Reports of Cases

OPINION OF ADVOCATE GENERAL
SAUGMANDSGAARD ØE
delivered on 15 July 2021 [1]

Case C-160/20

Stichting Rookpreventie Jeugd,
Stichting Inspire2live,
Rode Kruis Ziekenhuis BV,
Stichting ClaudicatioNet,
Nederlandse Vereniging voor Kindergeneeskunde,
Nederlandse Vereniging voor Verzekeringsgeneeskunde,
Accare, Stichting Universitaire en Algemene Kinder- en Jeugdpsychiatrie Noord-Nederland,
Vereniging Praktijkhoudende Huisartsen,
Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose,
Nederlandse Federatie van Kankerpatiëntenorganisaties,
Nederlandse Vereniging Arbeids- en Bedrijfsgeneeskunde,
Nederlandse Vereniging voor Cardiologie,
Koepel van Artsen Maatschappij en Gezondheid,
Nederlandse Vereniging voor Kindergeneeskunde,
Koninklijke Nederlandse Maatschappij tot bevordering der Tandheelkunde,
College van Burgemeester en Wethouders van Amsterdam
v
Staatssecretaris van Volksgezondheid, Welzijn en Sport,
intervener:
Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten (VSK)

(Request for a preliminary ruling from the rechtbank Rotterdam (District Court, Rotterdam, Netherlands))

(Reference for a preliminary ruling – Manufacture, presentation and sale of tobacco products – Directive 2014/40/EU – Filter cigarettes – Maximum emission levels – Article 4(1) – Measurement methods for tar, nicotine and carbon monoxide emissions based on ISO standards – Failure to publish the content of those standards in the *Official Journal of the European Union* – Publication requirements – Third subparagraph of Article 297(1) TFEU – Conditions of access to the content of those standards – Principle of free access)

[1] Original language: French.

I. Introduction

1. Can the EU legislature, in the legislative acts which it adopts, reference international standards drawn up by a private organisation (in this instance ISO standards),[2] without publishing the content of those standards in the *Official Journal of the European Union*, or making that content available directly and free of charge to citizens of the European Union, if those standards are available from that organisation on payment of a fee for the copyright which it claims?

2. That, in essence, is one of the questions referred by the rechtbank Rotterdam (District Court, Rotterdam, Netherlands) and which the Court is asked to answer in the present case.

3. The request for a preliminary ruling has been submitted in proceedings between the Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation, Netherlands; 'the Stichting') and 15 other entities (together, 'the applicants in the main proceedings') and the Staatssecretaris van Volksgezondheid, Welzijn en Sport (State Secretary for Public Health, Welfare and Sport, Netherlands; 'the Staatssecretaris').

4. In that context, the referring court seeks, more specifically, to ascertain whether the *conditions of access* to the content of the ISO standards referenced in Article 4(1) of Directive 2014/40/EU,[3] which establishes a measurement method for tar, nicotine and carbon monoxide emissions from filter cigarettes, are compatible with the publication requirements laid down in the third subparagraph of Article 297(1) TFEU[4] and with the underlying principle of transparency.

5. At the end of my presentation, I shall propose that the Court rule that the third subparagraph of Article 297(1) TFEU does not require that the content of the ISO standards at issue be published in the Official Journal. In addition, I shall set out the reasons why I consider that the *conditions of access* to the content of those standards are not contrary to the general principles of which that provision constitutes an expression.

2 Namely, the standards established by the International Organisation for Standardisation (ISO). That non-governmental organisation, whose seat is in Geneva (Switzerland), consists of a network of national standardisation bodies, in which, inter alia, all Member States are represented (one body per Member State). ISO is a private entity whose funds are derived from the dues and contributions of its members, from the sale of publications, from the provision of services and from the contributions of donors (see Article 21.1 of the ISO Statutes, available at the following internet address: https://www.iso.org/en/publication/PUB100322.html).

3 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).

4 It is apparent from the request for a preliminary ruling that the referring court is also asking the Court, in essence, whether the failure to publish the ISO standards at issue is compatible with Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ 2013 L 69, p. 1). I would state at the outset that that regulation does not seem to me to be relevant for the purposes of the present reference for a preliminary ruling, as there is nothing in that regulation that is intended to clarify the documents that should be published in the Official Journal.

II. Legal framework

A. Regulation (EC) No 1049/2001

6. Article 12 of Regulation (EC) No 1049/2001 [5] provides:

‘1. The institutions shall as far as possible make documents directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned.

2. In particular, legislative documents, that is to say documents drawn up or received in the course of procedures for the adoption of acts which are legally binding in or for the Member States, should, subject to Articles 4 and 9, be made directly accessible.

…’

7. In the words of Article 4(2) of that regulation:

‘The institutions shall refuse access to a document where disclosure would undermine the protection of:

– commercial interests of a natural or legal person, including intellectual property,

– …’

B. Regulation (EU) No 1025/2012

8. Article 6(1) of Regulation (EU) No 1025/2012 [6] provides:

‘National standardisation bodies shall encourage and facilitate the access of SMEs to standards and standards development processes in order to reach a higher level of participation in the standardisation system, for instance by:

…

(c) providing free access or special rates to participate in standardisation activities;

(d) providing free access to draft standards;

(e) making available free of charge on their website abstracts of standards;

…’

[5] 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).

[6] Regulation of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ 2012 L 316, p. 12).

9. In the words of Article 10(6) of that regulation:

'Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the [Official Journal] or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.'

C. Directive 2014/40

10. Recital 11 of Directive 2014/40 states:

'For measuring the tar, nicotine and carbon monoxide yields of cigarettes (hereinafter referred to as "emission levels"), reference should be made to the relevant, internationally recognised ISO standards. …'

11. In the words of Article 3(1) of that directive:

'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.'

12. Article 4(1) of that directive provides:

'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.'

III. The main proceedings, the question referred for a preliminary ruling and the procedure before the Court

13. By letters dated 31 July and 2 August 2018, the applicants in the main proceedings requested the Nederlandse Voedsel- en Warenautoriteit (Netherlands Food and Consumer Product Safety Authority, Netherlands; 'the NVWA') to ensure that filter cigarettes offered for sale to consumers in the Netherlands comply when used as intended with the maximum emission levels for tar, nicotine and carbon monoxide laid down in Article 3(1) of Directive 2014/40 and, if necessary, to adopt an implementing measure so that products not complying with those

requirements would be withdrawn from the market.[7]

14. By decision of 20 September 2018, the NVWA rejected the request for an implementing measure submitted by one of the applicants in the main proceedings, the Stichting, whose objective is to ban tobacco use by young persons. The Stichting, and all the other applicants in the main proceedings, lodged an administrative objection against that decision before the Staatssecretaris.

15. On 31 January 2019, the Staatssecretaris rejected the Stichting's objection as unfounded and the objection lodged by the other applicants in the main proceedings as inadmissible.

16. The applicants in the main proceedings lodged a judicial appeal against that decision before the referring court. The Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten (Netherlands Tobacco Manufacturers' Association, Netherlands; 'the VSK') requested to be recognised as a third party in the main proceedings. That request was granted.

17. In the main proceedings, the Stichting claims, in essence, that the measurement method for tar, nicotine and carbon dioxide levels of filter cigarettes that is referred to in Article 4(1) of Directive 2014/40 is not binding. In its submission, those emissions should be measured by reference, in particular, to the intended use of those products and, more specifically, to the fact that smokers' fingers and lips partially obscure the small holes made in cigarette filters. Consequently, those emissions are in reality higher than can be determined by that method.[8] In those circumstances, the use of a different method, providing greater protection for consumers' health, is required.[9]

18. The Staatssecretaris, supported by the VSK, rejects that argument and maintains that Article 4(1) of Directive 2014/40 is binding. The national authorities cannot therefore depart, on their own initiative, from the method prescribed in that provision. In any event, it is for the EU legislature to decide whether to amend that provision.

19. In the light of those arguments, the referring court seeks to ascertain, *in the first place*, whether the fact that the ISO standards on the basis of which the tar, nicotine and carbon monoxide emissions from filter cigarettes are measured are not published in the Official Journal and are accessible from ISO only for payment is compatible, in particular, with the publication regime established in the third subparagraph of Article 297(1) TFEU and with the principle of transparency.

7 It is apparent from the order for reference that the request for an implementing measure was based, in accordance with the applicable Netherlands law, on Article 14 of the Tabaks- en rookwarenwet (Law on tobacco products and smoking-related products). That provision confers on the NVWA the power to issue an administrative injunction against manufacturers, importers and distributors of tobacco products where they do not comply with Article 17a(1) and (2) of that law, that is to say, where they fail to take the necessary measures to ensure that their products comply with the applicable requirements or to withdraw them from the market, as appropriate.

8 According to the applicants in the main proceedings, the method referred to in Article 4(1) of Directive 2014/40 is based on the use of a smoking machine in which the small holes in the cigarette filters are not obstructed. These small holes allow clean air to be inhaled through the filter and the tar, nicotine and carbon monoxide levels are therefore reduced. Conversely, a smoker whose fingers and lips partly close that filter absorbs smoke in which the concentrations of those substances are higher.

9 The Stichting claims that the 'Canada Intense' measurement method should be employed. Under that method, according to the Stichting, the actual conditions in which filter cigarettes are used can be reproduced more closely, since the small holes made in the filter are blocked. I note, as a matter of interest, that that method is currently being examined by ISO (see, in that regard, https://www.iso.org/obp/ui/#iso:std:iso:tr:19478:-2:ed-1:v1:en).

20. *In the second place*, the referring court wonders about the binding nature of the measurement method for emission levels provided for in Article 4(1) of Directive 2014/40 and about the validity of that provision in the light of the objectives of that directive and of other higher-ranking rules of law. [10]

21. In those circumstances, the rechtbank Rotterdam (District Court, Rotterdam), by decision of 20 March 2020, received at the Court on 24 March 2020, decided to stay the proceedings and to refer to the Court, inter alia, the following question for a preliminary ruling: [11]

'Is the form of the measurement method provided for in Article 4(1) of Directive 2014/40, based on ISO standards which are not freely accessible, in accordance with Article 297(1) TFEU and with the underlying principle of transparency?'

22. The Stichting, the VSK, the Netherlands Government, the European Parliament, the Council of the European Union and the European Commission lodged written observations before the Court. There was no hearing in the present case. The parties and interested parties nonetheless answered in writing the questions put by the Court on 9 February 2021.

IV. Analysis

A. Preliminary considerations

23. In accordance with the Court's request, this Opinion will be targeted at the first question referred for a preliminary ruling.

24. By that question, which is divided into two parts, the referring court is asking the Court, *first*, to clarify whether the third subparagraph of Article 297(1) TFEU requires that the ISO standards referenced in Article 4(1) of Directive 2014/40 be published in the Official Journal and, *second*, to determine whether the conditions of access to those standards (which, apart from the fact that they are not published in the Official Journal, are made available to the public by ISO only in return for payment, while the EU institutions do not make their content accessible directly and free of charge) are consistent with the principle of transparency.

25. By way of preliminary point, I would emphasise that, since the Court is dealing here with a question which ultimately concerns the *accessibility of the content of the law*, that is to say, the possibility for citizens to become aware of it, the starting point of the answer to this question must in my view clearly be that, in a democratic society, every citizen must have free access to the content of the law. That is one of the bases of the rule of law. [12]

26. That principle of free access to the content of the law must in my view be guaranteed for at least two reasons. The first derives from the adage that 'ignorance of the law is no excuse', which necessarily means that the law cannot be *imposed* on citizens before they have the opportunity to

[10] More precisely, the referring court wonders about the compatibility of that method with Article 114(3) TFEU, relating to the approximation of laws concerning health, and with the World Health Organisation Framework Convention on Tobacco Control (signed in Geneva on 21 May 2003, to which the European Union and its Member States are parties) and Articles 24 and 35 of the Charter of Fundamental Rights of the European Union ('the Charter'), which concern, respectively, the rights of the child and health care.

[11] Since this Opinion focuses on particular aspects of the present case, only the relevant question is set out here. All the questions for a preliminary ruling may be consulted on the internet and in the Official Journal (OJ 2020 C 222, p. 17).

[12] I would recall that the principle of the rule of law is enshrined in Article 2 TEU.

become aware of it. The second comes from the need, for citizens in the broad sense, to be in a position to consult all of the texts adopted by the public authorities that govern life in society in order to be able to ensure that they are observed [13] and to exercise effectively the rights conferred on them in a democratic society. [14] That, moreover, is the very essence of the approach taken by the applicants in the main proceedings: by their action before the referring court, those entities, whose common objective is the prevention of smoking, seek specifically to establish that Article 4(1) of Directive 2014/40 prescribes a measurement method which in their submission fails to provide sufficient protection for consumers' health.

27. Does it follow from that principle that the ISO standards referenced in a legislative act of the European Union, such as, in this instance, Directive 2014/40 [15] must be published in the Official Journal or, at least, that the EU institutions are required to ensure that the content of those standards is made available to the public directly and free of charge?

28. In that regard, first of all, I must make clear that no provision of EU law specifically deals with the publication requirements with which *international standards* such as the ISO standards at issue must comply where they are thus referenced in a legislative act. In particular, Article 10(6) of Regulation No 1025/2012, which contains precise obligations concerning the publication of *harmonised standards*, [16] does not extend to ISO standards. In that context, it seems important to me to bear in mind that the present reference for a preliminary ruling does not concern whether the publication of other technical standards in the Official Journal, whether national, harmonised or European, [17] must be in full or whether their content must be freely available to the public. The only issue in this case relates to international standards and, more specifically, ISO standards drawn up by a private organisation, whose funding comes from, inter alia, the sale of the standards of which it is the author. [18]

29. Next, and as I shall underline further on in my presentation, the answer to the first question depends, in my view, on the way in which the EU legislative act which makes reference to ISO standards aims to use such standards.

[13] I would add that, in that respect, the European Court of Human Rights has itself held that where an interference with a fundamental right must be 'prescribed by law', that assumes that the law (which covers both statute and unwritten law) is *adequately accessible*: the citizen must be able to have an indication that is adequate in the circumstances of the legal rules applicable to a given case. In addition, that court has stated that a norm cannot be regarded as a 'law' unless it is formulated with sufficient precision to enable the citizen to regulate his or her conduct: he or she must be able – if need be with appropriate advice – to foresee, to a degree that is reasonable in the circumstances, the consequences which a given act may entail (see ECtHR, 26 April 1979, *The Sunday Times v. the United Kingdom*, CE:ECHR:1979:0426JUD000653874, § 49).

[14] See, to that effect, judgment of 1 July 2008, *Sweden and Turco* v *Council* (C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 46).

[15] I would add that other regulations and directives use ISO standards in a similar way to Article 4(1) of Directive 2014/40, that is to say, by including only a reference to those standards. See, for example, Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ 2013 L 178, p. 1), Annex II to which, entitled 'Technical requirements for transponders', makes reference to ISO standards 11784 and 11785. See also, by way of further example, Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ 2014 L 257, p. 146), Annex III to which, entitled 'Requirements to be met by conformity assessment bodies in order to become notified bodies', refers to the standards ISO/IEC 17065:2012 and 17025:2005.

[16] In accordance with those requirements, only the reference to the harmonised standards, and not their content in full, must be published in the Official Journal.

[17] Within the European Union, standards are known as national standards, international standards or harmonised standards, depending on whether they are adopted by a national or an international standards body, a European standards organisation or on the basis of a request from the Commission for the application of the EU harmonisation legislation (see Article 2(1)(a), (b), (c) and (d) of Regulation No 1025/2012).

[18] I refer, in that regard, to footnote 2 to this Opinion.

30. A number of elements seem to me to be relevant in that respect. The present case leads me to identify three of those elements. *First*, are the standards at issue necessary in order to become aware of the 'essential requirements' of the legislative act that makes reference to them, or are they, rather, of a technical and ancillary nature by comparison with such requirements? *Second*, do those standards aim to impose obligations on the undertakings whose products or activities are concerned by those standards? *Third*, in the event that those standards are of a technical and ancillary nature and do not aim to impose obligations on such undertakings, from which it follows (as I shall explain in section B of this Opinion) that they are not required to be published in the Official Journal pursuant the third subparagraph of Article 297(1) TFEU, does the fact that the EU institutions do not provide for more generous conditions of access than those already envisaged by ISO constitute a disproportionate barrier to the possibility for the public to become aware of them and thus to the general principles which underlie that provision (section C)?

31. I would add that the last element seems to me to be less important when it is clear that the ISO standards referenced in a legislative act resemble a form of codification of technical knowledge *by* and *for* professionals.[19] Conversely, the more closely the standard relates to an area in which citizens are likely to seek to exercise the rights conferred on them in a democratic society (for instance, as in the present case, the field of health and consumer protection), the more that element must be taken into account and the more appropriate it is to ascertain whether the content of the standard must be freely accessible to the public.

B. Publication on the basis of the third subparagraph of Article 297(1) TFEU (first part of the first question)

32. It will be recalled that Article 297(1) TFEU requires, in the words of the third subparagraph, that *legislative acts* be published in the Official Journal.

33. In the present case, two situations must in my view be examined. *Either* the ISO standards at issue may themselves be regarded as 'legislative acts' and, if so, it is clear that their content must be published in full pursuant to that provision (section 1); *or* those standards cannot be considered to meet that definition, and it is then appropriate to ascertain whether the publication of their content is nonetheless required under that provision, in that they constitute 'elements' of a legislative act (namely of Directive 2014/40) (section 2).

1. The ISO standards at issue do not constitute in themselves 'legislative acts'

34. The concept of 'legislative acts' is defined, in Article 289(3) TFEU, as covering 'legal acts adopted by legislative procedure'. The Court has held that, under that provision, a legal act can be classified as a 'legislative act' of the European Union only if it has been adopted on the basis of a provision of the Treaties which expressly refers *either* to the ordinary legislative procedure referred to in Article 289(1) and Article 294 TFEU, *or* to the special legislature procedure described in Article 289(2) TFEU.[20]

[19] See Brunet, A., 'Le paradoxe de la normalisation : une activité d'intérêt général mise en œuvre par les parties intéressées', *La normalisation en France et dans l'Union européenne : une activité privée au service de l'intérêt général* ?, Presses universitaires d'Aix-Marseille, Aix-en-Provence, 2012, p. 51.

[20] See judgment of 6 September 2017, *Slovakia and Hungary* v *Council* (C-643/15 and C-647/15, EU:C:2017:631, paragraph 62).

35. In this instance, all the parties to and interveners in the present proceedings, with the exception of the applicants in the main proceedings, maintain that the ISO standards referenced in Article 4(1) of Directive 2014/40 cannot be regarded as constituting, in themselves, 'legislative acts'.

36. I have no difficulty in sharing that view.

37. In fact, it is clear that those standards – which, as the Commission has correctly observed, were drawn by a private body, namely ISO [21] – were not the subject of a *specific* ordinary or special legislative procedure, that is to say, a procedure aimed specifically at their adoption by the EU legislature, on the basis of a provision of the Treaties.

38. *Nor*, to my mind, does the fact that, after having been adopted by ISO, those standards were chosen by the EU legislature, during the legislative procedure that led to the adoption of Directive 2014/40, in order to measure the emission levels of filter cigarettes and to ascertain that they remain below the maximum levels fixed in Article 3(1) of that directive permit the conclusion that they themselves were 'adopted' as 'legislative acts' by that procedure. In fact, the sole purpose of that procedure was the adoption of that directive.

39. Having regard to those elements, and since it is clear from the abovementioned provisions of the FEU Treaty that the framers of the Treaty took a *formal approach*, [22] according to which legislative acts are not classified as such unless they are adopted according to the ordinary legislative procedure or according to a special legislative procedure, it seems clear to me that the ISO standards at issue cannot be regarded as themselves belonging to that category of acts. [23]

2. The ISO standards at issue are 'elements' of a legislative act whose publication in full in the Official Journal is, however, not required

40. It follows from the preceding sub-section that, in the context of the present case, only Directive 2014/40, which was published in the Official Journal, may be considered to meet the definition of 'legislative act', within the meaning of Article 289(3) TFEU. To use the Netherlands Government's expression, the ISO standards referenced in Article 4(1) of that directive constitute, at most, 'elements' of that legislative act.

41. Must those elements be published in full in the Official Journal pursuant to the third subparagraph of Article 297(1) TFEU? In my view, the answer is no.

[21] Unlike in the case of the harmonised standards that are the result of collaboration between the European standardisation bodies, the Member States and the Commission, since they are prepared by private bodies at the request of the Commission (made on the basis of a directive), the EU institutions are not involved in the procedure for drawing up ISO standards.

[22] In the words used by Advocate General Bot in his Opinion in *Slovakia* v *Council* and *Hungary* v *Council* (C-643/15 and C-647/15, EU:C:2017:618, point 63).

[23] As to whether publication in full in the Official Journal of the ISO standards at issue might be expressly required under other provisions of EU law, I note, as a matter of interest, that Article 13 of Regulation No 1049/2001 provides for the publication of documents other than the 'legislative acts' and 'non-legislative acts' referred to in Article 297 TFEU. However, the technical standards referenced in directives or regulations cannot be placed in any of the categories of document covered by that provision.

42. In that regard, I note that, in her Opinion in *Heinrich*,[24] which concerned a case where an annex to a regulation[25] had not been published in the Official Journal, Advocate General Sharpston stated that the failure to publish such an annex amounted to 'the publication of the skeleton [of the act] without the substance' and constituted a 'defective and inadequate publication' that did not satisfy the requirements of Article 297(2) TFEU (on the publication of *non-legislative acts* adopted in the form of regulations, directives or decisions).

43. I endorse that analysis, which seems to me to be capable of being transposed to the regime of the publication of *legislative acts* provided for in the third subparagraph of Article 297(1) TFEU. To my mind, that provision would be deprived of its meaning if only the 'skeleton' formalising the adoption of such an act, and not its entire 'substance', had to be published in the Official Journal.

44. As I shall explain below, publication in the Official Journal does not however seem to me to be required by that provision where, as in this instance, the 'elements' referenced in one or more provisions of the legislative act are ISO standards which correspond to mere clarification of a technical and ancillary nature by comparison with the 'essential requirements' of that act (first criterion) and do not aim to *impose* obligations on the undertakings whose products or activities are concerned by such standards (second criterion).

(a) The ISO standards at issue are of a technical and ancillary nature by comparison with the 'essential requirements' set out in Article 3(1) of Directive 2014/40 (first criterion)

45. 'Essential requirements', as I understand them, are the rules which, in an EU legislative act the purpose of which is to define the preconditions for the placing of products on the internal market (such as, in this instance, filter cigarettes), relate specifically to those preconditions and thus reflect the essence of the political choice made by the legislature for the purpose of implementing its objectives.[26]

46. In the light of that definition, I consider that the question whether the ISO standards which are referenced in such a legislative act must be published in the Official Journal depends on the way in which they are linked to such 'essential requirements' and thus relate to the 'substance' of the act. More specifically, it is necessary, in my view, to distinguish the situation in which such standards are *technical* and *ancillary* by comparison with those essential requirements from the situation in which such standards are necessary for an understanding of the scope or the content of those requirements.

47. In the present case, I note, *in the first place*, that the ISO standards referenced in Article 4(1) of Directive 2014/40 are intended to provide details, on a *technical* level, of the method on the basis of which tar, nicotine and carbon monoxide emissions from filter cigarettes are measured.

[24] C-345/06, EU:C:2008:212, point 67.

[25] Namely, Commission Regulation (EC) No 622/2003 of 4 April 2003 laying down measures for the implementation of the common basic standards on aviation security (OJ 2003 L 89, p. 9).

[26] I borrow that concept from the Commission's *Guide to the implementation of directives based on the New Approach and the Global Approach* published in 2000 (which concerns, more specifically, the harmonised standards adopted on the basis of that new approach), and in which the 'essential requirements' are described as all the provisions necessary to *attain the objective* of a directive and on which *the placing of a product on the market is conditional*.

48. *In the second place*, it follows from the interrelationship between that provision and Article 3(1) of that directive that, while those standards relate *solely* to the measurement method applied in order to verify compliance with the maximum emission levels fixed in Article 3(1), those levels reflect the essence of the political choice made by the EU legislature for the purpose of implementing its objectives of protecting consumers and, in particular, protecting health.[27] In addition, *first*, the filter cigarettes covered by Directive 2014/40 cannot be placed on the market if those levels are exceeded (in other words, those levels are a precondition of the placing of those products on the market) and, *second*, those levels, the values of which are expressly set out in Article 3(1) of that directive,[28] may be known to every citizen of the EU independently of those standards.

49. I infer from those elements that, in the context of the application of Directive 2014/40, it is *not* the ISO standards at issue, but the maximum emission levels set out in Article 3(1) of that directive, that must in my view be regarded as 'essential requirements'. In addition, the ISO standards referenced in Article 4(1) of that directive are *ancillary* by comparison with such requirements.

50. I shall explain below that that conclusion is supported by the fact that those standards do not impose an obligation on manufacturers and importers of filter cigarettes (second criterion).

(b) The ISO standards at issue do not seek to impose obligations on undertakings whose products are concerned by those standards (second criterion)

51. As regards the second criterion, it is important to bear in mind that 'standards' in the broad sense are defined, within the European Union, as 'technical specification[s], adopted by … recognised standardisation bod[ies] … with which compliance is *not* compulsory'.[29] They are not generally intended to impose obligations on the undertakings whose products are concerned by such standards.

[27] See, in particular, recital 59 of Directive 2014/40: 'It is … necessary to ensure that the obligations imposed on manufacturers, importers and distributors of tobacco and related products … guarantee a high level of health and consumer protection …'

[28] See point 11 of this Opinion.

[29] See Article 2(1) of Regulation No 1025/2012 (emphasis added).

52. That having been made clear, I recognise, in the light of the preceding section, that where ISO standards were used by the EU legislature to create obligations for those undertakings, such standards should, in principle, come within the category of 'essential requirements'[30] and therefore be published in the Official Journal.[31] In fact, compliance with those standards would become a precondition of the placing of the products concerned on the internal market.[32]

53. In the present case, I consider that the ISO standards listed in Article 4(1) of Directive 2014/40 do not seek to impose obligations on manufacturers and importers of filter cigarettes.

54. It is true that, in adopting that provision, the EU legislature does not seem to me to have envisaged[33] that the emissions from filter cigarettes might be measured on the basis of a different method from that prescribed by the ISO standards at issue, by the laboratories responsible, in accordance with Article 4(2) of that directive, for checking those emissions.

55. However, and while recognising that binding nature with regard to those test laboratories,[34] I consider that the only real obligation borne by manufacturers and importers of filter cigarettes in this instance is the obligation to ensure that those emissions comply with the maximum emission levels laid down in Article 3(1) of that directive. Those importers and manufacturers are not themselves required to apply the measurement method prescribed by the ISO standards listed in Article 4(1) of that directive.

56. In addition, since it is always *solely* by reference to those maximum emission levels that the compliance of those products must be evaluated, it seems to me that it is possible, for those importers and manufacturers, to satisfy themselves, even without being aware of the content of the ISO standards at issue, that those maximum levels are complied with and, therefore, to introduce on to the market products that comply with those essential requirements.

57. In the light of the foregoing, I consider that those standards do not seek to impose obligations on manufacturers and importers of filter cigarettes, which confirms their *technical and ancillary* nature by comparison with the 'essential requirements' which are fixed in Article 3(1) of Directive 2014/40 and impose obligations on those manufacturers and importers.

30 In that regard, I note that, in a wider context than that of the present case, the Court has recognised that the publication in the Official Journal of the acts issued by the public authorities of the European Union and of their elements is required when, in particular, they seek to impose *obligations on individuals*. More specifically, in its judgment of 10 March 2009, *Heinrich* (C-345/06, EU:C:2009:140, paragraph 61), the Court considered, in essence, that the publication of the annex which had not been published in the Official Journal was required, in any event, in so far as the adapting measures provided for in that annex sought to impose obligations on individuals. It also held, in another judgment (namely, in the judgment of 12 May 2011, *Polska Telefonia Cyfrowa*, C-410/09, EU:C:2011:294, paragraph 34), that Commission guidelines the adoption of which was provided for in one of the provisions of a directive should be published in the Official Journal where they contain 'obligation[s] capable of being imposed, directly or indirectly, on individuals'.

31 I note, as a matter of interest, that some Member States (namely, more specifically, the French Republic, Hungary, the Kingdom of the Netherlands and the Slovak Republic) provide that, where technical standards are mandatory, they must be available freely and free of charge. In that regard, the Conseil d'État (Council of State, France) has held, moreover, that 'in accordance with the objective, of constitutional value, of accessibility of rules of law, … standards the application of which is mandatory must be capable of being consulted free of charge' (Conseil d'État, 6th Chamber, 28 July 2017, No 402752, FR:CECHS:2017:402752.20170728). That said, access to such standards proves very restricted in practice. In that regard, the Association française de normalisation (AFNOR) (French association on standards) states that, at ISO's request, consultation free of charge was suspended for all standards drawn up by that organisation.

32 I would point out that whether the ISO standards at issue are used in a binding manner or not forms, more specifically, the subject matter of the second, and not the first, question referred for a preliminary ruling. Nonetheless, I consider it useful, in the context of the answer to the first question, to provide at this stage some information concerning that aspect of the present reference for a preliminary ruling.

33 Except that, in application of Article 4(3) of Directive 2014/40, the Commission adopts delegated acts to adapt the methods of measurement of those substances.

34 To that extent, I support the opinion of the Commission, which submits that the standards at issue *must* be used to determine whether filter cigarettes placed on the market observe those maximum emission levels.

(c) Intermediate conclusion

58. Examination of the criteria identified in point 44 of this Opinion leads me to conclude that the ISO standards referenced in Article 4(1) of Directive 2014/40 are not covered by the rule on publication laid down in the third subparagraph of Article 297(1) TFEU. By comparison with the maximum emission levels laid down in Article 3(1) of that directive, which constitute 'essential requirements' of that measure, those standards are *technical* and *ancillary* elements which in my view do not have to be published in the Official Journal.

59. I would add that, since they satisfy those two criteria, it appears to me that those standards are used by the EU legislature in a manner which, ultimately, resembles that laid down for the *harmonised standards* adopted on the basis of the 'new approach' directives,[35] for which the legislature considered that publication in the Official Journal of the references to those standards was sufficient.

60. On that point, I would observe that, in the judgment in *James Elliott Construction*,[36] which concerned such a harmonised standard,[37] the Court held, after observing that the legal effects of such a standard were subject to prior publication of its references in the Official Journal, that it had jurisdiction to give a preliminary ruling on the interpretation of the content of those standards. It took no account of the fact that the content of the harmonised standards is not published in full in the Official Journal.

61. I observe, in that regard, that the Court does not hesitate, including in preliminary-ruling procedures, to call into question premisses relating to the interpretation of EU law which it considers dubious.[38] However, it did not do so in that case, even though failure to satisfy the applicable publication requirements would have directly affected the possibility for that standard to have legal effects.[39]

[35] That is to say the directives that were adopted on the basis of the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (OJ 1985 C 136, p. 1) (which is not the case of Directive 2014/40). Standards drawn up on the basis of that 'new approach' have in common that they are not binding on undertakings whose products are concerned by those standards (whereas compliance with those standards by those undertakings gives rise, on the other hand, to a *presumption of conformity* with the essential requirements to which they are subject). In addition, those standards seek only to clarify, in the form of technical specifications, 'essential requirements' the scope of which may be understood independently of those specifications on reading the applicable directive.

[36] Judgment of 27 October 2016 (C-613/14, EU:C:2016:821; 'the judgment in *James Elliott Construction*').

[37] Since that standard was adopted on the basis of a 'new approach' directive (namely, Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ 1989 L 40, p. 12)). I refer in that regard to footnote 35 to this Opinion.

[38] See, for example, concerning intellectual property, judgment of 29 July 2019, *Funke Medien NRW* (C-469/17, EU:C:2019:623, paragraphs 16 to 26).

[39] In the light of the judgment in *James Elliott Construction*, I do not see why different publication requirements should apply with respect to the ISO standards at issue. It is true that harmonised standards which, like the one at issue in the judgment in *James Elliott Construction*, were adopted on the basis of the 'new approach' have the particular characteristic that they were drawn up following the adoption of the directives the essential requirements of which they must help to clarify and that, accordingly, there is no reference to those standards in the body of those directives. However, I am not convinced that that difference might mean that the ISO standards to which a legislative act makes direct reference would be more closely related to the 'substance' of that act and that their content should be published in full in the Official Journal. If that were so, then the question of the publication of a technical standard in the Official Journal would become dependent on whether the standard already exists at the time when the legislative act is adopted, since different publication requirements would apply depending on whether the legislative act makes direct reference to a standard which has already been drawn up by a private body or merely provides that it is to be drawn up by such a body. That, in my view, would amount to a distinction that could only be described as 'artificial' and would no longer have any relationship with the substantive criteria which I have highlighted in points 43 and 44 of this Opinion and which in my view are the only relevant criteria.

62. In the light of all of those considerations, I consider that the answer to the first part of the first question should be that the failure to publish in full in the Official Journal the content of the ISO standards referenced in Article 4(1) of Directive 2014/40 does not infringe the third subparagraph of Article 297(1) TFEU.

C. The general principles underlying the third subparagraph of Article 297(1) TFEU (second part of the first question)

63. By the second part of its first question, the referring court seeks to ascertain whether the *conditions of access* to the content of the ISO standards at issue are consistent with the principle of transparency, which, among others, underlies the third subparagraph of Article 297(1) TFEU.

64. My analysis of this issue will be organised as follows. In the first part, I shall clarify what is to be understood by the principle of transparency to which the referring court refers in its question. I shall explain that, in my view, that court is referring, in reality, to the principle of free access to the content of the law, the importance of which I have already mentioned in point 25 of this Opinion. In the second part, I shall state that the question to be considered at this stage is whether the EU institutions must make provision for more generous conditions of access than those already envisaged by ISO (which requires payment of a fee from persons wishing to have access to the content of the standards which it draws up), that is to say, ensure that those standards are made available to all directly and free of charge. I shall emphasise that the answer to that question depends on whether the conditions of access to those standards are justified and do not disproportionately impede the possibility for the public to become aware of them.

1. The relevance of the principle of transparency

65. The concept of 'transparency' is not mentioned in that precise formulation in the provisions of the Treaties. It is the word 'openly' that was chosen by the framers of the Treaties in the second paragraph of Article 1 TEU, which refers to decisions taken as openly as possible and as closely as possible to the citizen, and in Article 15(1) TFEU, which provides that, 'in order to promote good governance and ensure the participation of civil society', the European Union's institutions, bodies, offices and agencies are to conduct their work as openly as possible.

66. The Court has interpreted the principle of openness as being set out in general terms in those provisions and given specific shape, in particular, by the 'right of access' to documents enshrined in Article 15(3) TFEU, Article 42 of the Charter and Regulation No 1049/2001. [40]

[40] See judgments of 28 June 2012, *Commission* v *Agrofert Holding* (C-477/10 P, EU:C:2012:394, paragraph 53), and of 21 January 2021, *Leino-Sandberg* v *Parliament* (C-761/18 P, EU:C:2021:52, paragraph 37 and the case-law cited).

67. Transparency is linked to the right of access to documents by recital 2 of that regulation. [41] As I understand it, that right does not underlie the obligation to publish already laid down in Article 297 TFEU but enhances it, by requiring the institutions to make available to the public categories of documents not covered by that provision. [42]

68. In that context, it seems to me that transparency therefore refers more to the possibility for citizens to scrutinise all the information that constituted the basis of a legislative act [43] than to the possibility of having access to the content of the legislative act in itself and of the 'elements' of that act, which constitutes the essence of the problem that arises in the present case.

69. In the light of the foregoing, it seems to me that, by the second part of its first question, the referring court seeks, in reality, to ask the Court not about the principle of transparency but about the principle of free access to the content of the law. In my view, it is clear that that principle – admittedly unwritten in the Treaties and the Charter, but binding as a basis of the principle of the rule of law enshrined in Article 2 TEU – underlies the third subparagraph of Article 297(1) TFEU. In fact, what stronger and more specific expression of that principle could there be than the obligation to publish the content of the law?

70. To my mind, where that provision does not require publication in the Official Journal of the elements referenced in provisions of a legislative act (such as, in this instance, the ISO standards referenced in Article 4(1) of Directive 2014/40), that principle requires the EU institutions to ensure *as wide an access as possible* to those elements for all citizens. Thus, any restriction of the possibility for citizens to become aware of those elements freely must be justified and must not disproportionately impede that possibility.

71. As I stated in point 26 of this Opinion, the principle of free access to the content of the law has a twofold *raison d'être*. First, it is a corollary of the principle of legal certainty, which requires that legal rules be clear, precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law. [44] Second, by guaranteeing citizens free access to the law, that is to say, to all the texts adopted by the public authorities that govern life in society, it permits them to exercise their democratic rights. No one could challenge the law and contribute to its development if it were not possible to know what the law is.

72. The present case relates to this second dimension of the principle of free access to the content of the law. The case has arisen in a specific context in which entities which were clearly aware of the content of the ISO standards referenced in Article 4(1) of Directive 2014/40 object to the method prescribed by those standards with a view to securing the withdrawal of products which they consider to be non-compliant and seek, ultimately, to challenge the EU legislature's decision to rely on those standards.

[41] In accordance with recital 2 of Regulation No 1049/2001, openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to citizens.

[42] For example, it extends to 'documents drawn up or received in the course of procedures for the adoption of acts which are legally binding in or for the Member State' (see Article 12(2) of Regulation No 1049/2001). In that regard, I note, moreover, that it would in my view always be possible to rely on that provision in order to establish that the content of ISO standards at issue should be directly made available as documents '*received* in the course of procedures for the adoption of acts which are legally binding in or for the Member State' (emphasis added), since I presume that the legislature received a copy of those documents during the procedure that led to the adoption of Directive 2014/40. Having said that, I note that Article 4 of Regulation No 1049/2001 sets out a number of exceptions to access to the documents of the institutions and that, pursuant to Article 4(2), the institutions are to refuse, in particular, access to a document where disclosure would undermine the protection of commercial interests, including intellectual property. As ISO claims copyright in those standards, their disclosure might thus, in theory, be refused under the latter provision unless an overriding public interest justified disclosure.

[43] See, to that effect, judgment of 1 July 2008, *Sweden and Turco* v *Council* (C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 46).

[44] See judgment of 8 December 2011, *France Télécom* v *Commission* (C-81/10 P, EU:C:2011:811, paragraph 100 and the case-law cited).

73. I shall explain, in the following sub-section, the reasons why I consider that, in this instance, the conditions of access to the ISO standards referenced in Article 4(1) of Directive 2014/40, namely the fact that the EU institutions do not provide, for the *public in the broad sense*, conditions of access more generous than those already envisaged by ISO, are justified and do not disproportionately impede the possibility for the public to become aware of them.

2. The conditions of access to the content of the ISO standards at issue are not contrary to the principle of free access to the content of the law

(a) Justification

74. In this instance, access for a fee to the content of the ISO standards at issue is justified by the fact that those standards are drawn up by a private organisation (ISO) funded, in particular, from sales of the standards which it draws up. The smooth operation of that organisation is based on the possibility for it to receive a return on its investment, in view, in particular, of the fact that, owing to their complexity and their technical nature, those standards entail a significant use of ISO's human and material resources. In addition, since ISO claims copyright in the standards which it adopts, making them directly available free of charge would amount to negating the existence of such copyright.

75. It is also important, for the members of ISO (that is to say, for the national standardisation bodies), to be able to sell those standards, since they keep a significant part of the profits made on those sales. [45]

76. In the light of those factors, it is clear that making those standards available free of charge, which would be the result if the EU institutions were under an obligation to provide direct access to them by the public, would have the consequence of reducing [46] investment by those standardisation bodies in the research and development of standards.

77. In that regard, it is in my view undeniable that ISO standards occupy an important place in the standardisation landscape of the European Union, since, in particular, numerous European standards are drawn up on the basis of those standards [47] and since the European Committee for Standardisation (CEN) and ISO have entered into a technical cooperation agreement [48] under which ISO standards essentially take priority over European standards. [49] The use of international

[45] See, in that regard, Barrios Villarreal, A., *International Standardisation and the Agreement on Technical Barriers to Trade*, Cambridge University Press, Cambridge, 2018, pp. 25 and 45. According to that author, around 70% of the profits are thus kept by the national standardisation bodies that are members of ISO and only the remaining 30% are paid to ISO as fees.

[46] See, in that regard, Van Cleynenbreugel, P. and Demoulin, I., 'La normalisation européenne après l'arrêt *James Elliott Construction* du 27 October 2016 : la Cour de justice de l'Union européenne a-t-elle élargi ses compétences d'interprétation ?', *Revue de la Faculté de droit de l'Université de Liège*, vol. 2, 2017, p. 325.

[47] See, in particular, in that regard, Medzmariashvili, M., *Regulating European Standardisation through Law: The Interplay between Harmonised European Standards and EU Law*, thesis, Lund University, Lund, 2019, pp. 59-61. Other authors emphasise that standardisation and certification carried out under the aegis of ISO continually increase their potential in respect of the development of the globalisation of trade (see, in particular, Penneau, A., 'Standardisation et certification : les enjeux européens', *La Standardisation internationale privée : aspects juridiques*, Larcier, Brussels, 2014, p. 120).

[48] Agreement on technical cooperation between ISO and CEN (Vienna Agreement), signed in 1991, and available, in the electronic version, at the following internet address: https://isotc.iso.org/livelink/livelink/fetch/2000/2122/4230450/4230458/Agreement_on_Technical_Cooperation_between_ISO_and_CEN_%28Vienna_Agreement%29.pdf?nodeid=4230688&vernum=-2.

[49] See Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020' of 1 June 2011 (COM(2011) 311 final), available at the following internet address: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52011DC0311.

standards and, in particular, ISO standards is also required under the Agreement on Technical Barriers to Trade (TBT),[50] to which all members of the World Trade Organisation (WTO), including the European Union, are parties.

78. In addition is the fact that, more broadly, standardisation is perceived by the legislature as a strategic tool[51] that allows the legislation and policies of the European Union to be maintained.[52]

79. Although standards have traditionally been presented as a form of codification of knowledge by and for professionals,[53] they are essential for the development of the internal market. They are also recognised as being of increasing importance for international trade.[54] Beyond their considerable economic advantages (notably with regard to the competitiveness of undertakings[55] and the facilitating of trade[56]), they are ubiquitous in everyday life[57] and also in numerous areas of public policy.[58]

80. In the light of those considerations, I am of the opinion that the fact that the EU institutions do not make provision for more generous conditions of access to the content of ISO standards than those imposed by ISO (and by certain national standardisation bodies) is justified by the need for that organisation and those bodies to fund the drawing up of their standards and their activities, *on the one hand*, and by the importance of those standards for EU legislation, *on the other hand*. However, it remains for me to examine whether the burden which those fees entail for citizens constitutes a disproportionate interference with the possibility for them to become aware of the content of those standards.

[50] Agreement on Technical Barriers to Trade of the World Trade Organisation (WTO). That agreement is available at the following internet address: https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf. More specifically, Article 2.4 of that agreement provides: 'Where … relevant international standards exist …, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards … would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.' See also, in that regard, Mattli, W. and Büthe, T., 'Setting International Standards: Technological Rationality or Primacy of Power?', World Politics, vol. 56, No 1, 2003, p. 2.

[51] See recital 9 of Regulation No 1025/2012.

[52] See recital 25 of Regulation No 1025/2012. As regards, more specifically, international standards, I note that the Council has emphasised the need to promote the use of such standards within the European Union (see, in that regard, Council Resolution of 28 October 1999 on the role of standardisation in Europe (OJ 2000 C 141, p. 1)).

[53] See Brunet, A., 'Le paradoxe de la normalisation : une activité d'intérêt général mise en œuvre par les parties intéressées', *La normalisation en France et dans l'Union européenne : une activité privée au service de l'intérêt général* ?, Presses universitaires d'Aix-Marseille, Aix-en-Provence, 2012, p. 51.

[54] See recital 6 of Regulation No 1025/2012. See also Medzmariashvili, M., op. cit., p. 18.

[55] See recital 20 of Regulation No 1025/2012.

[56] According to the Commission, standards lead to cost reduction derived mainly from 'economies of scale, the possibility to anticipate technical requirements, the reduction of transaction costs and the possibility to access standardised components' (see Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020' of 1 June 2011, COM(2011) 311 final, p. 6).

[57] 'Standards are ubiquitous in our daily life. We encounter hundreds of standards as we go about our day … As such, it is difficult to imagine what the world would look like without standards; nothing would fit, and life would be fraught with danger' (Medzmariashvili, M., op. cit., p. 53).

[58] See recitals 19 and 22 of Regulation No 1025/2012, which state that standards can help in addressing 'major societal challenges' such as climate change, sustainable resource use, innovation, ageing population, integration of people with disabilities, consumer protection, workers' safety and working conditions, and also the well-being of citizens.

(b) The absence of a disproportionate impediment to the possibility for the public to have access to the content of the ISO standards at issue

81. In that regard, I observe, *first of all*, that any citizen of the EU may have access to the content of the standards drawn up by ISO. The only obstacle to that access is of a pecuniary nature, since the availability of that content provided by ISO is conditional on payment of the access fees which it imposes.

82. *Next*, the following elements, in particular, must in my view be emphasised.

83. *In the first place*, the burden placed on citizens must be weighed against the interest of the EU legislature in having an effective and functioning standardisation system which not only constitutes a flexible and transparent basis but is also financially viable. [59]

84. I would note, in that regard, that the fact that standards are drawn up by private entitles (like ISO) has advantages on which the EU legislature has decided, by making reference to those standards in regulations and directives, to base its legislative technique. Those advantages include their high degree of expertise, their ability to adapt rapidly to new technical developments and the flexibility of their procedures which permits, in particular, the participation of private actors. [60]

85. *In the second place*, that burden must also be weighed against the interest of professionals in the EU legislature not ceasing to use those standards because of the fees charged. On that point, the Commission has observed that, since it is common that the relevant market players are represented in the standardisation bodies, [61] it is also in their interest that the EU legislation should use the standards drawn up by those private bodies and not itself define those technical specifications.

86. The interest of professionals seems to me to be less important, however, in a case such as that at issue in the main proceedings, since the standards at issue relate to areas, more specifically those of health and consumer protection, where, as I emphasised in point 31 of this Opinion, citizens are much more likely to seek to enforce their rights. In that case, the EU institutions must, in my view, take very particular care to ensure that citizens have as wide an access as possible to the content of those standards.

87. *In the third place*, and in that regard, I would add that while it follows, in particular, from Article 6(1) of Regulation No 1025/2012 that the EU legislature did not envisage that access to standards (in the broad sense) should automatically be free of charge, the fact nonetheless remains that national standardisation bodies are required, under that provision, to encourage and facilitate the access of small and medium-sized enterprises (SMEs). [62] That provision thus already reflects, in itself, the wish to strike a fair balance between the desire to make such access as easy as possible and recognition of the fact that the charging of fees for those standards continues to be an essential component of the EU standardisation system.

[59] See recital 9 of Regulation No 1025/2012.

[60] See Medzmariashvili, M., op. cit., p. 21.

[61] According to the ISO website, its standards are 'the distilled wisdom of people with expertise in their subject matter … – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators' (source: https://www.iso.org/en/standards.html).

[62] In particular, by making available free of charge on their website abstracts of standards, applying special rates for the provision of standards or providing bundles of standards at a reduced rate (see Article 6(1)(e) and (f) of that regulation).

88. Even though those requirements were not expressly extended in such a way as to facilitate access by the public in the broad sense, it seems to me that, in practice, that may be the case.[63] More specifically, the fact that the content of the ISO standards referenced in Article 4(1) of Directive 2014/40 is accessible from ISO only on payment of a fee does not mean that it is impossible to become aware of that content, free of charge, by other means.

89. On that point, the Parliament and the VSK observe, correctly, that in this instance the Netherlands standardisation body allows the content of the ISO standards at issue to be consulted free of charge.[64] Other national standardisation bodies also provide that facility.[65]

90. *In the fourth and last place*, the sums payable by citizens of the EU[66] who wish to have access to the content of those standards and request access from ISO or national standardisation bodies do not seem to me, *in any event*, to be excessive.[67]

91. In the light of all of the foregoing considerations, I consider that the principle of free access to the content of the law does not require either that direct access, free of charge, to the ISO standards referenced in Article 4(1) of Directive 2014/40 be guaranteed *unconditionally* or that those standards be published in the Official Journal. The conditions of access to those standards do not disproportionately impede the possibility for the public to become aware of them and reflect a *fair balance* between, on the one hand, the requirements of that principle and, on the other, the various interests involved.

92. I would add, in conclusion, that the policy of *consultation free of charge* implemented by the Netherlands standardisation body (from which it follows that, on the assumption that they requested access, the applicants in the main proceedings were able to become aware, free of charge, of the content of those standards)[68] seems to me to be perfectly laudable,[69] a fortiori because it does not deprive the national standardisation bodies of the possibility of selling ISO standards to anyone wishing to download them or to obtain a copy. To my mind, that policy

63 That, moreover, is what national standardisation bodies are encouraged to do. On that point, I observe that in its Green paper on the development of European standardisation: Action for faster technological integration in Europe of 8 October 1990 (COM(90) 456 final, p. 51 (OJ 1991 C 20, p. 1)), the Commission emphasised that technical specifications included in standards should, *as a matter of principle*, be publicly available.

64 That body is the Nederlands Normalisatie Instituut (NEN). It should be noted that, as the Parliament moreover correctly points out, the ISO standards at issue were transposed into NEN-ISO standards (namely, more specifically, standards NEN-ISO 4387, 10315, 8454 and 8243) and can be consulted *directly* and *free of charge* at NEN's headquarters. It is apparent from that body's website (available at the following address: https://www.nen.nl/en/contact-en) that, 'if you do not want to purchase a standard, but just want to examine a specific standard, you can do so at NEN in Delft. You can examine all the standards there, but you cannot store them or copy any contents of the standards'.

65 In its observations, the VSK emphasises, by way of example, that the ISO standards at issue are available free of charge, by appointment, at the German and Irish standardisation bodies (the Deutsches Institut für Normung (DIN) and the National Standards Authority of Ireland (NSAI), respectively).

66 According to ISO's website, the price lists are as follows: 118 Swiss francs (CHF) for ISO standard 4387 and CHF 58 for ISO standards 10315, 8454 and 8243.

67 I do not rule out the possibility that in other cases the prices of standards may, especially where a significant number must be added together, constitute an obstacle for actors in civil society (see, in that regard, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020', COM(2011) 311 final).

68 As I stated in point 72 of this Opinion, it is clear that the applicants in the main proceedings had access to that content (although it has not been specified, in the present proceedings, by what means).

69 As I understand it, that approach is based on the fact that, in order to compensate for that free access, the Netherlands Government pays a fee to the NEN, in order to ensure its financial *viability*. I would add that, so far as European standards, at least (that is to say, those adopted by European standardisation bodies), are concerned, the EU legislature has clearly stated that one of its objectives is to ensure *fair and transparent* access to European standards for *all* market players throughout the European Union, especially in cases where the use of standards enables compliance with relevant EU legislation (see recital 43 of Regulation No 1025/2012).

should be extended as much as possible, or indeed be encouraged by the EU legislature, by means of a formal decision, which would aim to supplement the guarantees put in place by Article 6(1) of Regulation No 1025/2012.

V. Conclusion

93. Having regard to all of the foregoing considerations, I propose that the Court answer the first question referred for a preliminary ruling by the rechtbank Rotterdam (District Court, Rotterdam, Netherlands) as follows:

The conditions of access to the ISO standards referenced in Article 4(1) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC do not infringe either the third subparagraph of Article 297 TFEU or the underlying principle of free access to the law.