



Reports of Cases

OPINION OF ADVOCATE GENERAL
EMILIOU

delivered on 4 September 2025¹

Case C-155/24

**Nederlandse Voedsel- en Warenautoriteit,
Staatssecretaris van Volksgezondheid, Welzijn en Sport,
Philip Morris Benelux BV,
Philip Morris Investments BV,
JT International Company Netherlands BV,
Vereniging Nederlandse Sigaretten- & Kerftabakfabrikanten,
Van Nelle Tabak Nederland BV,
British American Tobacco International (Holdings) BV**
v
Stichting Rookpreventie Jeugd

(Request for a preliminary ruling from the College van Beroep voor het bedrijfsleven (Supreme Administrative Court for Trade and Industry, Netherlands))

(Reference for a preliminary ruling – Approximation of laws – Manufacture and sale of tobacco products – Directive 2014/40/EU – Maximum emission levels – Measurement method – Measurement of emissions on the basis of ISO standards – Article 4(1) of Directive 2014/40 – Standards not published in the *Official Journal of the European Union* – Enforceability of the ISO standards referred to in Article 4(1) of Directive 2014/40 – Conclusions to be drawn from the judgment of 22 February 2022, *Stichting Rookpreventie Jeugd and Others* (C-160/20, EU:C:2022:101))

I. Introduction

1. The present reference for a preliminary ruling invites the Court to clarify, in essence, the applicable method to establish whether the cigarettes put on the market of a Member State comply with the maximum emission levels for tar, nicotine and carbon monoxide that are set in Directive 2014/40/EU ('maximum emission levels').² It is the second reference made within the context of the same national judicial proceedings.

¹ Original language: English.

² Directive 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. To understand the reasons having prompted the questions referred, it should be observed that Directive 2014/40 also provides for the methods through which compliance with the above levels is to be established. This is carried out by reference to several standards of the International Organization for Standardization (ISO) which, to date, have not been published in the *Official Journal of the European Union* ('the Official Journal'). As I will explain in more detail, this is due to the fact that those standards are protected by intellectual property rights claimed by ISO.

3. In its judgment in *Stichting Rookpreventie Jeugd and Others* the Court confirmed that Directive 2014/40 makes the use of those standards mandatory.³ However, it also held that if they have not been published in the Official Journal, they do not bind 'the public generally', while they do bind 'undertakings' (manufacturing the cigarettes or placing them on the market) where those undertakings could access them.⁴ As a consequence of that conclusion, the Court held, in essence, that compliance with the maximum emission levels could be verified without taking the ISO standards into account, should it be established that they are not binding.⁵

4. That clarification was part of a reply provided to the Rechtbank Rotterdam (District Court, Rotterdam, Netherlands), which was seised with a claim brought by, inter alia, the Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation, Netherlands) ('the Foundation'). That party alleged that the cigarettes put on the national market did not comply with the maximum emission levels, when tested using a method *different* from (and, as I understand it, more stringent than) the ISO standards referred to in Article 4(1) of Directive 2014/40. Based on the Court's reply, that national court adopted an order for the withdrawal of the cigarettes concerned from the market.

5. That order has been appealed, in particular, by several cigarette manufacturers, before the College van Beroep voor het bedrijfsleven (Supreme Administrative Court for Trade and Industry, Netherlands), which entertains doubts about the implications of the Court's judgment.

6. It enquires inter alia whether the conclusion about the lack of binding effect of the ISO standards at issue vis-à-vis 'the public generally' stands when a party, such as the Foundation, could access them. Furthermore, it asks whether that party has a right, arising under Directive 2014/40, to see the maximum emission levels respected (by application of an alternative measurement method). It also seeks to ascertain the consequences for the cigarette manufacturers of the possible finding that the cigarettes (although placed on the market in conformity with the requirements of Directive 2014/40) do not meet the maximum emission levels if measured by such an alternative method.

7. It follows that besides the issue of the method to be used to verify whether marketed cigarettes meet the maximum levels for emissions of tar, nicotine and carbon monoxide, the present reference raises the issue of the legal effects, within the EU legal order, of technical standards which were elaborated outside the institutional structure of the European Union, whose use was made mandatory and whose content remains unpublished in the Official Journal. No less importantly, it concerns the broader issue of the legal certainty that should benefit those who, generally speaking, abide by the binding rules of law, and tests the fundamental premiss of free accessibility of law.

³ Judgment of 22 February 2022, *Stichting Rookpreventie Jeugd and Others* (C-160/20, 'the judgment in *Stichting Rookpreventie Jeugd and Others*' and 'the judgment under discussion', EU:C:2022:101, paragraph 33).

⁴ *Ibidem*, paragraphs 48 and 52.

⁵ *Ibidem*, paragraphs 74 and 79 and point 5 of the operative part.

II. Legal framework

A. *European Union law*

8. According to recital 8 of Directive 2014/40 ‘in accordance with Article 114(3) of the Treaty of the Functioning of the European Union (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.’

9. According to Article 1 of Directive 2014/40, the objective of the latter ‘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”).

10. Pursuant to point 10 of Article 2 of Directive 2014/40, ‘cigarette’ ‘means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU’.⁶

11. According to point 21 of Article 2 of Directive 2014/40, ‘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. Article 3 of the same directive is about ‘maximum emission levels for tar, nicotine, carbon monoxide and other substances’. It provides as follows:

‘1. 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.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to decrease the maximum emission levels laid down in paragraph 1, where this is necessary based on internationally agreed standards.

⁶ Directive of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco (OJ 2011 L 176, p. 24).

...'

13. Article 4 of Directive 2014/40 concerns 'measurement methods'. It reads as follows:

'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.

...

3. The 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.

...'

14. Article 24(1) of Directive 2014/40 is entitled 'Free movement' and states that 'Member States may not, for considerations relating to aspects regulated by [Directive 2014/40], 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.'

B. National law

15. Article 2.1 of the Besluit van 14 oktober 2015, houdende samenvoeging van de algemene maatregelen van bestuur op basis van de Tabakswet tot één besluit (Tabaks- en rookwarenbesluit) (Decree of 14 October 2015, merging the general administrative measures based on the Tobacco Act into one decree (Tobacco and Smoking Products Decree) ('the Decree')) provides that 'the maximum emission levels of a cigarette placed on the market or produced shall comply with Article 3(1) of [Directive 2014/40]'.

16. Article 2.1 of the Regeling van de Staatssecretaris van Volksgezondheid, Welzijn en Sport van 10 mei 2016 houdende regels inzake de productie, de presentatie en de verkoop van tabaksproducten en aanverwante producten (Tabaks- en rookwarenregeling) (Regulation of the State Secretary for Health, Welfare and Sport of 10 May 2016 laying down rules for the manufacture, presentation and sale of tobacco products and related products (the Ministerial Regulation on tobacco and smoking products)) provides that:

'1. Examination methods which alone determine whether a cigarette meets the requirements of Article 2.1(1) of the Decree are designated as measures meeting the following standards:

- a. NEN-ISO 4387:2000/A1:2008 Cigarettes – Determination of the total particulate matter and nicotine-free anhydrous particulate matter content with a routine analytical smoking machine as regards the level of tar emission;
- b. NEN-ISO 10315:2013 Cigarettes – Determination, as regards the nicotine emission level, of the nicotine content in smoke condensates – Method by gas chromatography;

- c. NEN-ISO 8454:2007/A1:2009 Cigarettes – Determination, as regards the emission level of carbon monoxide, of the carbon monoxide content in the gaseous phase of cigarette smoke – IRND method.
2. The results of the measurements shall be checked against standard NEN ISO 8243:2013 Cigarettes – Sampling.’

III. Facts, national proceedings and the questions referred

17. The case in the main proceedings started with a letter of the Foundation, dated 31 July 2018, requesting the Nederlandse Voedsel- en Warenautoriteit (Netherlands Food and Consumer Product Safety Authority) (‘the NVWA’) to ensure that filter cigarettes on the Netherlands market comply, when consumed as intended, with the maximum emission levels set in Article 3(1) of Directive 2014/40, determined based on a method widely considered in the scientific community to be the closest to the cigarettes’ intended use.

18. According to the Foundation, the ISO measurement standards referred to in Article 4(1) of Directive 2014/40 do not reflect the cigarettes’ intended use, because they do not take into account the way in which a cigarette is smoked, that is with the micro-ventilation holes in the filter being obstructed by the lips and fingers of the smoker.

19. The Foundation relied on a 2018 study by the Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment, Netherlands; ‘the RIVM’) (‘RIVM study’) according to which, where the emissions are measured by the so-called Canadian Intense method, the maximum emission levels are significantly exceeded. It thus asked the NVWA to remove non-compliant filter cigarettes from the national market.

20. The NVWA rejected that request, in essence, with the explanation that no other method than the one referred to in Article 4(1) of Directive 2014/40 can be used.

21. The Foundation (and several other entities) brought an action before the rechtbank Rotterdam (District Court, Rotterdam). The Vereniging Nederlandse Sigaretten- & Kerftabakfabrikanten (Netherlands Cigarette and Tobacco Manufacturers’ Association) (‘the VSK’) was admitted to participate as a third party. By its decision of 20 March 2020, that court referred several questions to the Court of Justice for a preliminary ruling concerning the validity and interpretation of Article 4(1) of Directive 2014/40.

22. The Court answered those questions by means of its judgment in *Stichting Rookpreventie Jeugd and Others*, a summary of which is presented in points 3 and 4 above, and to which I will turn in more detail later.

23. In reaction to that judgment, the rechtbank Rotterdam (District Court, Rotterdam) held in its decision of 4 November 2022 that the national provisions implementing the ISO measurement standards at issue are not enforceable against the Foundation as an individual in general, and that the method described therein does not comply with Directive 2014/40, since it does not measure the emission levels generated when a cigarette is consumed as intended.

24. According to that court, in the absence of a measurement method compliant with Directive 2014/40, it was not possible to determine whether filter cigarettes sold in the Netherlands comply with the cigarettes' maximum emission levels. Taking into account the RIVM study and the Canadian Intense method, the rechtbank Rotterdam (District Court, Rotterdam) concluded that there were strong indications that the cigarettes on the market did not comply with those levels. Accordingly, it upheld the Foundation's action.

25. That decision has been appealed by the NVWA, the Staatssecretaris van Volksgezondheid, Welzijn en Sport (State Secretary for Health, Welfare and Sport, Netherlands; 'the State Secretary'), the VSK and the following parties (together, 'the tobacco manufacturers concerned in the main proceedings'): Philip Morris Benelux BV and Philip Morris Investments BV (together, 'Philip Morris'), JT International Company Netherlands BV ('JTI'), Van Nelle Tabak Nederland BV, operating under the name of Imperial Tobacco Nederland ('Imperial') and British American Tobacco International (Holdings) BV ('BAT').

26. By letter of 10 May 2023, the NVWA and the State Secretary presented the results of a new RIVM study commissioned by the NVWA on the emission levels of filter cigarettes available in the Netherlands, measured using the World Health Organization ('WHO') method TobLabNet (Standard operating procedure for intense smoking of cigarettes) SOP 01. Those results show that the maximum emission levels are exceeded.

27. In those circumstances, the College van Beroep voor het bedrijfsleven (Supreme Administrative Court for Trade and Industry) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

- '(1) Is Article 4(1) of [Directive 2014/40] to be interpreted as meaning that ISO standards not published in the [Official Journal] cannot, without exception, be enforced against individuals, including the Foundation, even if that individual was able to inspect those standards and obtain them (against payment)?
- (2) Is the unenforceability of Article 4(1) of [Directive 2014/40] against individuals, in so far as that provision refers to ISO standards not published in the [Official Journal], to be understood as meaning that it is not permitted to refuse the right to respect the maximum emission levels for tar, nicotine and carbon monoxide laid down in Article 3(1) of [Directive 2014/40]?
- (3) Is the expression "consumed as intended", which is included in the definition of "emissions" in [point 21 of Article 2] of [Directive 2014/40], to be interpreted as meaning that it is approximated as closely as possible to human smoking behaviour, in which case the measurement would have to take into account the at least partial covering of the micro-ventilation holes in the cigarette filter and/or the volume and frequency of smoke, or does that expression refer only to the method of consuming cigarettes through a process of combustion?

- (4)(a) If, in view of the answer to question 3, the ISO standards referred to in Article 4(1) of [Directive 2014/40] are not suitable for measuring emission levels: [(a)] does a high level of public health protection, in particular for young people, which [Directive 2014/40] includes as one of its objectives, mean that the principles of legal certainty and legal precision of the applicable law do not preclude an alternative method of measurement from being enforced against tobacco manufacturers?

If, also having regard to the principles of legal certainty and legal precision of the applicable law, question [(4)(a)] is answered in the affirmative:

- (4)(b) are Member States authorised to establish or apply an alternative measurement method themselves, whether temporarily or otherwise, and to enforce this alternative measurement method (also) against tobacco manufacturers, and
- (4)(c) how does the application of an alternative measurement method relate to the (maximum) harmonisation and improved functioning of the internal market, which [Directive 2014/40] includes amongst its objectives?

- (5)(a) In the event that an alternative measurement method has to be applied, do the maximum emission levels of Article 3(1) of [Directive 2014/40] remain fully applicable?

If question [(5)(a)] is answered in the negative:

- (5)(b) are Member States authorised to adopt or apply themselves, whether temporarily or otherwise, alternative maximum emission levels and to enforce these (also) against tobacco manufacturers, and
- (5)(c) how does the application of alternative maximum emission levels relate to the (maximum) harmonisation and improved functioning of the internal market, which [Directive 2014/40] includes amongst its objectives?

- (6)(a) If Member States are authorised to adopt or implement an alternative measurement method and that method can be enforced against tobacco manufacturers, in that case, does a high level of public health protection, in particular for young people, which [Directive 2014/40] includes amongst its objectives, in combination with Article 23(2) of the Directive, mean in that case that cigarettes on the market in the Netherlands must be withdrawn from the market until a new measurement method has been established, such that it cannot be determined whether the cigarettes consumed as intended comply with the maximum emission levels?

If question [(6)(a)] is answered in the affirmative:

- (6)(b) Are tobacco manufacturers entitled to a transitional period in that case?
- (7) If an alternative measurement method has been established or implemented, whether or not in combination with alternative maximum emission levels, are tobacco manufacturers in that case entitled to a transitional period during which they can adapt to that alternative measurement method and any alternative maximum emission levels?

28. Written observations have been submitted by Stichting Rookpreventie Jeugd, Philip Morris, JTI, Imperial and BAT, by the Netherlands, Bulgarian, Czech, Hungarian, and Portuguese Governments and by the European Commission. Those interested persons, with the exception of the Czech, Hungarian and Portuguese Governments, presented oral argument at a hearing that took place on 10 March 2025.

IV. Assessment

29. By its questions, the referring court enquires, in essence, about the precise consequences flowing from the Court's judgment in *Stichting Rookpreventie Jeugd and Others*.

30. More specifically, by its first question, it asks, whether the conclusion reached in that judgment that the ISO measurement standards referred to in Article 4(1) of Directive 2014/40 do not bind 'the public generally' applies when the respective party (such as the Foundation) could access them and, by its second question, if the lack of binding effect of those ISO standards vis-à-vis such a party is confirmed, whether that party derives, from Directive 2014/40, a right to, in essence, enforce compliance with the maximum emission levels before the national courts.

31. By the third and fourth questions, the referring court enquires, in essence, whether the method set out in the ISO standards referred to above measures those emission levels in an appropriate manner and, if that is not the case, whether Member States' authorities may, or even must, use alternative measurement methods, such as the one invoked by the Foundation before the Netherlands courts, and whether the enforcement of such alternative standards against the tobacco manufacturers is compatible with the principle of legal certainty.

32. By the fifth question, the referring court asks whether the conclusion that an alternative measurement method may, or must, be applied by the national authorities affects the applicability of the maximum emission levels provided for by Article 3(1) of Directive 2014/40.

33. Finally, the sixth and seventh questions concern whether, in essence, until an alternative method is established, the respective cigarettes must be withdrawn from the market and whether a transitional period must be provided, to mitigate the negative consequences that such a measure would bring about to the affected undertakings.

34. At the Court's request, the present Opinion shall deal only with the *first to fourth* questions referred.

35. To be able to carry out that analysis (B), I will turn to the Court's judgment in *Stichting Rookpreventie Jeugd and Others* and to the legal conundrum it addressed (A). I will close with a postscript addressing some aspects of the persisting lack of publication of the ISO standards at issue (C).

A. The judgment in Stichting Rookpreventie Jeugd and Others

36. To explain the proper scope of the judgment under discussion, first I will highlight the main elements of the relevant legal background and the key parts of the reply that the Court delivered (1). Second, I will place that reply into the context of the Court's previous case-law regarding the

legal effects of unpublished acts of EU law (2). Third, I will turn to the doubts that may arise in relation to the above judgment's *ratio decidendi* (3) and I will clarify how that *ratio decidendi* is to be understood (that clarification being necessary for answering the questions referred) (4).

1. Legal context and the key elements of the judgment under discussion

37. I recall that, on the one hand, the cigarettes placed on the market or manufactured in the Member States must respect the maximum emission levels for certain harmful substances (tar, nicotine and carbon monoxide) set in Article 3(1) of Directive 2014/40. On the other hand, pursuant to Article 4(1) of that directive, emissions of those substances shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide. Moreover, the accuracy of the measurements shall be determined in accordance with ISO standard 8243.

38. Given the centrality of ISO standards in the present case, I will make brief comments about their features (a) before turning to the clarification given in the judgment under discussion about their legal effects under EU law (b).

(a) Standards developed by ISO

39. First, the ISO standards are elaborated in what appears to be a rather complex procedure in which, within various ISO bodies, different ISO members (of, currently, 174 countries) and various public or private stakeholders participate.⁷ Those standards have been described as codification of technical knowledge *by* and *for* professionals.⁸ ISO presents its standards as 'market driven'.⁹ ISO itself is a non-governmental organisation (established under Swiss law),¹⁰ having the mission 'to promote the development of standardisation and related activities in the world with a view to facilitating international exchange of goods and services ...'¹¹ (the mission to develop unified standards being reflected in its name, ISO, which comes from the Greek for 'equal').

40. Second, the elaboration of standards is not decided by ISO itself but results from requests made, in particular, by respective national member bodies, typically based on requests by the industry.¹²

⁷ National standards bodies seem to constitute one of three categories of ISO membership as described in Article 3.1. of the ISO Statutes, 21st edition, 2025, English version, ISBN 978-92-67-02042-6 ('the ISO Statutes'), available at <https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/statutes.pdf>.

⁸ Opinion of Advocate General Saugmandsgaard Øe in *Stichting Rookpreventie Jeugd and Others* (C-160/20, EU:C:2021:618, point 31 and the footnote thereto).

⁹ *ISO/IEC Directives, Part 1, Procedures for the technical work – Consolidated ISO Supplement – Procedures specific to ISO*, Edition 01/2024, English version, ('ISO/IEC Directives, Part 1'), Annex SO, 'Principles for developing ISO and IEC Standards related to or supporting public policy initiatives' ('Annex SO to ISO/IEC Directives') point SO.2., 'Principles', under (a), p. 146.

¹⁰ Article 22.1 of the ISO Statutes.

¹¹ Article 2.1 of the ISO Statutes; Annex SO to ISO/IEC Directives', point SO.2, 'Principles', under (b), states that 'ISO and IEC are committed to developing International Standards that are market relevant, meeting the needs and concerns of all relevant stakeholders, including public authorities where appropriate, without seeking to establish, drive or motivate public policy, regulations, or social and political agendas.' (I would add that IEC stands for the International Electrotechnical Commission).

¹² Article 14.2 of the ISO Statutes and <https://www.iso.org/developing-standards.html>.

41. Third, the ISO standards are in themselves voluntary¹³ and it seems that the typical way in which regulators rely on them (when they decide to do so) is through a reference. Such reference can be ‘open’, containing only the basic identification, which leads to a reference such as ‘ISO 10315’, or it can identify the specific version of the standard, which leads to a reference such as ‘ISO 10315:2021’ (the indication of the year refers to the last available update or confirmation of the standard). I note that the reference in Article 4(1) of Directive 2014/40 is ‘open’, while the Netherlands’ national ‘implementation’ is specific.¹⁴

42. Fourth, the ISO standards are covered by intellectual property rights claimed by ISO¹⁵ and can in principle be accessed against payment. To illustrate this, at the time of writing the present Opinion, the ISO standards at issue could be purchased (from ISO) for the amount of 132 Swiss francs (CHF) for the ISO standard 4387:2019 and for the amount of CHF 65 for each of the standards ISO 10315:2021, ISO 8454:2024 and ISO 8243:2013 respectively.¹⁶

43. Fifth, the sale of the ISO standards is presented as a major source of ISO’s income¹⁷ together, nevertheless, with other resources, such as contributions from the members, provision of services, contributions of donors to specific ISO activities or possibly funds received from other sources.¹⁸

44. Finally, the ISO standards are in principle available in English, French and Russian, the official languages of ISO.¹⁹ The respective member bodies may prepare translations into other languages (which, under certain conditions, may be considered by ISO as official translations).²⁰ The ISO standards at issue here seem to be offered for sale (by ISO) in English and French.²¹ The national versions of these standards seem to be available in English (only).²²

45. Following those clarifications, I will now turn to the legal effects that the ISO standards at issue produce in the EU legal order.

(b) The ISO standards at issue in the EU legal order

46. First, I note that the judgment under discussion is the first in which the Court addressed the legal effects of an externally elaborated technical standard in EU law. It is true that a related issue was at the heart of the seminal judgment in *James Elliott*, in which the Court held that a standard

¹³ *Using and referencing ISO and IEC standards to support public policy*, ISO, 2015, pp. 3 and 23. See also Annex SO to ISO/IEC Directives, point SO.1, ‘Background Context’, p. 146.

¹⁴ See point 16 above. The information available to the public suggests that these versions have been replaced. See, for NEN-ISO 4387:2000/A1:2008 <https://www.nen.nl/en/nen-iso-4387-2000-a1-2008-en-127640>; for NEN-ISO 10315:2013 <https://www.nen.nl/en/nen-iso-10315-2013-en-182020>; for NEN-ISO 8454:2007/A1:2009 <https://www.nen.nl/en/nen-iso-8454-2007-a1-2009-en-140295> and for NEN-ISO 8243:2006 <https://www.nen.nl/en/nen-iso-8243-2006-en-113052>.

¹⁵ ISO/IEC Directives, Part 1, p. 49. I note that the webpages of the Royal Netherlands Standardisation Institute (‘NEN’) where the national implementation standards can be purchased contain the following information: ‘This publication [containing the respective standard] is protected by copyright and for personal use only.’ See the sources quoted in the previous footnote.

¹⁶ As regards the latest available versions of these standards at the time of writing.

¹⁷ *Using and referencing ISO and IEC standards to support public policy*, ISO, 2015, pp. 34 to 36.

¹⁸ Article 21.1 of the ISO Statutes.

¹⁹ The ISO Statutes are available in these three languages on the ISO website.

²⁰ Articles 23.1, 23.2 and 23.3 of ISO Statutes.

²¹ See for the available options respectively <https://www.iso.org/standard/76549.html>, <https://www.iso.org/standard/79002.html>, <https://www.iso.org/standard/85345.html> and <https://www.iso.org/standard/60154.html>.

²² See, for the relevant source of information, footnote 14 above.

approved by the European Committee for Standardisation ('CEN') forms part of EU law. The Court reached that conclusion even though the standard in question had not been published in the Official Journal (only the reference of that standard had).²³

47. However, that judgment did not address the legal consequences of the lack of publication. The main issue for the Court in that case was whether it had jurisdiction to interpret the standard concerned. That question was answered in the affirmative and the fact that the standard was unpublished was not referred to, let alone discussed. Accordingly, when, in the judgment in *Stichting Rookpreventie Jeugd and Others*, the Court was asked to adopt a position on the validity of Article 4(1) of Directive 2014/40 (as it refers to unpublished ISO standards), it could not (and did not) rely on its judgment in *James Elliott*.

48. The Court confirmed, *first*, that the maximum emission levels must be measured in accordance with the measurement methods arising from ISO standards to which Article 4(1) refers (to the exclusion of any other method, as the Bulgarian Government recalls).²⁴

49. *Second*, the Court found that the fact that the EU legislature provided for the measurement methods by reference to (externally elaborated) ISO standards which had *not* been published in the Official Journal did not affect the validity of Article 4(1) of Directive 2014/40.

50. That issue was examined from several perspectives, in particular through the lens of the principle of legal certainty. That principle was considered to have been complied with because the reference to the ISO measurement standards in Article 4(1) of Directive 2014/40 was, according to the Court, clear, precise and predictable, and because the above directive has itself been published in the Official Journal.²⁵

51. The Court also recalled that the principle of legal certainty prevents acts of EU law from being enforced against natural and legal persons before those persons have had the opportunity to acquaint themselves with them through their publication in the Official Journal.²⁶ Turning to the ISO measurement standards (made mandatory by the above directive), it held that they bind 'the *public generally* only if they themselves have been published in the [Official Journal]'.²⁷ However, it also added, that where the 'undertakings' (manufacturing the cigarettes or placing them on the market) could access their official and authentic version, those standards do bind them.²⁸

52. *Third*, and given the conclusion that Article 4(1) of Directive 2014/40 does not bind 'the public generally', in so far as it imposes the use of the unpublished ISO standards, the Court held, in paragraph 74 of the judgment in *Stichting Rookpreventie Jeugd and Others*, that it was for the referring court in that case 'to determine whether the methods actually used to measure the emission levels [of the harmful substances concerned] comply with Directive 2014/40, without taking account of Article 4(1) thereof'.

²³ Judgment of 27 October 2016, *James Elliott Construction* (C-613/14, 'the judgment in *James Elliott*', EU:C:2016:821, paragraph 40). For the features of the CEN system see, most recently, Opinion of Advocate General Medina in *Public.Resource.Org and Right to Know v Commission* (C-588/21 P, EU:C:2023:509, points 23 to 31).

²⁴ The judgment in *Stichting Rookpreventie Jeugd and Others*, paragraphs 33 and 31.

²⁵ *Ibidem*, paragraphs 39 to 47.

²⁶ *Ibidem*, paragraph 40 and the case-law cited.

²⁷ *Ibidem*, paragraph 48. Emphasis added.

²⁸ *Ibidem*, paragraph 52.

53. In that way, the Court confirmed the national court's power to use an alternative measurement method (whose general characteristics it specified)²⁹ 'should', as it added, 'Article 4(1) of Directive 2014/40 not be binding on individuals'.³⁰

54. It follows that the above judgment's *ratio decidendi* contains two main elements: the confirmation of the above provision's validity and the simultaneous observation about its (conditional) enforceability.

55. As I will explain now, that solution relies on, and further develops, the Court's previous case-law concerning the legal effects of unpublished acts of EU law.

2. *Validity versus enforceability of acts of EU law*

56. The above distinction follows from the Court's case-law according to which if an EU law act is not published in the Official Journal (even though it should have been), this leads to its unenforceability against individuals (natural or legal persons) but does not affect its validity.

57. In particular, in *Skoma-Lux*³¹ the Court determined that customs authorities cannot enforce, vis-à-vis an importer, the EU customs legislation where the respective language version of the applicable EU regulation was not published, at the material time, in the Official Journal. It was in that context that the Court also made it clear that the lack of publication of the respective language version is a matter of unenforceability of the legislation in question against individuals but does not affect the binding character of the provisions concerned vis-à-vis the given Member State³² (meaning that the individual concerned may rely on them against the public authorities).³³ Hence non or delayed publication of such an act results, in fact, in *delayed enforceability* of the obligations imposed upon individuals until the language version in question has been published in the Official Journal.³⁴

58. The Court adopted the same solution in *Heinrich*,³⁵ a case about an air passenger who was excluded from a flight because he took tennis racquets on board. In that judgment, the Court concluded that an (unpublished) annex to a (published) regulation detailing items that airplane passengers are not allowed to bring on board an aircraft was not enforceable against that individual.

59. In the above cases (to which the judgment in *Stichting Rookpreventie Jeugd and Others* refers), the Court recalled that 'the principle of legal certainty requires that [EU] legislation must allow those concerned to acquaint themselves with the precise extent of the obligations it imposes upon them, which may be guaranteed only by the proper publication of that legislation ...'.³⁶ The Court

²⁹ In paragraph 79 of the judgment in *Stichting Rookpreventie Jeugd and Others*. I will turn to those characteristics in more detail later.

³⁰ Paragraph 79 and point 5 of the operative part of the judgment in *Stichting Rookpreventie Jeugd and Others*.

³¹ Judgment of 11 December 2007, *Skoma-Lux* (C-161/06, 'the judgment in *Skoma-Lux*', EU:C:2007:773).

³² *Ibidem*, in particular paragraphs 51 and 59.

³³ Which aspect had previously been emphasised in the judgment of 20 September 1990, *Sevince* (C-192/89, 'the judgment in *Sevince*', EU:C:1990:322, paragraph 24).

³⁴ The judgment in *Skoma-Lux*, paragraph 60.

³⁵ Judgment of 10 March 2009, *Heinrich* (C-345/06, 'the judgment in *Heinrich*', EU:C:2009:140, paragraph 63).

³⁶ The judgment in *Skoma-Lux*, paragraph 38 and the case-law cited.

also explained that a different approach ‘would result in individuals ... bearing the adverse effects of a failure by the Community administration to comply with its obligation to make available to those individuals ... the entire *acquis communautaire* ...’.³⁷

60. While in the judgment in *Stichting Rookpreventie Jeugd and Others* the Court relied on those premisses, it has also established a derogation from the main rule that follows from them.³⁸

61. Indeed, in *Skoma-Lux*, the Court was very clear that the conclusion as to the unenforceability of an unpublished act of EU law vis-à-vis natural and legal persons stands irrespective of whether such party could access it by other means.³⁹ However, in the judgment under discussion, the Court relied on the fact that the national standards bodies may grant, upon request, access to the official and authentic version of the ISO standards⁴⁰ to conclude that when access could be obtained to those standards, they are binding upon the undertakings. It was only for the case in which such access could not be obtained that the Court stated the lack of their binding nature against ‘the public generally’. Moreover, and addressing the consequences of such lack of enforceability, it also stated the possibility for the national court to verify compliance with the maximum emission levels based on an alternative measurement method (paragraph 74).

62. As the Netherlands Government noted in essence, during the hearing, the legal implications of, in particular, paragraph 74 of the judgment in *Stichting Rookpreventie Jeugd and Others* (when combined with the confirmed mandatory nature of the ISO standards at issue) call for clarification. That, in turn, requires that the distinction drawn by the Court between the categories of ‘the public generally’, on the one hand, and the ‘undertakings’, on the other, be examined for the purpose of ascertaining whether and when the ISO measurement standards at issue can be considered to be binding.

3. Should the reading of the judgment under discussion be ‘narrow’ or ‘broad’?

63. It follows from the above section that, in the judgment in *Stichting Rookpreventie Jeugd and Others*, the Court considered that the ISO standards at issue are enforceable against undertakings when they can access them. The Court also recognised the possibility to apply an alternative method of measurement when the ISO standards cannot be considered to be binding against ‘the public generally’. In that light, the crux of the present case is to ascertain whether national authorities may apply such an alternative method only where the undertaking concerned could not access the standards concerned, or whether they may do so when a claim is brought by a party such as the Foundation (as a member of ‘the public generally’), seeking the withdrawal of cigarettes from the market (irrespective of whether the undertakings concerned could access the ISO standards at issue and of whether they complied with them).

64. Turning to those aspects, in the light of the explicit statement, in paragraph 52 of the judgment in *Stichting Rookpreventie Jeugd and Others*, that the unpublished ISO standards can be imposed on the *undertakings* when those undertakings can access them, the statement in

³⁷ *Ibidem*, paragraph 42 and the case-law cited.

³⁸ Although the two judgments above both concerned an unpublished regulation (or a part thereof), the solution established therein applies to obligations set out in a directive, as the Court observed in paragraph 42 of the judgment in *Stichting Rookpreventie Jeugd and Others*.

³⁹ The judgment in *Skoma-Lux*, paragraphs 47 to 51.

⁴⁰ *Ibidem*, paragraph 52.

paragraph 74 of the same judgment seems to denote that the national court may disregard Article 4(1) of Directive 2014/40 and use an alternative method of measurement *should* it be established that the undertakings concerned could *not* access the ISO standards at issue.

65. That conclusion is supported by the fact that paragraph 79 of the judgment and point 5 of the operative part thereof (which relates to the developments of which paragraphs 74 and 79 form part) are worded as *a hypothesis*.⁴¹ Those parts of the judgment describe the characteristics of an alternative method of measurement, *should* Article 4(1) of Directive 2014/40 not be binding on ‘the individuals’ concerned. At the same time, the only part of the Court’s reasoning which makes the enforceability of the ISO standards at issue subject to any condition is the paragraph 52 of the judgment, where the Court confirms the binding nature of the ISO standards for ‘the undertakings’ (where they can access them).

66. In those circumstances, it seems to follow that the possibility for the national court to use an alternative measurement method (confirmed in paragraph 74 of the judgment in *Stichting Rookpreventie Jeugd and Others*) is given when the *undertakings* concerned (as a specific category of ‘individuals’ referred to in paragraph 79 of that judgment and in point 5 of the operative part thereof) cannot access the relevant ISO standards.

67. That interpretation corresponds to what I will refer to here as the ‘narrow’ scope or understanding of the judgment under discussion.

68. Nevertheless, the present reference relies on the premiss that the *ratio decidendi* of that judgment is precisely *not* limited to that narrow scope, but that it also follows therefrom that the lack of publication of the ISO standards at issue means that they are not binding on *other persons* such as the Foundation, which entails specific legal consequences.

69. In the context of the main proceedings, that understanding means (or could mean, since the question whether it is indeed the case forms part of the questions referred) that, while the cigarettes placed on the market by the undertakings concerned meet the maximum emission levels defined in Article 3(1) of Directive 2014/40, when measured by the ISO standards referred to in Article 4(1) of the same directive, a party such as the Foundation can successfully claim failure to respect the maximum emission levels based on an alternative measurement method. It would follow that, to be able to place (or maintain) the cigarettes on the market, the undertaking concerned would also have to comply with the maximum emission levels measured through the use of such an alternative method.

70. That understanding of the possible implications of the above judgment, which I will refer to here as ‘broad’, is evidenced by the content of the questions referred. I recall that the referring court enquires, in particular, as to whether the conclusion about the lack of enforcement of the ISO standards at issue vis-à-vis ‘individuals, including the Foundation’ applies also when the Foundation could access those standards or whether the enforcement of an alternative method of measurement against the tobacco manufacturers is at odds with the principle of legal certainty (those questions being raised in the context of national proceedings where there appears to be no doubt that the tobacco manufacturers could in fact access the ISO standards at issue and that they complied with the requirements of Directive 2014/40).

⁴¹ Point 5 of the operative part of the judgment in *Stichting Rookpreventie Jeugd and Others* reads as follows: ‘*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 ...’. Emphasis added.

71. While that broad understanding of the judgment under discussion may have been inspired by the way in which the terms ‘the undertakings’ and ‘the public generally’ are used in that judgment (which, I admit, may lead to confusion), I will explain now why that judgment’s *ratio decidendi* must be understood in the narrow sense, described in points 64 to 67 above.

4. Clarification of the *ratio decidendi*

72. First, I recall that, as the Court made clear in the above judgment, Article 4(1) of Directive 2014/40 imposes upon the undertaking manufacturing cigarettes or placing them on the market an obligation to use the ISO measurement standards referred to therein.

73. In that light, adopting the broad understanding of the judgment under discussion would bring about a complete lack of predictability and legal certainty about whether those cigarettes can be placed on the market or not, as the Netherlands Government observed, in essence, at the hearing. While the possibility to place cigarettes on the market results from compliance solely with the applicable requirements set in Directive 2014/40, the broad understanding allows for that possibility to be questioned every time a private party (other than an undertaking manufacturing cigarettes or placing them on the market) decides to bring a claim seeking the withdrawal of the cigarettes from the market. Moreover, the applicability of an alternative method could be triggered only by a legal action initiated by a party such as the Foundation, because in its absence there would be no ground for its application, given that the Court clearly confirmed the mandatory nature of the ISO standards at issue for the undertakings (unless they cannot access them). In other words, the conditions under which the products at issue could be marketed and with which the respective undertakings would have to comply would vary depending on whether legal proceedings are brought and whether they are brought by a member of ‘the public generally’, on the one hand, or by a State authority or a competitor, on the other.

74. Second, pursuant to paragraph 1 of Article 24 of Directive 2014/40, entitled ‘Free movement’, ‘Member States may not, for considerations relating to aspects regulated by [Directive 2014/40] ... prohibit or restrict the placing on the market of tobacco or related products which comply with [that directive].’ While Article 24 contains two exceptions, neither of them is relevant to the present case.⁴² Accordingly, embracing the broad understanding of the judgment and allowing a party such as the Foundation to prevent, effectively, the placement on the market of cigarettes which comply with the requirements of Directive 2014/40 would deprive Article 24(1) of Directive 2014/40 of its practical effect, force the national authorities to act in at variance with it and undermine the degree of harmonisation attained.⁴³

75. Third, the broad understanding would also emasculate the power given to the Commission in Article 4(3) of Directive 2014/40 to modify the applicable measurement methods ‘where this is necessary, based on scientific and technical developments or internationally agreed standards’.

⁴² One of the exceptions, provided in Article 24(2), concerns additional requirements that can be adopted in relation to the packaging of tobacco products, while the other one (provided in Article 24(3)) introduces the possibility to prohibit a certain category of tobacco or related products on grounds relating to the specific situation in that Member State, such national measure having to be notified to the Commission. The latter exception was invoked in one of the questions having led to the judgment under discussion and the Court dismissed it, in paragraphs 80 to 85 of that judgment, as inadmissible because the facts of the case did not involve its implementation.

⁴³ Which seeks to avoid various methods of measurement to be applied in the Member States as the Court observed in paragraph 32 of the judgment in *Stichting Rookpreventie Jeugd and Others*.

76. While disregarding Article 4(1) of Directive 2014/40 (when the given undertaking cannot access the applicable ISO standards) does, of course, affect the Commission's power, that is the necessary consequence of the lack of enforceability due to non-publication in the Official Journal. However, that consequence is not a reason to provide another party with the power to tamper with the content of the obligation in Article 4(1) of Directive 2014/40 aimed at a different category of persons.⁴⁴

77. Fourth, embracing the broad understanding of the judgment under discussion would contradict the conclusion reached by the Court in the judgment in *Skoma-Lux* that enforcement of the obligations defined in unpublished acts of EU law would result in the individuals concerned bearing the adverse effects of the EU administration's failure to make the respective rules of EU law available to them.⁴⁵

78. In that respect, and although that judgment establishes a derogation from the above premiss (in that it allows for conditional enforceability of the unpublished ISO standards at issue), the broad understanding of that judgment would bring about, for the individuals concerned (the tobacco manufacturers), particularly severe adverse effects. Irrespective of the fact that they complied with the unpublished standard at issue, that standard may be replaced to their detriment by a different one, which, contrary to the ISO standards at issue, is not (even) identified in advance.

79. Fifth, the resulting situation would also run counter to the Court's finding, in the judgment in *Sevince*, the implications of which were discussed at the hearing and according to which the lack of publication of an act of EU law does not prevent the individual concerned from relying on such an act against the public authorities to claim his or her rights defined therein.⁴⁶

80. However, the broad understanding of the judgment under discussion would make it impossible for the tobacco manufacturers to rely on their right, which in my view flows from Directive 2014/40, to place on the market the cigarettes that satisfy the requirements defined therein (that right being the necessary corollary of the prohibition referred to above which is aimed at the Member States in Article 24 of the same directive).

81. To be clear, these observations are not to understate the health-related concerns that appear to have prompted the action in the main proceedings, nor are they to cast a doubt on the legitimacy of the civic engagement of a party such as the Foundation to improve the protection of, especially, young people against the harmful effects of smoking (which are widely recognised including by the EU legislature itself). I will come back to that aspect later. My observations above aim simply at highlighting that the legal consequences associated with the broad understanding of the judgment under discussion would deprive the relevant aspects of the harmonisation achieved by the legislature of much of their effectiveness (irrespective of what one might think of the desirability of the products concerned), defy some of the basic features of the operation of EU law as such and be flagrantly incompatible with the principle of legal certainty,

⁴⁴ That, again, would happen should a party such as the Foundation be allowed successfully to argue for the withdrawal of the cigarettes from the market due to the fact that they fail to meet the maximum emission levels when measured by a method that is not provided by the legislature, although they comply with those levels when measured using the method that is provided in Article 4(1) of Directive 2014/40.

⁴⁵ The judgment in *Skoma-Lux*, paragraph 42 and the case-law cited.

⁴⁶ See the judgment in *Sevince* (paragraph 24), where the Court held that the non-publication of decisions of the Council of Association established by the Association Agreement between the European Economic Community and Türkiye 'may prevent their being applied to a private individual, [but] a private individual is not thereby deprived of the power to invoke, in dealings with a public authority, the rights which those decisions confer on him'.

to which I have already referred and which implies that operators can define their conduct in the light of the standards regulating their trade (including, here, the methods of measurement laid down in the ISO standards at issue).

82. A closer look at the judgment under discussion shows that its *ratio decidendi* accommodates the above concerns. In fact, despite the drafting ambiguities referred to above, several parts of that judgment show, in my view, that the Court intended it to be understood in the ‘narrow’ sense.

83. *First*, the sequence of the Court’s reasoning in paragraphs 48 to 52 of that judgment, concerning the conditional enforceability of the ISO standards at issue, shows that the term ‘undertakings’ may be understood as a sub-category of ‘the public generally’⁴⁷ which would be in fact used as a synonym of the terms ‘natural and legal persons’ and ‘individuals’ on whom the resulting obligations are imposed. I recall that those terms appear in the parts of the same judgment related to unenforceability of unpublished acts (paragraphs 40 and 41 referring to the judgments in *Skoma-Lux* and in *Heinrich*) and are also used in the abovementioned point 5 of the operative part of the judgment in *Stichting Rookpreventie Jeugd and Others* (referring to ‘individuals’).

84. To explain, in paragraph 48 of the judgment under discussion (which constitutes the first of two relevant occurrences of the term ‘the public generally’) the Court states that ‘in accordance with the principle of legal certainty ... [the ISO standards at issue] ... are binding on the public generally only if they themselves have been published in the [Official Journal]’. In that respect, I fail to see any way in which the implications of the principle of legal certainty would be relevant for a party to whom no obligation is imposed on to use the standard at issue.

85. In paragraph 51 of that judgment (the second relevant occurrence of the same term) the Court states that ‘in the absence of publication in the [Official Journal] of the standards [at issue], the public generally is unable ... to ascertain the methods of measuring the [maximum emission levels].’ Here, the Court explains that the lack of possibility to consult the above methods contrasts with the requirements following, in particular, from the judgments in *Skoma-Lux* and in *Heinrich* which, as already stated, concern the legal situation of persons subject to obligations, as defined in (unpublished) acts of EU law.⁴⁸ That, in my view, also shows that the intention of the Court was to discuss the consequences of the lack of publication as they affect the persons subject to the legal obligation at issue.

86. Alternatively, and given that all the interested persons who submitted observations in the present proceedings seem to understand the above categories as being contradictory, it is also possible that the Court did indeed intend to distinguish between them in that way. However, that would then mean that when it refers to the ISO standards being (or not) *binding*, that term does not have the same meaning depending on whether it concerns the undertakings or ‘the public generally’. In the first case, that term would describe the (classical, State-sponsored) enforceability of legal obligations. In the second case, it would refer to the Foundation’s role of ‘law compliance watchdog’ (which may be impliedly referred to in paragraph 51 quoted in the previous point). This is a reading that the Commission suggested in essence at the hearing.

⁴⁷ The Dutch-language version of the judgment refers to ‘aan particulieren in het algemeen’ while the French-language version of the judgment refers to ‘particuliers en général’.

⁴⁸ The term ‘the public generally’ also occurs in paragraphs 49 and 73 of the judgment in *Stichting Rookpreventie Jeugd and Others* but those occurrences merely develop or repeat what has already been stated.

87. Even if that specific content of the above distinction between the undertakings and ‘the public generally’ is accepted, the narrow understanding of the *legal consequences* that the judgment under discussion entails is at any rate still borne out by the relevant part of its operative part that concerns the possibility, for the national court, to use an alternative method of measurement.

88. I recall that that possibility is envisaged in paragraph 74 of the reasoning set out in that judgment and further developed in paragraph 79 thereof. However, the only relevant part of the operative part that refers to those elements is point 5, which makes the possibility to use an alternative method of measurement subject to the finding that Article 4(1) of Directive 2014/40 is not binding on ‘individuals’ (‘should Article 4(1)’ of the latter directive ‘not be binding on individuals’).

89. In other words, as I have already explained, that point is worded as a *hypothesis* to be verified. In that regard, the only part of the Court’s entire reasoning that makes the enforceability of the ISO standards at issue subject to any condition is the part that refers to the enforceability of those standards against the *undertakings* (paragraph 52). Accordingly, what matters, and should be verified, is whether the defendant manufacturers concerned in the main proceedings could access the ISO standards at issue, and not the fact that the claimant Foundation could not do so.

90. Hence, the implication of the above judgment is that the lack of publication in the Official Journal of the ISO standards at issue does not prevent the possibility to enforce them vis-à-vis the undertakings producing cigarettes or placing those cigarettes on the market when those undertakings can access them. When that is the case, the measurement methods laid down in the ISO standards referred to in Article 4(1) of Directive 2014/40 must be applied by national authorities, including national courts, to establish whether cigarettes placed on the market by those undertakings comply with the maximum emission levels defined in Article 3(1) of that directive, irrespective of who (be it the State, a competitor, or an association such as the Foundation) claims that those emission levels have not been respected. By contrast, when those undertakings could not access those standards, the national court may establish whether cigarettes placed on the market comply with the maximum emission levels defined in Article 3(1) of Directive 2014/40 based on a different method (which must comply with the general criteria specified in the judgment in *Stichting Rookpreventie Jeugd and Others*).

91. It is with those clarifications in mind that I shall address the questions put to the Court.

B. Reply to the first to fourth questions

92. I recall that in compliance with the Court’s request, the present Opinion deals only with the first to fourth questions referred.

93. I note that the first, second and fourth questions are entirely premised on the broad understanding of the judgment in *Stichting Rookpreventie Jeugd and Others*. For that reason I will address them together (1). I will then examine the third question referred, which enquires into the meaning of the concept of intended consumption of (filter) cigarettes and which, as I will explain, questions, in reality, the validity of Article 4(1) of Directive 2014/40 (2).

1. *The first, second and fourth questions referred*

94. By its first question, the Court is asking whether the conclusion reached in the judgment in *Stichting Rookpreventie Jeugd and Others* that the ISO measurements standards referred to in Article 4(1) of Directive 2014/40 are not binding on ‘the public generally’ applies also when the interested party (such as the Foundation) could obtain them.

95. As already observed, the referring court understands the above judgment as establishing a distinction between ‘the undertakings’ (such as the tobacco manufacturers), on the one hand, and other persons such as the Foundation, on the other. In that regard, it seeks clarification of the term ‘the public generally’⁴⁹ and wonders whether an exception to the lack of enforceability against ‘the public generally’ can be made in the light of the fact that the ‘NEN-ISO’ standards (which, as I understand it, correspond to the ISO standards referred to in Article 4(1) of Directive 2014/40⁵⁰) can be consulted (free of charge) at the library of the NEN and that they can also be purchased. It explains that, under those conditions, and according to the national case-law, knowledge of the NEN-ISO standards is sufficiently ensured. I add that there seems to be no doubt about the fact that the Foundation did in fact access those standards.

96. By its second question, the referring court asks whether a party such as the Foundation derives a right from Directive 2014/40 to seek the enforcement of the maximum emission levels by application of an alternative measurement method. That question is asked in the eventuality that the Court confirms that the ISO standards at issue are not binding on the Foundation despite the fact that the Foundation could access them. Although the referring court acknowledges that Directive 2014/40 does not contain any obligation to which the Foundation could be subject, it considers that the existence of the above right is not excluded. A reply in the negative would, in its view, mean that paragraphs 74 to 79 of the judgment in *Stichting Rookpreventie Jeugd and Others* do not have any practical effect.

97. Finally, the fourth question (containing several sub-questions) aims at determining whether the application of an alternative measurement method against the undertakings respects the principle of legal certainty. The referring court observes that Directive 2014/40 does not allow for any measurement method to be used by the tobacco manufacturers other than the one referred to in Article 4(1) thereof. It notes, however, that the objective to pursue a high level of protection of public health, especially of young people, expressed in recital 8 and Article 1 of Directive 2014/40, read in combination with Articles 24 (the rights of the child) and 35 of the Charter (health care),⁵¹ may justify the negative impact that the application of an alternative method of measurement would have on those manufacturers. At the same time, it raises the question whether the possibility for the Member States to adopt another measurement method could be at odds with, first, the competence conferred to that effect on the Commission by Article 4(3) of Directive 2014/40, and second, the objective of harmonisation pursued, referring in particular to Article 24(1) of that directive.

⁴⁹ It refers to different language versions of the above judgment to explain its doubts about whether the term ‘the public generally’ means the ‘general public’ (as opposed to, as I understand the argument, the ‘undertakings’) or whether it refers to the idea that the ISO standards at issue do not bind the public ‘in general’, that is ‘in principle’ (and unless, again as I understand it, the respective party could access them).

⁵⁰ See also the explanation in point 41 above.

⁵¹ It seems to me that the referring court considers paragraph 2 of Article 24 of the Charter to be particularly relevant, since that provision states that ‘in all actions relating to children, whether taken by public authorities or private institutions, the child’s best interests must be a primary consideration.’ As regards Article 35 of the Charter, I note that its second sentence states that ‘a high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities.’

98. The explanation provided in the previous part of this Opinion allows for those questions to be addressed rather succinctly.⁵²

99. Indeed, it follows from that explanation that the judgment in *Stichting Rookpreventie Jeugd and Others* does not envisage any conditions under which the lack of publication of ISO standards at issue could lead to the possibility for a party such as the Foundation effectively to prevent the placing on the market of cigarettes that comply with the requirements of Directive 2014/40. That conclusion stands irrespective of whether or not the Foundation could access those standards and under what conditions. Indeed, the observations, in the judgment under discussion, about the (conditionally) binding nature of those standards (in the sense of their enforceability by public authorities against the persons who are subject to the legal obligations in question) concern the undertakings manufacturing cigarettes or placing them on the market. They do not concern parties such as the Foundation because Directive 2014/40 cannot impose any obligations on such a party.

100. That clarification addresses the referring court's concerns that paragraphs 74 to 79 of the judgment in *Stichting Rookpreventie Jeugd and Others* would not have any practical meaning should a party such as the Foundation not be allowed to exercise 'its right' to see the maximum emission levels respected.

101. As I have explained, in those paragraphs the Court drew conclusions from the previous statement about the conditional enforceability of the ISO standards at issue vis-à-vis the undertakings and addresses the problem of legal vacuum should it be established that the ISO standards at issue could not be considered as binding on them.

102. It follows that, in agreement with the tobacco manufacturers concerned in the main proceedings, all the governments that submitted observations and the Commission, I am of the view that irrespective of the persisting lack of publication of the ISO standards at issue and irrespective of the question whether a party such as the Foundation could access them, that party does not derive, from Directive 2014/40, any right that would allow it successfully to prevent the placement on the market of cigarettes that comply with, in particular, maximum emission levels when measured using the methods referred to in Article 4(1) of Directive 2014/40. I also agree with the above parties and other interested persons that a conclusion to the contrary would be in breach of the principle of legal certainty that should protect those who abide by valid and enforceable rules law.

103. That position is not affected by the objective to seek a 'high level of protection of human health, especially for young people' which Directive 2014/40 follows and to which the referring court draws attention.

104. As is obvious from Article 1 of Directive 2014/40 and as the Court has repeatedly recalled, the objective pursued by that provision is in fact twofold.⁵³ That directive seeks to facilitate the smooth functioning of the internal market for tobacco and related products, while ensuring a high level of protection of human health, especially for young people. Its provisions must be

⁵² I note that the Bulgarian Government argues that the first question is inadmissible due to the lack of precision about the ISO standards concerned by it. I am of the view that the wording of the above question and the explanation given in the order for reference make it clear that that question concerns the ISO standards referred to in Article 4(1) of Directive 2014/40.

⁵³ See, for instance, judgment of 26 June 2025, *PJ Carroll and Nicoventures Trading* (C-759/23, EU:C:2025:477, paragraph 37 and the case-law cited).

therefore be interpreted in the light of both of the above goals, among which the EU legislature necessarily sought to establish a certain balance as the Commission also observed during the hearing.

105. In that respect, I note that the objective underlying Article 3(1) of Directive 2014/40 setting out the maximum emission levels is not only to promote the smooth functioning of the internal market but also, of course, to ensure that cigarettes are less harmful to human health. However, when determining the level of harmful substances in cigarettes and choosing a precise method for establishing those levels, the EU legislature decided on a specific harmonised level of protection. One cannot therefore invoke the general public-health objective pursued by Directive 2014/40 to override a legislative choice, clearly expressed in the text of the law, because such a purposive interpretation would be *contra legem*.

106. While Directive 2014/40 does not seek to establish rules for the safe consumption of tobacco products (given the inherent harmfulness of such products⁵⁴ and because no safe consumption of them exists), it can certainly be considered as (also) seeking to mitigate the harmful effects of smoking. The pursuance of such an objective is reflected not only in the obligation to warn consumers, in various ways, of the possibly fatal consequences of smoking,⁵⁵ but also in the provisions at issue here which set the maximum emission levels and provide for the obligation to measure them. That follows from recital 12 of the directive, which links the emissions of tar, nicotine and carbon monoxide to the toxicity or addictiveness of tobacco products, as the Foundation observes.⁵⁶

107. Moreover, the confirmation of the relevance of that health-related objective as regards the directive's provision on maximum emission levels does not transform it into a tool that can override the clear content of legislative provisions. In the present context and to recall, that content means that cigarettes which are compliant with the maximum emission levels set out in Article 3(1) of Directive 2014/40, as measured using the method referred to in Article 4(1) of the same directive, cannot be prohibited from being placed on the market, as follows from Article 24 thereof (subject to exceptions defined therein that are inapplicable here).

108. The only way in which, in my view, the objective to pursue the high protection of human health could affect the relevant normative content, namely the legislative choice of the ISO measurement standards at issue, would be to question the validity of Article 4(1) of Directive 2014/40, which makes their use mandatory. This is an issue to which I will turn now in the context of the examination of the third question referred.

2. *The third question referred: when is a cigarette 'consumed as intended'?*

109. By its third question, the referring court enquires as to the characteristics that the alternative method of measurement must have. That question reacts to paragraph 79 (and point 5 of the operative part) of the judgment in *Stichting Rookpreventie Jeugd and Others*, according to which such a method must 'be appropriate, in the light of scientific and technical developments or

⁵⁴ See, in particular, recital 8 of Directive 2014/40, which states that 'tobacco products are not ordinary commodities', given 'the particularly harmful effects of tobacco on human health'.

⁵⁵ See, in particular, Article 9(1) and Article 10(1) of, as well as Annexes I and II to, Directive 2014/40.

⁵⁶ 'As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to *reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness*.' Emphasis added.

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 ...’.⁵⁷

110. The referring court enquires as to the precise meaning of the term ‘when consumed as intended’, appearing not only in the above quote but especially in the definition of the term ‘emissions’ in point 21 of Article 2 of Directive 2014/40. That definition describes ‘emissions’ as ‘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’.⁵⁸

111. By the above question, the referring court asks more specifically whether the alternative method used must consider, in particular, the fact that smokers’ lips and fingers cover the micro-ventilation holes in the cigarette filters and the intensity and length of the smoke.

112. Like the three questions examined above, this question is premised on a broad understanding of the judgment in *Stichting Rookpreventie Jeugd and Others*. It is asked in the event that the Court confirms that the Foundation has a right to seek the enforcement of the maximum emission levels through the use of an alternative measurement method. Because that right does not exist, as I have explained previously, and because it is not alleged that the manufacturers concerned in the main proceedings could not access the ISO standards at issue, that question seems irrelevant for the resolution of the dispute pending before the referring court.

113. However, the reason why that question, in my view, merits separate consideration is that, on closer inspection, it concerns in reality the validity of Article 4(1) of Directive 2014/40, as was in essence observed by Philip Morris in its written observations.⁵⁹

114. Indeed, should the Court reply to that question to the effect that any (alternative) measurement method must take such aspects into account (because that would follow from the term ‘consumed as intended’ used in conjunction with the term ‘emissions’) then, logically, the method envisioned by the EU legislature in Article 4(1) of that directive should do the same. However, it is undisputed that those standards *do not take* those aspects into account, the inevitable consequence being that the ISO standards at issue would be regarded as not suitable to measure such ‘emissions’ released from the cigarettes.

115. As regards the specific parameter in the light of which the validity of the above provision should be assessed, it follows from the order for reference that the referring court’s doubts are due, in particular, to the imperative of a high protection of human health.

116. In that light, I am of the view that the third question referred must be understood as enquiring whether the concept of ‘emissions’, and in particular the term ‘consumed as intended’, must, in the light of the public health objective pursued by Directive 2014/40, and Article 35 of the

⁵⁷ Emphasis added.

⁵⁸ Emphasis added.

⁵⁹ I recall that the possibility for the Court to reformulate a question about interpretation as a question about validity is given, in short, where that approach is commanded by the Court’s task to ‘derive from all the information provided by the national court those aspects of EU law which, having regard to the subject matter of the dispute, require interpretation, or whose validity requires appraisal’. Judgment of 25 January 2022, *VYSOČINA WIND* (C-181/20, EU:C:2022:51, paragraph 36 and the case-law cited).

Charter⁶⁰ and Article 114(3) TFEU,⁶¹ be interpreted as meaning that any method to be used for the measurement of those emissions must take into account the fact that smokers' lips and fingers cover the micro-ventilation holes in the cigarette filters and/or the intensity and length of the smoke, with the consequence that Article 4(1) of that directive, which refers to a method which does not take those parameters into account, is invalid.⁶²

117. To examine that question, I recall that the present case concerns an area in which the EU legislature's action involves political, economic and social choices, where it is called upon to undertake complex assessments and where it enjoys, therefore, a broad discretion.⁶³ Accordingly, the judicial review of the measures adopted in such an area must be limited to verifying the existence of *manifest* errors such as, in the present context, the manifestly inappropriate nature of the measure at issue in the light of the above objective. In contrast, the question whether the given measure is the only conceivable measure or the most appropriate one is not decisive for the purposes of that review.⁶⁴

118. The discussion in the present proceedings leads me to consider that by choosing the ISO standards at issue, the EU legislature did not commit a manifest error.

119. First, it is undisputed that the above measurement method referred to in Article 4(1) of Directive 2014/40 consists in the cigarettes being combusted and in verifying compliance with the maximum levels set out in Article 3(1) of the same directive under such circumstances.

120. Additionally, it has also been clarified that it was in the light of the above method that the existing maximum emission levels in Article 3(1) of Directive 2014/40 were in fact established. In other words, the ISO measurements standards referred to in Article 4(1) of Directive 2014/40, on the one hand, and the maximum emission levels defined in Article 3(1) thereof, on the other, are mutually interconnected.

121. Thus, when determining the conditions under which the cigarettes may be placed on the market as regards their content in tar, nicotine and carbon monoxide, the legislature decided to establish and measure that content by reference to emissions released during the (simple) combustion of a cigarette.

⁶⁰ See, for its relevant part, footnote 51 above.

⁶¹ It follows from Article 114(3) TFEU (which as such constitutes one of the legal bases of Directive 2014/40) that a high level of health protection should be taken as a base for the relevant legislative proposals, as acknowledged in recital 8 of Directive 2014/40. As the Court recalled in the context of the same directive, a similar imperative is also stated in Article 9 TFEU and Article 168(1) TFEU. See judgment of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, 'the judgment in *Philip Morris*', EU:C:2016:325, paragraph 157).

⁶² I note that in the judgment in *Stichting Rookpreventie Jeugd and Others* the Court was already invited to assess the validity of the above provision 'on account of the fact that scientific studies are said to establish that the measurement methods to which [it] refers do not reflect the levels of tar, nicotine and carbon monoxide from cigarettes that are actually inhaled by smokers' (paragraph 64 concerning Question 3(b)). However, the Court noted that that question relied on studies that post-dated the adoption of the directive at issue which made them irrelevant for the above examination because, as the Court recalled, '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'. The judgment in *Stichting Rookpreventie Jeugd and Others*, paragraph 67 and the case-law cited. The angle from which the validity of the above provision was examined does not, therefore, pre-empt the examination as requested in the present proceedings.

⁶³ The judgment in *Stichting Rookpreventie Jeugd and Others*, paragraph 44.

⁶⁴ Opinion of Advocate General Kokott in *Philip Morris Brands and Others* (C-547/14, EU:C:2015:853, points 149 and 150), and the judgment in *Philip Morris*, paragraph 166 and the case-law cited.

122. Secondly, it seems equally undisputed that the real exposure experienced by a smoker to the above harmful substances may be significantly higher than the toxicity allowed under the test resulting from a combined reading of Article 3(1) and Article 4(1) of Directive 2014/40. Indeed, the Commission observed at the hearing that that exposure may, in reality, be multiple times higher.⁶⁵

123. The Commission likewise confirmed that a stricter method (such as the so-called Canadian Intense method) existed when Directive 2014/40 was adopted. I understand that that method takes into account, in particular, the covering of the micro-ventilation holes in filters, which means that when emissions released from cigarettes are measured using that method, the maximum emission levels set in Article 3(1) of Directive 2014/40 are exceeded. However, the Commission also explained at the hearing that had the above method (or another similar method) been adopted, that would likely have led to the need to set the maximum emission levels higher because, as I understand the argument, the conditions under which the cigarettes would be tested would lead to a higher content of the above harmful substances being released.

124. Thirdly, the Commission explained at the hearing that when Directive 2014/40 was adopted, the legislature weighed up the advantages and disadvantages of the (then) existing methods and opted for the ISO measurements standards at issue due, in short, to ease of use. Moreover, it also explained, in line with the positions of the manufacturers concerned in the main proceedings and the Bulgarian and Portuguese Governments, that no method existed (or exists) that would allow human smoking behaviour to be approximated due to the many patterns that that behaviour may have. That finding was, according to the Commission, also the result of discussions having taken place in the context of the WHO Framework Convention on Tobacco Control.⁶⁶

125. In that respect, one can suggest that the variety of smoking patterns is not, per se, a reason not to choose a method that seeks to approximate real smoking behaviour in *some* way, rather than choosing a method that entirely fails to fulfil such an aim. One can further suggest that if a more stringent method were to lead to higher emission levels being set in the legislation, while that might not ultimately change the resulting exposure to the harmful substances referred to above, the result would have provided for a more transparent way in which information about the toxicity of cigarettes is communicated to consumers (by setting the emission levels at values that are closer to those actually experienced).

126. However, I have already explained that the broad discretion that the EU legislature enjoys in the area covered by Directive 2014/40 does not oblige the legislature to opt for a method that is, from a certain point of view, better, if the method actually chosen is not manifestly inappropriate for attaining the stated objectives.

127. As regards the specific objective of ensuring a high level of protection of human health, the above provisions of primary law do not oblige the legislature to set, in the present context, any specific level of such high protection. It would certainly have been otherwise should it have been established that specific levels of tar, nicotine and carbon monoxide make the consumption of cigarettes safe or significantly safer. However, it is undisputed that that appears impossible because, as follows from the discussion in the present proceedings, there is currently no scientific evidence to prove that the maximum emission levels of those harmful substances should be set at

⁶⁵ See also Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive [2014/40] concerning the manufacture, presentation and sale of tobacco and related products, COM(2021) 249 final, Section 3.1., footnote 21.

⁶⁶ *Ibidem*, Section 3.1.

a given value. Under such circumstances, the specific parameters of the toxicity under which the cigarettes may be placed on the EU market is a matter subject to a complex assessment which, in my view, does not exclude the choice of such maximum levels that are attained (and have to be respected) when measured under the conditions of the method referred to in Article 4(1) of Directive 2014/40.

128. The final question for me to address is the relevance, for the present analysis, of the term ‘when ... consumed as intended’, which appears in the legislative definition of ‘emissions’ contained in point 21 of Article 2 of Directive 2014/40 (referred to in point 110 above).

129. The first remark to be made in that respect is that the validity of a provision of secondary law (such as Article 4(1) of Directive 2014/40) cannot be questioned in the light of another provision of secondary law (such as point 21 of Article 2 of the same directive).

130. The second issue to be addressed is whether there is perhaps some fundamental internal incoherence between the above definition and the test that follows from a combined reading of Article 3(1) and Article 4(1) of Directive 2014/40 which would prevent the stated objectives, and in particular the one relating to the high level of protection of human health, from being attained.

131. Indeed, as I understand the argument, the referring court asks whether the above definition referring to substances being released when a tobacco product *is consumed as intended* must lead to the conclusion that the ISO measurement standards (but in fact, and in my view, the entire test resulting from a combined reading of Article 3(1) and Article 4(1) of Directive 2014/40) are inconsistent with it.

132. The definition of ‘emissions’ may indeed suggest, at least when taken at face value, that those emissions are measured, as regards cigarettes, under such conditions that are closer to those described by the referring court (partial covering of the micro-ventilation holes in the filter and so on) rather than by a simple combustion process. Indeed, a simple combustion process does not correspond to the intended use of a cigarette as commonly understood, because, as the Foundation observed, cigarettes are not incense sticks.

133. However, as the Commission explained, the above definition of emissions is a general provision that applies to various tobacco products that Directive 2014/40 covers and should be read, in the present circumstances, together with the definition of ‘cigarette’ in point 10 of Article 2 of Directive 2014/40 where the latter is defined in particular as ‘a roll of tobacco that can be consumed via a combustion process ...’.

134. That definition of ‘cigarette’, combined with the toxicity test (under which it can be placed on the market, as follows from a combined reading of Article 3(1) and Article 4(1) of Directive 2014/40), in my view shows that the legislature decided to narrow the concept of ‘intended consumption’, featuring in the general definition of ‘emissions’ in point 21 of Article 2, in the case of cigarettes, to simple combustion. Although that is of course not the entire process of how a cigarette is, within the usual meaning of those terms, consumed, combustion is clearly part of such a consumption. In that respect, I have already explained that the broad discretion that the legislature enjoys in the present area of law allows it to set the toxicity limits by reference to that part of the process of the intended consumption of cigarettes only.

135. Accordingly, the above definition of ‘emissions’ does not affect my previous conclusion about the lack of manifest error, with regard to the achievement of the objective of a high level of protection of human health, in the legislature’s choice to measure the admissible toxicity of cigarettes based on the standards defined in Article 4(1) of Directive 2014/40.

136. That observation closes the examination of the first to fourth questions referred in the present case which, as previously explained, seek to establish the conclusions to be drawn from the judgment in *Stichting Rookpreventie Jeugd and Others*, as regards the enforceability of the ISO measurement standards at issue against specific categories of private parties. The discussion at the hearing also revisited the initial legal conundrum which the Court had to deal with, namely the lack of publication of the ISO measurement standards at issue in the Official Journal, which still persists. For that reason, and to assist the Court as much as possible, I will offer the following closing remarks.

C. Postscript: the persisting lack of publication of the ISO measurement standards at issue

137. The Commission explained at the hearing that the fact that non-publication still persists is due to ISO’s claim over intellectual property rights which is generally attached to its standards. It further observed that following the judgment in *Public.Resource.Org*,⁶⁷ it has granted access to certain ISO standards (different from those at issue here) based on Regulation (EC) No 1049/2001⁶⁸ and that that decision is now challenged by ISO before the General Court on account of, precisely (but not exclusively), infringement of intellectual property rights.⁶⁹

138. That, in my view, indicates that the publication of the ISO standards at issue in the Official Journal is, in the Commission’s view and at least currently, impossible due to legal obstacles beyond the EU legislature’s control.

139. The question that arose in essence during the hearing was, as I understand it, whether the Court should act upon that persisting non-publication by raising, of its motion, the invalidity of Article 4(1) of Directive 2014/40 on that ground.

140. I consider that such course of action would require, in the context of the present proceedings, the reopening of the oral part of the procedure based on Article 83 of the Rules of Procedure of the Court of Justice.

141. This is due to three main reasons.

142. *First*, that question was not, as such, raised by the referring court (1). *Second*, there is, in my view, some uncertainty as to whether the Court required, in the judgment in *Stichting Rookpreventie Jeugd and Others*, the ISO standards at issue ultimately to be published in the Official Journal which requires that parties and other interested persons be provided with an

⁶⁷ Judgment of 5 March 2024, *Public.Resource.Org and Right to Know v Commission and Others* (C-588/21 P, ‘the judgment in *Public.Resource.Org*’, EU:C:2024:201). In that judgment, the Court required, in essence, the Commission to grant access to standards adopted by CEN, despite the existence of copyright claimed over them.

⁶⁸ Regulation 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).

⁶⁹ See the pending proceedings concerning the action brought on 6 December 2024, *International Electrotechnical Commission and ISO v Commission* (T-631/24). I understand that that action seeks annulment of the respective Commission decision.

opportunity to state their views (2). *Third*, whichever decision is taken on that point, each of them has major legal consequences, which alone calls for a full debate to be had with, in particular, the legislature's involvement (3).

1. *The scope of the present proceedings*

143. Turning to the *first* point above, it is true that the 'non-publication' issue was among the questions addressed in the proceedings having led to the judgment in *Stichting Rookpreventie Jeugd and Others*. The respective stakeholders had the opportunity to adopt a position on it and the present proceedings can therefore be viewed as merely pursuing that discussion when it comes to the specific legal consequences that the judgment in question entails.

144. However, I recall that the referring court enquires about those consequences to ascertain the conditions under which the standards at issue may be enforced against the manufacturers, whereas their lack of publication, while constituting the very cause of the specific regime of their enforceability, is now taken as the starting premiss. By contrast, that court has not enquired about that premiss as such, especially to ascertain whether it can still be maintained and whether the persisting lack of publication affects the validity of Article 4(1) of Directive 2014/40.

145. The interested persons in the present proceedings should therefore be given the opportunity to present their views on that issue which, in fact, is all the more necessary given that, in my view, there is a doubt as to whether the Court required, in the judgment in *Stichting Rookpreventie Jeugd and Others*, the above standards necessarily to be published. That brings me to the *second* point referred to in point 142 above.

2. *The position adopted in the judgment in Stichting Rookpreventie Jeugd and Others*

146. It is clear to me that the lack of enforceability of unpublished acts of EU law, as stated by the Court in the judgments in *Skoma-Lux* and *Heinrich*, constitutes a short-term solution to an anomaly that prevents the natural or legal persons subject to legal obligations from having adequate access to the source of law defining those obligations. In a democratic society governed by the rule of law that prevents the public authorities from enforcing them. At the same time, maintaining such a situation for a prolonged period of time is obviously not desirable. When the need for such dichotomy between validity and enforceability is identified, its causes should therefore be remedied. This is what follows when the Court refers, in the judgment in *Skoma-Lux*, to *delayed enforceability* of the rule affected by the lack of publication.

147. In that light, the question arises whether the conditional enforceability of the ISO standards at issue was, in accordance with the logic of the above case-law, designed by the Court as an immediately available but necessarily short-term fix pending the expected final remedy (publication in the Official Journal) or whether the Court in fact accepted the possibility of access ensured by the ISO system as an acceptable solution that the EU legal order could tolerate as such.

148. The following elements of the judgment in *Stichting Rookpreventie Jeugd and Others* indicate that publication was ultimately expected.

149. *First*, as previously explained, the Court relied on the judgments in *Skoma-Lux* and *Heinrich*, while it did not seek to distinguish the (rather different) situations having led to them, on the one hand, from the situation having led to the judgment in *Stichting Rookpreventie Jeugd and Others*,

on the other. Indeed, while the remedy in *Skoma-Lux* and in *Heinrich* was entirely in the hands of the EU legislature (and not prevented by any external factors), ISO's claim over intellectual property rights admittedly makes the situation more complex. Yet, that did not lead to any particular observation on the part of the Court.

150. *Second*, in paragraph 46 of the judgment in *Stichting Rookpreventie Jeugd and Others*, the Court confirms that the validity of Article 4(1) of Directive 2014/40 is not called into question by 'the mere fact that [that provision] refers to ISO standards that have not, *at this juncture*, been ... published'.⁷⁰ One can suggest that the part of that quote (with emphasis added) would not be necessary if, in fact, the lack of publication as such does not affect the validity of that provision (and not only that lack of publication at the given point in time).

151. *Third*, in paragraph 48 of that judgment, the Court notes that '... 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]'

152. Irrespective of the precise meaning of the term of 'the public generally' (which I addressed above), that paragraph ties the enforceability of the standards at issue vis-à-vis such public in clearly with their publication in the Official Journal.

153. However, and returning to my three lines of reasoning above, I also have to admit that, *first*, contrary to the judgment in *Skoma-Lux*, the Court does not refer to *delayed* (full) enforceability of the ISO standards at issue but links their (conditional) enforceability (against undertakings) to the specific features of the ISO system (in paragraph 52 of the judgment in *Stichting Rookpreventie Jeugd and Others*). That may imply recognition of the difference that distinguishes both types of situations described above (which therefore allows for a different outcome in each of them).

154. *Secondly*, the observation in paragraph 46 of the judgment in *Stichting Rookpreventie Jeugd and Others* (referred to in point 150 above) about the standards not having been published 'at this juncture' may constitute an acknowledgement of the fact that publication is certainly desirable but not necessary (because there is a specific system that allows access).

155. *Third*, should the term 'the public generally' in paragraph 48 of the judgment in *Stichting Rookpreventie Jeugd and Others* (referred to in point 151 above), be understood as referring to the parties entrusted with the task of acting as 'the law compliance watchdog', that paragraph may, for its part, constitute an acknowledgement of the difficulty that the lack of publication brings about for that task to be carried out without, however, also implying that that difficulty affects the enforceability of the standards at issue against the undertakings manufacturing cigarettes or placing them on the market.

⁷⁰ Emphasis added. See also paragraph 37 thereof for similar wording.

3. *The implication of Article 4(1) of Directive 2014/40 being declared invalid due to the persisting lack of publication of the ISO standards*

156. Turning to the last reason why reopening the oral part of the procedure would be desirable, should the Court consider examining the validity of the provision at issue due to the persisting lack of publication in the Official Journal, I note that the implications of a declaration of invalidity of Article 4(1) of Directive 2014/40 on that basis (but also of an explicit decision not to invalidate), would go far beyond the present case and far beyond the cigarette market.

157. In that respect, the Commission stated at the hearing that there are 1 200 acts of EU law referring to ISO standards, which means that the annulment of the provision in question is likely to affect all of those acts and, therefore, potentially numerous areas of law.

158. In that light, the considerable impact that the finding that Article 4(1) of Directive 2014/40 is invalid (due to continuing non-publication) would be likely to have, should lead to a broader discussion about what the acceptable consequences would be of one or the other solutions highlighted above.

159. On the one hand, should the judgment in *Stichting Rookpreventie Jeugd and Others* be understood as requiring the ISO standards ultimately to be published in the Official Journal, there should be a discussion as to whether there are options, at EU level, that would allow for such publication to occur considering the ISO's claim over intellectual property rights.

160. If it were to be confirmed that no plausible way currently exists to allow for the publication of the ISO standards at issue without exposing the European Union to adverse legal consequences, then there should be discussion on what the possible invalidation of the current legislative technique means for the effective operation of the affected fields of law and whether alternatives are in fact (reasonably) feasible.

161. Should, on the other hand, the judgment in *Stichting Rookpreventie Jeugd and Others* be understood as not requiring publication in the Official Journal, there should be a discussion on the tension that such a result would bring in the light of certain fundamental features underlying the operation of the EU legal order.

162. First, it seems to me that accepting non-publication as the final and acceptable outcome is the equivalent of accepting that, within the EU legal order, there may be a category of binding norms that are accessible only against payment or at the cost of travel to a specific place such as the library of the given national standards body. Because that would constitute a departure from the basic premiss that, in a democratic society, law should be accessible free of charge, that choice would merit further explanation.

163. Pursuing the same line of reasoning, the next question to be addressed is whether the EU legal order can tolerate the fact that the specific conditions of access are entirely left at the discretion of the external system of ISO and the respective national standards bodies or whether some EU law strings should be attached to it, such as an EU law obligation on the part of the Member States to ensure that that access is not subject to overly restrictive conditions.

164. Next, it should be recalled that the ISO standards are in principle available in English, French and Russian. Although the linguistic equality that normally constitutes the rule within the European Union may be subject to exceptions,⁷¹ that aspect of the case deserves further attention.

165. Finally, I consider it useful to turn back to the issue of access to documents governed by Regulation No 1049/2001. I have already referred to the judgment in *Public.Resource.Org*, on which the interested persons commented in particular during the hearing. I recall that in that judgment the Court required, in essence, the Commission to grant access to a standard elaborated by CEN despite the fact that intellectual property rights were similarly claimed. That has led, in the present proceedings, to some discussion as to whether that solution also applies to ISO standards (in general) and what the implications are of a possible affirmative reply for the issues raised here.

166. I certainly agree, in particular, with the Netherlands Government and the Commission that whether access to a document has to be granted to a party acting in the public interest (which, as I understand it, was the case of the claimant in the proceedings having led to the above judgment) does not determine the legal conclusions to be drawn, against the persons subject to legal obligations, from the lack of publication of the act detailing those obligations in the Official Journal.

167. Indeed, those two issues are simply different. At the same time, they may also be closely connected in a case such as the present one.

168. That is, should the position be adopted that the publication of the ISO standards at issue in the Official Journal is not required as such, that solution will likely be valid also for any other ISO standards on which the EU legislature may rely. Likewise, the impact of a possible conclusion, in other proceedings concerning different ISO standards, that access to such standards does not have to be granted under Regulation No 1049/2001 will also likely extend beyond any specific ISO standards concerned by those different proceedings. Thus, should a negative reply be reached in both of the situations set out above, the system of access to those standards at EU level will effectively be ‘blocked’ (and will remain open only at the level of ISO, which comprises the access provided by national standards bodies).

169. Should the position be adopted that publication in the Official Journal is ultimately required (for the ISO standards at issue here and, by implication, for any other ISO standards on which the EU legislature will similarly rely), that raises the need to clarify whether a document that is not published in the Official Journal, even though it should be, falls within the (generally worded) scope of Regulation No 1049/2001. I note that, in a different context (where there were no external factors similar to those at issue here), Advocate General Sharpston argued to the contrary.⁷² If that position were also to be accepted here (should, again, the Court conclude that the ISO standards have ultimately to be published in the Official Journal), there should be a discussion about whether an intermediate solution of access at EU level needs to be provided pending the effective publication of the standards in the Official Journal, to prevent the same ‘blocking’ effect from occurring in the meantime.

⁷¹ See, for acts subject to publication, the discussion in the Opinion of Advocate General Kokott in *Skoma-Lux* (C-161/06, EU:C:2007:525, point 37).

⁷² See Opinion of Advocate General Sharpston in *Heinrich* (C-345/06, EU:C:2008:212, points 122 to 133).

170. In other words, although the legal issues arising under the ‘access to documents’ heading, on the one hand, and under the ‘publication in the Official Journal’ heading, on the other, are different, they are part of the same broader issue of access, in the EU legal order, to externally developed standards which the Union legal order has made binding. The result of the analysis for one seems to imply consequences for the analysis of the other and, for that reason, they should not be treated in isolation.

V. Conclusion

171. In the light of the above, I propose that the Court answer the first to fourth questions referred by the College van Beroep voor het bedrijfsleven (Supreme Administrative Court for Trade and Industry, Netherlands) as follows:

Article 4(1) of Directive 2014/40/EU of the European Parliament and 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

must be interpreted as meaning that the ISO standards referred to therein, which have not been published in the *Official Journal of the European Union*, can be enforced against undertakings manufacturing cigarettes or placing them on the market when they can access them, under the conditions described in paragraph 52 of the judgment of 22 February 2022, *Stichting Rookpreventie Jeugd and Others* (C-160/20, EU:C:2022:101). However, that provision, and the lack of publication of the ISO standards referred to therein, cannot be understood as meaning that a legal person such as the Foundation derives a right, from the directive, to seek the enforcement against undertakings manufacturing cigarettes or placing them on the market of a method of measurement of maximum emission levels, provided for in Article 3(1) of Directive 2014/40, that would differ from the one referred to in Article 4(1) of the same directive.