, inter alia, by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43).

37 In that regard, it is true that Article 4(1) of Directive 2014/40 refers to ISO standards which, at this juncture, have not been published in the *Official Journal of the European Union*. However, that provision does not itself lay down any restriction concerning access to those standards, including by making that access subject to the submission of a request pursuant to Regulation No 1049/2001. It cannot therefore be considered to be invalid having regard to the principle of transparency as resulting from the provisions of primary EU law referred to in paragraph 35 above.

38 So far as concerns, in the second place, the validity of Article 4(1) of Directive 2014/40 having regard to Regulation No 216/2013, it must be pointed out that the substantive legality of an EU act cannot be examined in the light of another EU act of the same status in the hierarchy of legal rules, unless the former has been adopted pursuant to the latter or unless it is expressly provided, in one of those two acts, that one takes precedence over the other (judgment of 8 December 2020, *Hungary* v *Parliament and Council*, C-620/18, EU:C:2020:1001, paragraph 119). Directive 2014/40 was not adopted pursuant to Regulation No 216/2013 and the latter does not contain a provision expressly laying down that it takes precedence over that directive. In any event, in merely providing that the *Official Journal of the European Union* is to be published in electronic form, in the official languages of the EU institutions, Article 1(1) of that regulation does not lay down any requirement relating to the content of the EU acts that must thus be published, such as Directive 2014/40.

39 So far as concerns, in the third place, the validity of Article 4(1) of Directive 2014/40 having regard to Article 297(1) TFEU read in the light of the principle of legal certainty, it should be pointed out that it is clear from the very wording of the latter provision that legislative acts can enter into force and accordingly have legal effects only after they have been published in the *Official Journal of the European Union* (see, to that effect, judgments of 11 December 2007, *Skoma-Lux*, C-161/06, EU:C:2007:773, paragraph 33, and of 10 March 2009, *Heinrich*, C-345/06, EU:C:2009:140, paragraph 42).

40 Thus, acts adopted by the EU institutions cannot be enforced against natural and legal persons in a Member State before they have had the opportunity to make themselves acquainted with those acts by their proper publication in the *Official Journal of the European Union* (see, to that effect, judgments of 11 December 2007, *Skoma-Lux*, C-161/06, EU:C:2007:773, paragraph 37, and of 10 March 2009, *Heinrich*, C-345/06, EU:C:2009:140, paragraph 43).

41 That publication requirement flows from the principle of legal certainty, which requires that EU rules enable those concerned to know precisely the extent of the obligations which are imposed on them. Individuals must be able to ascertain unequivocally what their rights and obligations are (see, inter alia, judgment of 10 March 2009, *Heinrich*, C-345/06, EU:C:2009:140, paragraph 44).

42 The same applies where EU legislation, such as Directive 2014/40, obliges Member States, in order to implement it, to adopt measures imposing obligations on individuals. The measures adopted by the Member States to implement EU law must comply with the general principles of EU law. Therefore, national measures which, to implement EU legislation, impose obligations on individuals must, in accordance with the principle of legal certainty, be published in order for the individuals to be able to ascertain those obligations. In such a situation the individuals must also have the possibility of determining the source of the national measures imposing obligations upon them, since the Member States have adopted such measures in order to implement an obligation imposed by EU law (judgment of 10 March 2009, *Heinrich*, C-345/06, EU:C:2009:140, paragraphs 45 and 46).

43 That said, according to the Court's case-law, the fact that a provision does not prescribe any specific method or process does not mean, however, that it infringes the principle of legal certainty (judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraph 101). Thus, it is not necessary for a legislative act itself to provide details of a technical nature, since the EU legislature may have recourse to a general legal framework which is, if necessary, to be made more precise at a later date (judgment of 30 January 2019, *Planta Tabak*, C-220/17, EU:C:2019:76, paragraph 32 and the case-law cited).

44 By analogy, and in the light also of the broad discretion that the EU legislature has in the exercise of the powers conferred on it where its action involves political, economic and social choices and where it is called on to undertake complex assessments and evaluations (judgment of 30 January 2019, *Planta Tabak*, C-220/17, EU:C:2019:76, paragraph 44), it is open to the EU legislature to refer, in the acts that it adopts, to technical standards determined by a standards body, such as the International Organisation for Standardisation (ISO).

45 However, the principle of legal certainty requires that the reference to such standards be clear and precise and predictable in its effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law (judgment of 3 December 2019, *Czech Republic* v *Parliament and Council*, C-482/17, EU:C:2019:1035, paragraph 148 and the case-law cited).

46 In the present instance, first, the reference made by Article 4(1) of Directive 2014/40 to the ISO standards complies with that requirement and, second, it is not disputed that that Directive 2014/40 was, in accordance with Article 297(1) TFEU, published in the *Official Journal of the European Union*. That being so, in the light of what has been stated in paragraphs 43 and 44 above, the mere fact that Article 4(1) of the directive refers to ISO standards that have not, at this juncture, been so published is not capable of calling into question the validity of that provision having regard to Article 297(1) TFEU read in the light of the principle of legal certainty.

47 It follows that consideration of Question 1 has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency, to Regulation No 216/2013, and to Article 297(1) TFEU read in the light of the principle of legal certainty.

48 Nevertheless, in view of the doubts of the referring court – summarised in paragraph 22 above – at the root of Question 1, it should also be stated that, in accordance with the principle of legal certainty as explained in paragraphs 41, 42 and 45 above, technical standards determined by a standards body, such as ISO, and made mandatory by a legislative act of the European Union are binding on the public generally only if they themselves have been published in the *Official Journal of the European Union*.

49 Where those standards have been amended by such a body, that principle also means that only the version of those standards that has been published is binding on the public generally.

50 In the present instance, as follows from Article 3(1) of Directive 2014/40 read in conjunction with Article 4(1) thereof, undertakings may neither place on the markets of the Member States nor manufacture cigarettes whose levels of tar, nicotine and carbon monoxide emissions exceed the maximum levels prescribed by the first of those provisions as measured by applying the methods provided for by the ISO standards to which the second of those provisions refers. That being so, Article 4(1) of the directive must be regarded as imposing an obligation owed by those undertakings.

51 In the absence of publication in the *Official Journal of the European Union* of the standards to which Article 4(1) of Directive 2014/40 refers, the public generally is unable, contrary to the case-law recalled in paragraphs 41, 42 and 45 above, to ascertain the methods of measuring the emission levels of tar, nicotine and carbon monoxide applicable to cigarettes.

52 That said, account must be taken of the specific features of the system established by ISO, which consists of a network of national standards bodies, enabling those national bodies to grant, upon request, access to the official and authentic version of the standards determined by ISO. Accordingly, where undertakings have access to the official and authentic version of the standards referred to in Article 4(1) of Directive 2014/40, those standards and, therefore, the reference made thereto by that provision are binding on them.

53 In the light of all the foregoing, it must be held that consideration of Question 1 has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency, to Regulation No 216/2013, and to Article 297(1) TFEU read in the light of the principle of legal certainty.

Question 3(a)

54 By Question 3(a), the referring court asks, in essence, whether Article 4(1) of Directive 2014/40 is valid having regard to the basic principles of that directive, Article 4(2) of that directive and Article 5(3) of the FCTC, on account of the fact that the tobacco industry participated in the determination of the standards to which Article 4(1) of the directive refers.

55 First of all, it should be noted that the referring court does not state the basic principles of Directive 2014/40 having regard to which the validity of Article 4(1) of that directive should be examined.

56 It should also be noted that Article 4(2) of Directive 2014/40 requires the measurements of tar, nicotine and carbon monoxide emissions to be verified by laboratories which are approved and monitored by the competent authorities of the Member States, and are not owned or controlled directly or indirectly by the tobacco industry. That provision thus does not concern the actual drawing up of the ISO standards to which Article 4(1) of Directive 2014/40 refers.

57 The validity of Article 4(1) of Directive 2014/40 should therefore be examined having regard solely to Article 5(3) of the FCTC, on account of the fact that the tobacco industry participated in the determination at ISO of the standards in question.

58 Article 5(3) of the FCTC provides that, in setting and implementing their public health policies with respect to tobacco control, the parties to that convention are to act to protect these policies from interests of the tobacco industry in accordance with national law.

59 It is clear from the very wording of that provision that it does not prohibit all participation of the tobacco industry in the establishment and implementation of rules on tobacco control, but is intended solely to prevent the tobacco control policies of the parties to the convention from being influenced by that industry's interests.

60 That interpretation of Article 5(3) of the FCTC is borne out by the guidelines for the implementation of that provision, which do not themselves have binding force, but are intended, in accordance with Articles 7 and 9 of the FCTC, to assist the Contracting Parties in implementing the binding provisions of that convention. Those guidelines have been adopted by consensus, including by the European Union and its Member States, as is stated in recital 7 of Directive 2014/40 (judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraphs 111 and 112).

61 Those guidelines indeed recommend that interactions with the tobacco industry should be limited and transparent, while avoiding conflicts of interest for public officials or employees of each of the parties to the FCTC.

62 Consequently, the validity of Article 4(1) of Directive 2014/40 cannot be called into question having regard to Article 5(3) of the FCTC merely on the ground, set out by the referring court, that the tobacco industry participated in the determination at ISO of the standards in question.

63 In the light of the foregoing considerations, it must be held that consideration of Question 3(a) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 5(3) of the FCTC.

Question 3(b)

64 By Question 3(b), the referring court asks, in essence, whether Article 4(1) of Directive 2014/40 is valid having regard to the basic principles of that directive, Article 114(3) TFEU, the FCTC and Articles 24 and 35 of the Charter, on account of the fact that scientific studies are said to establish that the measurement methods to which Article 4(1) of that directive refers do not reflect the levels of tar, nicotine and carbon monoxide from cigarettes that are actually inhaled by smokers.

65 First of all, the finding in paragraph 55 above must be reiterated, namely that the referring court does not state the basic principles having regard to which the validity of Article 4(1) of Directive 2014/40 should be examined.

66 In support of the question referred to in paragraph 64 above, the referring court mentions various documents adduced by the Stichting Rookpreventie Jeugd in the main proceedings, cited in paragraph 21 above.

67 However, the Court has consistently held that the legality of an EU act must be assessed in the light of the information available to the EU legislature on the date of the adoption of the rules in question (judgment of 3 December 2019, *Czech Republic* v *Parliament and Council*, C-482/17, EU:C:2019:1035, paragraph 80).

68 As the studies and other documents referred to in paragraph 21 above all postdate 3 April 2014, the date on which Directive 2014/40 was adopted, they cannot be taken into account for the purpose of assessing the validity of Article 4(1) of that directive.

69 It follows that consideration of Question 3(b) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 114(3) TFEU, the FCTC and Articles 24 and 35 of the Charter.

Question 4(a)

70 By Question 4(a), the referring court asks, in essence, should Article 4(1) of Directive 2014/40 not be binding on individuals, what method of measuring tar, nicotine and carbon monoxide emissions from cigarettes may be used for the purpose of verifying compliance with the maximum emission levels prescribed in Article 3(1) of that directive.

71 This question arises in the context of a dispute that relates to the NVWA's refusal to order manufacturers, importers and distributors of tobacco products, by an administrative enforcement measure, to withdraw from the market filter cigarettes offered for sale to consumers in the Netherlands which allegedly do not comply, when used as intended, with the emission levels prescribed in Article 3(1) of Directive 2014/40.

72 Cigarettes intended to be placed on the EU market or to be manufactured in the European Union must comply with the maximum emission levels for tar, nicotine and carbon monoxide that are prescribed in Article 3(1) of Directive 2014/40.

73 However, it should be recalled that Article 4(1) of Directive 2014/40 is not binding on the public generally in so far as it refers to ISO standards not published in the *Official Journal of the European Union*.

74 Therefore, it is for the referring court, for the purpose of deciding the dispute before it, to determine whether the methods actually used to measure the emission levels of those substances comply with Directive 2014/40, without taking account of Article 4(1) thereof.

75 In that regard, it should be pointed out, first, that it is clear from Article 2(21) of Directive 2014/40 that the term 'emissions' refers to 'substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products'.

76 Second, pursuant to Article 4(2) of Directive 2014/40, measurements of the levels of tar, nicotine and carbon monoxide emissions are to be verified by laboratories which are approved and monitored by the competent authorities of the Member States. Those laboratories are not to be owned or controlled directly or indirectly by the tobacco industry.

77 Third, in accordance with Article 4(3) of Directive 2014/40, adaptation by the Commission of the methods of measuring those emission levels must take account of scientific and technical developments or internationally agreed standards.

78 Fourth, any method of measuring the maximum emission levels prescribed in Article 3(1) of Directive 2014/40 must effectively meet its objective, reflected in Article 1 thereof, of ensuring a high level of protection of human health, especially for young people.

79 Accordingly, the answer to Question 4(a) is that, should Article 4(1) of Directive 2014/40 not be binding on individuals, the method used for the purpose of applying Article 3(1) of that directive must be appropriate, in the light of scientific and technical developments or internationally agreed standards, for measuring the levels of emissions released when a cigarette is consumed as intended, and must take as a base a high level of protection of human health, especially for young people, while the accuracy of the measurements obtained by means of that method must be verified by laboratories approved and monitored by the competent authorities of the Member States as referred to in Article 4(2) of that directive.

Question 4(b)

80 By Question 4(b), the referring court asks, in essence, whether Article 24(3) of Directive 2014/40 is applicable to the dispute in the main proceedings.

81 Article 17a(4) of the Law on tobacco products and smoking-related products, which transposed Article 24(3) of Directive 2014/40, enables the State Secretary to prohibit by ministerial regulation, on grounds relating to the protection of public health, certain categories of tobacco products which meet the requirements laid down by the law or prescribed pursuant to it.

82 It should be recalled that, according to settled case-law of the Court, questions on the interpretation of EU law referred by a national court in the factual and legislative context which that court is responsible for defining, and the accuracy of which is not a matter for the Court to determine, enjoy a presumption of relevance. The Court may refuse to rule on a question referred by a national court only where it is quite obvious that the interpretation of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 20 December 2017, *Erzeugerorganisation Tiefkühlgemüse*, C-516/16, EU:C:2017:1011, paragraph 80).

83 There is nothing in the documents before the Court to indicate that the dispute in the main proceedings relates, even in part, to the power available to the State Secretary under Article 17a(4) of the Law on tobacco products and smoking-related products, which transposed Article 24(3) of Directive 2014/40.

84 It follows that to answer Question 4(b) in those circumstances would clearly amount to providing an advisory opinion on a hypothetical question, in disregard of the task assigned to the Court in the context of the judicial cooperation established by Article 267 TFEU (see, to that effect, judgment of 20 December 2017, *Erzeugerorganisation Tiefkühlgemüse*, C-516/16, EU:C:2017:1011, paragraph 82).

85 Consequently, Question 4(b) is inadmissible.

Costs

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

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

1. **Article 4(1) 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 is to be interpreted as providing that the maximum emission levels for tar, nicotine and carbon monoxide from cigarettes intended to be placed on the market or manufactured in the Member States, prescribed in Article 3(1) of that directive, must be measured in accordance with the measurement methods arising from ISO standards 4387, 10315, 8454 and 8243, to which Article 4(1) refers.**

2. **Consideration of Question 1 has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency, to Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*, and to Article 297(1) TFEU read in the light of the principle of legal certainty.**

3. **Consideration of Question 3(a) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 5(3) of the World Health Organisation Framework Convention on Tobacco Control.**

4. **Consideration of Question 3(b) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 114(3) TFEU, the World Health Organisation Framework Convention on Tobacco Control and Articles 24 and 35 of the Charter of Fundamental Rights of the European Union.**

5. **Should Article 4(1) of Directive 2014/40 not be binding on individuals, the method used for the purpose of applying Article 3(1) of that directive must be appropriate, in the light of scientific and technical developments or internationally agreed standards, for measuring the levels of emissions released when a cigarette is consumed as intended, and must take as a base a high level of protection of human health, especially for young people, while the accuracy of the measurements obtained by means of that method must be verified by laboratories approved and monitored by the competent authorities of the Member States as referred to in Article 4(2) of that directive.**

[Signatures]