decision

ROTTERDAM COURT[α]

Administrative law

case number: ROT 19/1249

decision of the chamber of 4 November 2022 in the case between

1. **the Youth Smoking Prevention Foundation** , Amsterdam;
2. **the Inspire2Live Foundation** , Amsterdam;
3. **Rode Kruis Hospital BV** , Beverwijk;
4. **the ClaudicationNet Foundation** , Eindhoven;
5. **the Dutch Pediatric Association** , Utrecht;
6. **the Dutch Association for Insurance Medicine** , Utrecht;
7. **Accare , Foundation for University and General Child and Adolescent Psychiatry North Netherlands** (Groningen), Assen;
8. **the Association of Practical General Practitioners** , Amsterdam;
9. **the Dutch Association of Physicians for Pulmonary Diseases and Tuberculosis** , 's-Hertogenbosch;
10. **the Dutch Federation of Cancer Patient Organizations** , Utrecht;
11. **the Dutch Association of Occupational and Industrial Medicine** , Utrecht;
12. **the Dutch Society for Cardiology** , Utrecht;
13. **the Dome of Physicians Society and Health** , Utrecht;
14. **the Royal Dutch Society for the Promotion of Dentistry** , Utrecht;
15. **the college of mayor and aldermen of Amsterdam** ,

hereinafter: plaintiffs,

and

the State Secretary for Health, Welfare and Sport , defendant,

while as third party participated
the Association of Dutch Cigarette and Chip Tobacco Manufacturers (VSK), Leidschendam.

Procedural sequence

A number of persons and authorities, including plaintiffs 1 to 14 and the municipality of Amsterdam, have requested the Netherlands Food and Consumer Product Safety Authority (NVWA) by letters dated 31 July 2018 and 2 August 2018 to ensure that filter cigarettes offered to consumers in the Netherlands , when used as intended, comply with the maximum emission levels for tar, nicotine and carbon monoxide set out in Article 3 of Directive 2014/40/EU (the Directive). In addition, the NVWA was requested to take enforcement action by removing filter cigarettes from the market that do not meet the maximum emission levels for tar, nicotine and carbon monoxide (order under administrative coercion).

[α] informal translation

The NVWA rejected the enforcement request of the Youth Smoking Prevention Foundation (the Foundation) by decision of 20 September 2018. With regard to the other legal entities and the Municipality of Amsterdam, the NVWA has considered that their enforcement request does not constitute an application within the meaning of Article 1:3, paragraph 3, of the General Administrative Law Act (Awb), because they have no direct interest in their request.

By decision of 31 January 2019 (the contested decision), the respondent declared the objection of plaintiffs 2 to 15 inadmissible and declared the objection of the Foundation unfounded.

The plaintiffs appealed against the contested decision.

VSK has requested to be classified as a third party. She was given the opportunity to submit an opinion, but declined to do so.

Defendant has filed a statement of defence.

After a hearing where all parties were represented on 11 November 2019 took place and after the Court closed the hearing, the Court reopened the investigation in order to refer questions to the Court of Justice of the European Union (the Court) for a preliminary ruling . The parties were given the opportunity to express their views on a draft of the questions.

By interlocutory judgment of 20 March 2020 (ECLI:NL:RBROT:2020:2382), the court referred questions to the Court of Justice for a preliminary ruling and suspended the case pending the answers to the preliminary questions.

The Court delivered its Judgment on the request for a preliminary ruling on 22 February 2022 (Case C-160/20, ECLI:EU:C:2022:101).

The parties were given the opportunity to respond in writing to the judgment of the Court, which they have done. The plaintiffs also requested a hearing.

The second hearing took place on 2 September 2022. A.H.J. van den Biesen, Esq., R. Giebels and Drs. P.C. Dekker appeared on behalf of the plaintiffs. E. Brandwijk, D.W. Klerx , I.C.M. Nijland, P. Rijswijk and G. de Kort appeared on behalf of the defendant . J.H.J.M. Sträter appeared on behalf of VSK.

Considerations

Introduction

1.1. The enforcement request is based on research by the National Institute for Public Health and the Environment (RIVM) dated 13 June 2018, from which it follows that when using the 'Canadian Intense' measurement method, all filter cigarettes sold in the Netherlands by far exceed the maximum emission levels laid down in Article 3, first paragraph, of the Directive for tar, nicotine and carbon monoxide. According to the plaintiffs, this measuring method must be used because, unlike the measuring method prescribed in Article 4, paragraph 1, of the Directive, it measures the emissions of filter

cigarettes during intended use. In addition, the plaintiffs point out that the tobacco manufacturers make small holes in the filter of the cigarettes and that clean air is drawn through the filter (so-called filter ventilation), resulting in dilution of the levels of tar, nicotine and carbon monoxide. However, when used as intended, those holes are largely closed off by the smoker's fingers and lips so that they ingest levels of tar, nicotine and carbon monoxide that are significantly higher than the maximum emission levels set out in Article 3 of the Directive. The measuring method prescribed in Article 4 of the Directive does not take filter ventilation into account and, according to the plaintiffs, therefore does not measure the levels released during intended use. According to the plaintiff, the filter cigarettes sold in the Netherlands are therefore even more harmful to health and even more addictive than smokers are allowed to assume on the basis of the Directive.

1.2. The NVWA rejected the Foundation's request because, in its opinion, Article 4 of the Directive leaves no room for using a measurement method other than that prescribed therein and the filter cigarettes sold in the Netherlands when using that measurement method comply with the maximum emission levels of Article 3 of the Directive.

1.3. On appeal, questions have been raised about the interpretation and validity of Article 4 of the Directive. For that reason, the District Court has referred questions to the Court of Justice for a preliminary ruling, after which the Court of Justice has delivered itsjudgment in which the Court has answered most of the questions. Before the court arrives at the question of what consequences the court should attach to this, the court will first have to deal with a few preliminary questions.

Admissibility of the objections

2. In its interim decision, the District Court has already ruled that the Foundation is an interested party within the meaning of Article 1:2, third paragraph, of the Awb, so that a substantive decision has been made on its objection to the NVWA's refusal to enforce. Because the Foundation is an interested party, it was considered in the interlocutory judgment that the question whether the objections of the other plaintiffs in the contested decision were rightly declared inadmissible, remains open in the context of the interlocutory judgment. Since, in any event, the court will have to assess the appeal. This consideration must be seen in the light of the subject-matter of that interim judgment which seeks to refer questions to the Court of Justice for a preliminary ruling. In its present, final judgment, the court will consider whether the other plaintiffs are admissible in their objection.

3.1. In the view of the District Court there is no application within the meaning of Article 1:3, paragraph 3, of the Awb for plaintiffs 2 to 14, because they have no direct interest as referred to in Article 1:2, third paragraph of the Awb. In view of their statutory objectives and actual activities, they do not also promote the general interest of public health involved in compliance with the aim and purport of Article 3, first paragraph, of the Directive and the national laws and regulations based thereon.
In this regard, the court considers that the Dutch Federation of Cancer Patient Organizations does defend the collective interests of its members and that the organizations of doctors or other (medical) specialists involved also defend the collective interests of its members or a general interest, such as the provision of (medical) care as part of their objectives, but that those interests do not coincide with compliance with the aim and purport of Article 3, first paragraph, of the Directive and the national laws and regulations based on it. That the foundations or associations concerned offer support to persons to stop smoking, warn

against the dangers of smoking, offer (medical or other) help to persons who are ill as a result of smoking or that their work is indirectly hindered by the consequences of smoking (on their target group) does not change this. Furthermore, the court considers that although the Inspire2Live Foundation has argued in objection that it is pressing for a ban on the sale of tobacco products in discussions with representatives of the people and MEPs, its articles of association do not (partly) aim to prevent smoking, but to promote the interests of cancer patients, so that she too has no direct interest in the enforcement request.

3.2. However, as considered above, there is a decision to reject the Foundation's request for enforcement. Because plaintiffs 2 to 14 have no direct interest in this, their objection to that decision was rightly declared inadmissible. The action brought by them is therefore unfounded.

4.1. Although it follows from the additional enforcement request of 2 August 2018 that the Municipality of Amsterdam has joined the group of legal entities on whose behalf the enforcement request is submitted, the College intended to object, while the hearing on 11 November 2019 also showed that the appeal has been lodged by the college and not the municipality. In the opinion of this Court, the college is not an interested party within the meaning of Article 1:2, second paragraph, of the General Administrative Law Act with regard to the decision of 20 September 2018. The circumstance that the City Council of Amsterdam approved the 2017-2020 Public Health Policy Document entitled “Connecting preventively: profit for Amsterdam and Amsterdammers” – which includes the theme of smoking and alcohol use – and that it follows from Article 2, first paragraph, of the Public Health Act that the college is responsible for the establishment and the promote continuity of and coherence within public health care and its coordination with curative health care and medical assistance in the event of accidents and disasters, does not mean that the general interest of public health involved in compliance with the purpose and purport of Article 3 , first paragraph, of the Directive and the national laws and regulations based on it form part of the trusted interests.

4.2. The statement of the college that in a traffic case it was assumed that mayors and aldermen of municipalities that experienced the consequences of a traffic measure were regarded as interested parties by the Minister of Infrastructure and Water Management, does not alter this. An interest is entrusted to an administrative body if a statutory regulation grants this administrative body a power to represent this interest, as follows from the decision of the Administrative Jurisdiction Division of the Council of State (the Division) of 15 July 2015 (ECLI:NL: stainless steel:2015:2230). The Amsterdam District Court ruled in a judgment of 24 October 2017 (ECLI:NL:RBAMS:2017:7826) that councils of mayors and aldermen who objected to a traffic decision of the council of another municipality were interested, because in view of Article 25 of the Decision administrative provisions on road traffic consultations had to take place. In that case, there was therefore a legal provision as referred to in the aforementioned decision.
On the other hand, it follows from the decision of the Division of 13 July 2005 (ECLI:NL:RVS:2005:AT9239) that the fact that tasks in the field of public health and the environment are generally assigned to the municipal council is insufficient to speak of interests entrusted to them within the meaning of art. 1:2, second paragraph, of the General Administrative Law Act insofar as it concerns the determination of higher values for noise pollution due to a railway for homes in the municipality concerned by the provincial executive. In view of this case law, Article 2(1) of the Public Health Act is insufficiently specific to serve as a legal basis to consider compliance with the purpose and purport of

Article 3(1) of the Directive and the national law based thereon as legal interests entrusted to the college.

4.3. The objections of the college, therefore, were rightly dismissed as inadmissible. The appeal of the college is therefore unfounded.

Defendant's authority

5. The application concerns the application of Article 14 of the Tobacco and Smoking Products Act (the Act) by 'the supervisors'. In view of Article 7.1 of the Tobacco and Smoking Products Regulation (the Regulation), these are 'the civil servants of the NVWA'. This means that 'the officials of the NVWA' have been granted the power to decide on the application and on an objection made against that decision. However, the designation 'the officials of the NVWA' is too indefinite to qualify as 'another person or body vested with any public authority' as referred to in Article 1:1, first paragraph, under b, of the Awb. The court therefore reads Article 14 of the Act, in conjunction with Article 7.1 of the Regulation, as meaning that the authority to decide on an application as made by the plaintiffs belongs to the NVWA. The NVWA is an agency of the Ministry of Agriculture, Nature and Food Quality (LNV), but the Minister and the State Secretary of LNV have no role in the Act. In view of this, the NVWA acts as an independent administrative body under Article 14 of the Act (cf. ECLI:NL:CBB:2021:179 and ECLI:NL:CBB:2018:491). Defendant therefore wrongly decided on the objection. However, this lack of decision-making on objections does not mean that an assessment of the content of the appeal cannot be made, as the District Court also considered in its interim decision. Because the NVWA employees announced at the hearing on 11 November 2019 that the NVWA would have reached a substantive similar decision on the objection, the court sees reason to override the lack of competence by applying Article 6:22 of the Awb, because it is plausible that the Foundation was disadvantaged as a result (cf. ECLI:NL:RVS:2017:2943).

Relevant legal rules

6.1. For a more exhaustive enumeration of the legal rules relevant to the dispute, the court refers to the appendix of its interim judgment of 20 March 2020. The court suffices here with the following.

6.2. According to Article 2(21) of the Directive, “emissions” means substances released when a tobacco product or related product is used as intended, such as substances found in smoke, or substances released when using smokeless tobacco products. Article 3(1) states that the emission levels of cigarettes placed on the market or produced in the Member States (“maximum emission levels”) may not exceed: (a) 10 mg of tar per cigarette; (b) 1 mg of nicotine per cigarette; (c) 10 mg of carbon monoxide per cigarette. Article 4(1) provides that the emissions of tar, nicotine and carbon monoxide from cigarettes are measured in accordance with ISO standard 4387 (tar), ISO standard 10315 (nicotine) and ISO standard 8454 (carbon monoxide) and that the correctness of the measurements for tar, nicotine and carbon monoxide is determined on the basis of ISO standard 8243. Article 4, second paragraph, provides that the measurements referred to in the first paragraph are verified by laboratories approved and supervised by the competent authorities of the Member States. These laboratories must not be owned or controlled directly or indirectly by the tobacco industry. Member States shall communicate to the Commission a list of the approved

laboratories, specifying the criteria used for their approval and the methods used for their supervision, and update it whenever there is any change. The Commission shall make these lists of approved laboratories publicly available. Having regard to Article 4(3), the Commission shall be empowered to adopt delegated acts to adapt the methods for measuring tar, nicotine and carbon monoxide emissions, if necessary, on the basis of scientific and technical developments or internationally agreed standards.

6.3. In view of Article 3 of the Act in conjunction with Article 2.1 of the Tobacco and Tobacco Products Decree (the Decree) and Article 2.1 of the Regulation, the maximum emission levels of a cigarette placed on the market or produced must comply with Article 3, paragraph 1, of the Directive and the following ISO-NEN standards are used exclusively for the measurement of tar, nicotine and carbon monoxide and for verification: NEN-ISO 4387:2000/A1:2008, NEN-ISO 10315:2013, NEN-ISO 8454:2007 /A1:2009 and NEN-ISO 8243:2013. It follows from Article 14 of the Act in conjunction with Articles 3 and 17a of the Act that the NVWA is authorized to impose an administrative enforcement order if cigarettes placed on the market do not comply with the established emission values or if manufacturers, importers and distributors of tobacco products have reason to believe that cigarettes intended to be placed on the market or that have already been placed on the market do not comply with the determined emission values and that they themselves have not taken the necessary measures and have failed to inform the defendant about this .

Questions for a preliminary ruling and answers by the Court

7. In its interlocutory ruling, the District Court referred the following questions to the Court of Justice for a preliminary ruling:

> "Question 1: Is shaping the measurement method of Article 4(1) of the Directive on the basis of ISO standards that are not freely accessible, in accordance with Article 297(1) TFEU (and Regulation (EU) No. . 216/2013) and the transparency principle that underlies it?
>
> Question 2: Are ISO standards 4387, 10315, 8454 and 8243 to which Article 4(1) of the Directive refers to be interpreted and applied in such a way that in the context of the interpretation and application of Article 4(1) of Directive the emissions of tar, nicotine and carbon monoxide should not only be measured (and verified) using the prescribed method, but that those emissions may or should also be measured (and verified) in a different way and with a different intensity?
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> Question 3a: Is Article 4(1) of the Directive inconsistent with the principles of the Directive and with Article 4(2) of the Directive and Article 5(3) of the WHO Framework Convention on Tobacco Control because the tobacco industry has a played a role in establishing the ISO standards referred to in Article 4(1) of the Directive?
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> Question 3b: Does Article 4(1) of the Directive conflict with the principles of the Directive, with Article 114(3) TFEU, with the purport of the WHO Framework Convention on Tobacco Control and with Articles 24 and 35 of the Charter because the method of measurement prescribed therein does not measure emissions from filter cigarettes under intended use, because that method does not take into account

the effect of ventilation holes in the filter which, when used, are largely closed by the lips and fingers of the smoker ?

Question 4a: Which alternative measurement method (and verification method) can or must be used if the Court:
- answer question 1 in the negative?
- question 2 answered in the affirmative?
- answer question 3a and/or question 3b in the affirmative?

Question 4b: If the Court is unable to answer question 4a: is there a situation as referred to in Article 24(3) of the Directive if no measuring method is temporarily available?"

8. In its judgment of 22 February 2022, in which the WHO Framework Convention on Tobacco Control was abbreviated to FCTC, the Court considered, inter alia:

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

[…]

32 Finally, it should be pointed out that Directive 2014/40 pursues a twofold objective of facilitating the smooth functioning of the internal market for tobacco and related products while taking as a base a high level of protection of human health, especially for young people (judgment of 22 November 2018, *Swedish Match*, C-151/17, EU:C:2018:938, paragraph 40). Without prejudice to the examination of Question 3(b), concerning, in essence, the validity of Article 4(1) of the directive having regard to the requirement – laid down in particular in Article 114(3) TFEU – for a high level of protection of human health, to have recourse only to the methods provided for by the ISO standards referred to in Article 4(1) of the directive in order to measure the level of tar, nicotine and carbon monoxide emissions from cigarettes is consonant with that objective of smooth functioning of the internal market since it ensures that access of cigarettes to the EU market and their manufacture within the European Union will not be prevented on account of the application of various methods of measuring the levels of those substances in the Member States.

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

[…]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[…]

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

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

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

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

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

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

[…]

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

68 As the studies and other documents referred to in paragraph 21 above all postdate 3 April 2014, the date on which Directive 2014/40 was adopted, they

cannot be taken into account for the purpose of assessing the validity of Article 4(1) of that directive.

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

Question 4(a)

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

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

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

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

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

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

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

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

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

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

9 . In the operative part of the judgment, the Court made the following declaration:

> "1. Article 4(1) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC is to be interpreted as providing that the maximum emission levels for tar, nicotine and carbon monoxide from cigarettes intended to be placed on the market or manufactured in the Member States, prescribed in Article 3(1) of that directive, must be measured in accordance with the measurement methods arising from ISO standards 4387, 10315, 8454 and 8243, to which Article 4(1) refers.
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> 2. Consideration of Question 1 has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to the principle of transparency, to Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*, and to Article 297(1) TFEU read in the light of the principle of legal certainty.
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> 3. Consideration of Question 3(a) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 5(3) of the World Health Organisation Framework Convention on Tobacco Control.
>
> 4. Consideration of Question 3(b) has disclosed no factor of such a kind as to affect the validity of Article 4(1) of Directive 2014/40 having regard to Article 114(3) TFEU, the World Health Organisation Framework Convention on Tobacco Control and Articles 24 and 35 of the Charter of Fundamental Rights of the European Union.
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> 5. Should Article 4(1) of Directive 2014/40 not be binding on individuals, the method used for the purpose of applying Article 3(1) of that directive must be appropriate, in the light of scientific and technical developments or internationally agreed standards, for measuring the levels of emissions released when a cigarette is consumed as intended, and must take as a base a high level of protection of human health, especially for young people, while the accuracy of the measurements obtained by means of that method must be verified by laboratories approved and monitored by the competent authorities of the Member States as referred to in Article 4(2) of that directive."

10. The Court has declared question 4b inadmissible because it is not apparent from the documents in the possession of the Court that the dispute in the main proceedings, even if only in part, concerns the option available to the State Secretary under Article 17a(4) of the the Act, in which Article 24, third paragraph, of Directive 2014/40 has been transposed.

Further Foundation views

11.1. In summary, the Foundation has taken the following positions.

11.2. The common thread in the judgment of the Court is formed by the twofold objective of Directive 2014/40 (see, for example, point 32). On the one hand, it concerns harmonization of regulations with a view to improving the functioning of the internal market, embodied in particular by Article 4 of the Directive (methods of measurement) and, on the other hand, it concerns the pursuit of a high level of protection of public health, in particular for young people, especially embodied by Article 3 (maximum emission levels). The preliminary enforcement request in this case focused on enforcement of precisely those emission levels. On the one hand, the Court finds that Article 4 of the Directive contains clear obligations for entrepreneurs, while on the other hand the Court finds that the ISO measurement methods are not binding on private individuals because they have not been adequately disclosed. In addition, the Court ruled in paragraph 78 that any method of measuring the maximum emission levels laid down in Article 3(1) of that Directive must effectively meet the purpose of Directive 2014/40, as set out in Article 1 thereof, which aims to in ensure a high level of human health protection, especially for young people.

11.3. According to the Foundation, it follows from paragraphs 70 to 79 and section 5 of the declaratory judgment that it is for the referring court to determine, in order to resolve the dispute before it, whether the methods actually used for measuring emission levels of those substances are in accordance with the Directive, without taking into account Article 4(1) thereof. This ruling is not only binding for the three parties to these proceedings, but also for the entire European Union, according to the Foundation. According to the Foundation, the following step-by-step plan for the court follows from the aforementioned points of the judgment. The court must successively determine that:

- Article 4, first paragraph, of the Directive cannot be invoked against private individuals in the Netherlands either and that Article 2.1, first paragraph of the Regulation must be disapplied, except for the companies referred to by the Court;
- a measurement method – exclusive – for the purpose of enforcing Article 3 (read: of the Directive and the Act) must be used;
- it involves measuring emission levels that are released during intended use of a cigarette;
- the measurement method must be suitable for this purpose according to scientific and technical developments or according to internationally agreed standards;
- a high level of human health protection, especially for young people, should be taken as the basis when measuring;
- the correctness of the measurements obtained with this method must be verified in a manner that is equal to the verification method currently used by RIVM.

11.4. The Foundation recalls that the reason for these proceedings is that RIVM established that cigarettes for sale contain a considerably higher amount of tar, nicotine and carbon monoxide than the maximum permitted under the applicable legal provisions. RIVM also showed how the observed exceedance of the emission levels could arise and explained that during production the tobacco industry makes small holes, in patterns that sometimes vary per brand, in the filter and/or paper of the cigarette, which holes attract clean air leading to a significant dilution of the measured emissions. With this research by the RIVM, the "rigged cigarette" became a well-known phenomenon, according to the Foundation. The result is that smokers and second-hand smokers ingest considerably more tar, nicotine and

carbon monoxide than might be expected on the basis of Article 3, first paragraph, of the Directive. This completely disregards and violates the requirement of a “high level of protection of human health, especially for young people” laid down in European regulations. In its research, RIVM used “Canadian Intense”, a measurement method suitable for measuring the emission levels in cigarettes. A characteristic of this method is that, when measuring, the holes are closed/taped and compared with the method referred to in Article 4, first paragraph, of the Directive, in the simulation of inhalation, a higher pulling frequency is used and also a more intense way of inhaling.

11.5. There are now three measurement methods, all three of which have essentially “codified” the Canadian Intense method: the Canadian Intense, the WHO TobLabNet SOP 01 and the NEN-ISO 20778 standard. All three were already discussed in a document submitted by the Foundation on October 18, 2019; the TobLabNet standard was included in its entirety as Annex 10. All three methods provide for the taping of the holes and prescribe the same inhalation regimen as the Canadian Intense, thus providing a significantly better simulation of the “intended use” of Article 2(21) of the Directive.

11.6. In any event, the Canadian Intense is the result of scientific and technical developments and is therefore appropriate within the meaning of the Court's judgment. Canadian Intense cannot yet be classified as an internationally agreed standard. It is a method that is still cited in many scientific publications as the method that approximates smoking behavior better than the ISO standard from the Directive and that eventually also led to the TobLabNet SOP 01. SOP 01 has been over a number of years scientifically and technically developed – without the involvement of the tobacco industry – and was in 2012 validated according to the international standard procedure established by the approximately 40 scientific, international, laboratories that form the backbone of the Top-laboratory network of the World Health Organization (WHO) . Not long after it became known that TobLabNet was working on its own Canadian Intense standard, the International Standardization Organization (ISO) decided to also develop its “own” Canadian Intense standard, which standard was adopted in 2018 after validation according to the international standard procedure and after going through the ISO decision-making process. This ISO standard was given the number NEN-ISO 20778 and, like all ISO standards, is considered an international standard. This ISO standard is roughly an equivalent of the WHO standard and therefore also counts as a codification of the Canadian Intense method. All EU countries are represented within ISO, which has only one representation per country. NEN is the Dutch representative within ISO.

11.7. The Foundation is of the opinion that the TobLab Net standard fully complies with the conditions set by the Court of Justice for the quality of the measurement method. This standard is public, may be downloaded free of charge and – not unimportantly – was created without interference from the tobacco industry. From a technical point of view, the third standard, NEN-ISO 20778, also meets the conditions set by the Court for the quality of the measurement method; also with this method the filter holes are covered and the inhalation regimen is the same as the Canadian Intense regime. However, this standard also entails all the problems that the ISO standards included in Article 4(1) of the Directive suffer from: this standard is heavily protected by copyright, so it is not publicly available but only available for a fee. The standards once purchased may not be shared with third parties in any way. In addition, this standard contains references to yet other ISO standards that – for effective use – should also be purchased. The Foundation would thus like to opt for the

TobLabNet standard of the WHO. The Foundation also points out that the defendant has indicated that - if he had a choice - he would also prefer the TobLabNet standard.

Further views of the defendant

12.1. In summary, the defendant has taken the following positions.

12.2. Partly in view of the answer given by the Court to the second question, the defendant is of the opinion that Article 4(1) of the Directive prescribes mandatory how the emission levels of tar, nicotine and carbon monoxide from cigarettes must be determined. Article 4(1) of the Tobacco Products Directive does not provide for the option to determine the emission levels of tar, nicotine and carbon monoxide from cigarettes in any other way.

12.3. Following the Court's answer to the first question, the defendant is of the opinion that Article 4(1) of the Directive is known because it was published in the Official Journal of the European Union, but that this does not apply to the ISO standards to which Article 4, first paragraph, of the Directive refers. Since the ISO standards are nevertheless known to companies, because they have access to the official, authentic version of the ISO standards for a reasonable fee, the ISO standards are binding on companies. In doing so, the Court must have had in mind all types of enterprises that market or manufacture cigarettes (tobacco product manufacturers), because Article 4(1) of the Directive, read in conjunction with Article 3(1) of the Directive, imposes an obligation to tobacco product manufacturers. According to the defendant, tobacco product manufacturers can thus be expected to inform themselves or to obtain information about the obligations incumbent on them.

12.4. The Directive is aimed at harmonizing the rules surrounding the marketing of tobacco products and related products, in order to maintain the internal market on the one hand and to protect consumers and second-hand smokers on the other. As long as private individuals do not place tobacco products or related products on the market, they do not fall within the scope of the prescribed measurement methods in the Directive. Whether or not the ISO standards are binding on private individuals in general is therefore not relevant, according to the defendant.

12.5. In line with the Court's answer to the third question, under a, the defendant is of the opinion that the fact that the tobacco industry played a role in the establishment of the standards referred to in Article 4, first paragraph, of the Directive does not affect the validity of Article 4, first paragraph, of the Directive. There is no conflict between the first and second paragraph of Article 4 of the Directive, because these provisions regulate different matters. The first paragraph establishes the method of measurement. The second paragraph imposes a requirement on the laboratories that verify the results on the basis of the prescribed measuring method. The requirement that the laboratories must be independent of the tobacco industry is precisely a guarantee that the measurements/verifications – according to the measuring method determined separately in the first paragraph – are carried out objectively and independently. As the Court stated, Article 5(3) of the WHO Framework Convention on Tobacco Control aims to prevent the parties to this Framework Convention from allowing their tobacco control policies to be influenced by the interests of this industry. The defendant considers it undesirable that the tobacco industry played a role in the establishment of the ISO standards, but according to the defendant this does not mean that there is therefore a violation of Article 5, third paragraph, of the WHO Framework Convention on Tobacco Control.

12.6. Partly in view of the Court's answer to the third question, under b, the respondent is of the opinion that scientific insights from after the date of adoption of the Directive cannot be taken into account when assessing the validity of Article 4, first paragraph, of the Directive. In view of the eighth recital in the preamble, the Directive was drawn up with a focus on the pursuit of a high level of protection of public health, with particular emphasis on the position of young people, based on current scientific insights. Furthermore, in the evaluation and revision, as well as in the context of Article 4, paragraph 3, of the Directive, the Committee always bases itself on current scientific insights and makes a decision based on this. Therefore, according to the defendant, there is no reason to conclude that in determining the prescribed measuring method of Article 4, first paragraph, of the Directive, a violation occurred of the principles of the Directive, Article 114, third paragraph, of the Treaty on the Functioning of the European Union (TFEU), the WHO Framework Convention on Tobacco Control and/or Articles 24 and 35 of the Charter.

12.7. In view of the Court's answer to the fourth question, under a, the respondent is of the opinion that an alternative way of measuring the emission levels is only relevant if the measurement method of Article 4, first paragraph, of the Directive would not be binding on private individuals. According to the defendant, the question whether and, if so, which alternative measurement method is permitted for private individuals, since the Directive does is not meant to regulate private individuals with regard to the prescribed emission standards and measurement methods. Respondent notes in this regard that a private individual can submit an enforcement request directed against a company (as is also the case in the present case), but this does not mean that the standard is binding on that private person by rejecting the enforcement request. Because the measuring method of Article 4, first paragraph, of the Directive is, indeed, binding on companies, a request for enforcement action against a company must be assessed on the basis of the measuring method prescribed in Article 4, first paragraph, of the Directive. According to the respondent, an alternative measurement method for companies is not at issue, because this is not permitted in view of the mandatory measurement methods prescribed in Article 4(1) of the Directive.

12.8. Finally, the defendant considers that the Court of Justice was right to declare question 4 under b inadmissible. The situation that a ministerial regulation determined categories of tobacco products can be banned on grounds related to the protection of public health, in the situation where (temporarily) no measurement method would be available does not occur.

Further views of VSK

13.1. In summary, VSK has taken the following positions.

13.2. According to VSK, the Court has failed to clarify the relationship between its answers to the first and fourth questions, which appear to be ambiguous in some respects. According to VSK, however, in view of the judgment of 22 February 2022, there is no doubt that the ISO standards included in Article 4(1) of the Directive are binding on manufacturers, importers and distributors of tobacco products, because they have access to the official and authentic version of the ISO standards. In addition, the Dutch authorities that would enforce Article 2.1 of the Regulation (implementing Article 3(1) of the Directive), as well as the RIVM laboratories that would have to carry out any emission tests, are also

aware of the ISO standards. The clear conclusion, according to VSK, is therefore that cigarettes placed on the Dutch market that comply with the emission levels of Article 2.1 of the Decree (which implements Article 3(1) of the Directive), measured according to the standards of Article 2.1 of the Regulation (the NEN-ISO standards) as well as Article 4, first paragraph, of the Directive (the ISO standards), comply with Dutch law and the Directive. As such, these standards must be enforced by the NVWA and no other standards can be enforced by the NVWA. Another result would mean that the administrative court takes on the role of legislator and substitutes its judgment for that of the European Parliament. The Dutch court does not have this power (not even in the light of Article 4(3) of the Directive).

13.3. Whether the ISO standards referred to in Article 4(1) of the Directive are also binding on "individuals in general" (in English: " the public generally "), and what the legal consequences would be of a finding that this would not be the case, is according to VSK essentially not relevant to the issues at stake in the present dispute, as it cannot change the fact that manufacturers, importers and distributors are bound by, and that the NVWA only can monitor compliance with the NEN-ISO standards referred to in the Regulation (which correspond to the standards in the Directive). The NVWA enforces the NEN-ISO standards with regard to tobacco manufacturers, importers and distributors. The NVWA does not consider these standards to be binding on the Foundation or other private individuals who do not market tobacco products. The concept that ISO standards are "binding on" only applies in cases where a public authority enforces an administrative or criminal obligation against a private individual.

13.4. According to VSK, the fact that the NVWA refers to the ISO standards in its rejection of the Foundation's enforcement request does not mean that the NVWA considers the ISO standards to be binding on others. This view is supported by the case law cited by the Court in the judgment of 22 February 2022. In Heinrich (ECLI:EU:C:2009:140) and Skoma Lux (ECLI:EU:C:2007:773) and in the cases cited therein, the authorities sought to enforce an obligation (usually a prohibition) on individuals arising from an unpublished rule. It goes without saying that in the case of criminal or administrative enforcement, an obligation cannot be enforced against someone who was not (and could not be) aware of the obligation. In this regard, the Court has repeatedly stressed the importance of legal certainty where individuals or undertakings would otherwise be adversely affected (e.g. in the cases Förster, ECLI:EU:C:2008:630, paragraph 67 and ASM Brescia, ECLI:EU:C :2008:416 , item 69). In the present case there is no question of (potential or actual) criminal or administrative enforcement against the plaintiffs. Article 4, first paragraph, of the Directive does not impose any obligations on the Foundation or other parties who have lodged an appeal. The Foundation seeks to derive "a right" from its alleged lack of knowledge of the content of the ISO standards, and then argue that they should have the right to compel national authorities to impose obligations on other economic operators as a result.

13.5. In this context, when the Court has held that it is necessary for individuals to be "unambiguously able to know their rights and obligations and to make arrangements accordingly", the reference to "rights" refers to rights that are intertwined with their obligations. This is illustrated, for example, by the judgment in Euro Park Service (ECLI:EU:C:2017:177), where the applicants could not benefit from a tax exemption because they did not meet certain undisclosed conditions. When fined by the French authorities for paying too little tax due to non-compliance with the exemption, the Court considered that the rules governing the "right" to the tax exemption should be accessible, since private individuals (in accordance with the principle of legal certainty) should be able

to unambiguously identify their rights and obligations and take action accordingly. The Euro Park Service case shows how transparency and accessibility of “rights” are important for the principle of legal certainty. However, the present case is clearly different. There is no question of administrative or criminal enforcement against the plaintiffs.

13.6. It is striking, according to VSK, that the solution desired by the Foundation, namely that another emission method would replace the ISO standards included in Article 4(1) of the Directive, would in any case lead to the same “defect”. The content of any measurement method that would be used instead of the ISO methods referred to in Article 2.1 of the Regulation and Article 4(1) of the Directive has not been published in the Official Journal either. Thus, even that method might not be invoked against other individuals, let alone “individuals in general”. Moreover, if other methods were to replace the methods referred to in Article 4(1) of the Directive, this would infringe the rights of economic operators in the light of the principle of legal certainty.

13.7. Apart from the accusation that Article 3(1) of the Directive is not complied with by manufacturers, importers and distributors of tobacco products, it must be assumed that the basis for this assessment is not the Directive, but Dutch legislation and regulations. Where the Court's ruling relates to the enforceability of ISO standards as referred to in Article 4(1) of the Directive, the NVWA, like your Court, is obliged to apply Article 2.1 of the Regulation, which only refers to NEN-ISO standards. NEN-ISO standards are the versions of the ISO standards as they apply in the Netherlands and are sufficiently accessible without any hindrance at the Royal Netherlands Standardization Institute Foundation (NNI) in Delft. In this regard, the Dutch supreme courts have previously ruled that the NEN-ISO standards are sufficiently accessible to both companies and private individuals to be enforceable against them (ECLI:NL:HR:2012:BW0393; ECLI:NL:RVS:2011 :BP2750 and ECLI:NL:CBB:2012:BW2472). So even though the Court has ruled that the ISO standards as referred to in Article 4(1) of the Directive are too inaccessible to be binding on private individuals because of the lack of publication in the Official Journal, the NEN-ISO standards referred to in the Regulations – which the NVWA is obliged to enforce – are invoked against private individuals in general, because those standards are sufficiently accessible to the NNI without any obstacles. The distinction between the ISO standards and the NEN ISO standards is all the more relevant now that the Court's answers to question 4(a) in point 79 take the following as the starting point: “in the event that Article 4(1) of Directive 2014/ 40 could not be relied on against individuals'. The NVWA is obliged to apply Article 2.1 of the Regulation, which does not refer to the ISO standards included in Article 4, paragraph 1, of the Directive, but only to NEN-ISO standards that conform to the highest Dutch standards. courts are sufficiently accessible and therefore private individuals can be invoked as binding, according to VSK.

13.8. The fact that a directive requires implementation by the Member States means that, in principle, private individuals must invoke the national implementing legislation in proceedings before the national court, and not the directive, according to VSK. In that regard, it should be noted that the Directive has been correctly implemented in Dutch national law. Even if the Netherlands has incorrectly transposed the Directive into national law, this does not mean that the relevant national legislation (the Decree and the Regulation) can be disapplied by the court. That would only be possible if the State (or in this case the NVWA) invoked this legislation to create obligations for plaintiffs (a situation that would require direct vertical effect of a directive). Indeed, according to settled case-law, individuals must be able to rely on a directive against the State (or against organizations or bodies which were under the authority or control of the State or which had special powers

beyond those arising from the rules governing relations between private individuals) because "it must be prevented that the State benefits from its failure to observe Community law" (Foster v British Gas, ECLI:EU:C:1990:313, paras 17-18). This is not the case here: in the present case, the Foundation wants the State to create obligations for third parties and the Foundation accuses the NVWA of not enforcing these (alleged) obligations.

13.9. However, meeting plaintiffs' enforcement request and following their interpretation of the Directive would lead to horizontal direct effect of the Directive (with regard to manufacturers, importers and distributors of tobacco and related products). According to VSK, settled case-law clearly states that this is not possible (Marshall, ECLI:EU:C:1986:84, paragraph 48):

> "48 With regard to the argument that a directive may not be relied upon against an individual, it must be emphasized that according to Article 189 of the EEC Treaty the binding nature of a directive, which constitutes the basis for the possibility of relying on the directive before a national court, exists only in relation to 'each Member State to which it is addressed'. It follows that a directive may not of itself impose obligations on an individual and that a provision of a directive may not be relied upon as such against such a person. It must therefore be examined whether, in this case, the respondent must be regarded as having acted as an individual."

If the national legislation leaves room for interpretation, it may be possible to find a way to interpret the national legislation "in conformity" with the Directive. That is not possible in this case, because national legislation has correctly transposed the Directive. Moreover, this interpretation is in any event limited by legal certainty and the principle that a directive does not create (new) obligations for third parties (Mat-leasing, ECLI:EU:C:1990:395, point 6).
13.10. Even if the Directive could be directly be binding and if the ISO standards are to be understood as being binding on the Foundation by the NVWA, VSK argues that the ISO standards could in fact be invoked against the Foundation because it is not covered by the category "individuals in general" in respect of which the Court has concluded that the ISO standards referred to in Article 4(1) of the Directive can only be binding if their content has been published in the Official Journal. The use of the words "in general" necessarily implies that there are certain situations, such as in the present case, where an individual (who is not strictly a company) is fully aware of the ISO standards. This is underlined by the fact that point five of the declaratory judgment reads: "In the event that Article 4(1) of Directive 2014/40 cannot be enforced against individuals (…)". In other words, the fact that the ISO standard has not been published in the Official Journal does not automatically mean that it cannot be enforced against any individual. In the present situation, the Foundation is aware of the applicable ISO standards in question. According to VSK, it therefore does not fall under the category of "private individuals in general".

13.11. VSK further takes the position that the maximum TNCO emission levels are intrinsically linked to the measurement methods. In its view, the ISO standards referred to in Article 4(1) of the Directive are intrinsically linked to the maximum emission levels agreed by the EU Member States, as included in Article 3(1) of that Directive. This is also apparent from the following. In its written observations of 27 August 2020 in the preliminary ruling procedure before the Court, the Commission indicated that the emission levels laid down in Article 3(1) of the Directive are based on the assumption that the filter cigarettes, in accordance with the conditions set out in Article 4, first paragraph, mentioned 1SO standards, using the ISO 3008 smoke machine mentioned therein, would be measured. If the EU legislator had opted for a different measuring method, the Commission believes that it

cannot be ruled out that the maximum emission levels from Article 3(1) would have been different. The European Parliament also indicated in its written observations of 28 August 2020 that it is the producers and importers who should ensure that the cigarettes they produce or place on the market in the Union comply with the maximum emission levels resulting from the combined application of Articles 3 and 4 of the Directive. Respondent also stated in parliamentary questions that the maximum value for tar content and the measurement method are linked and that the maximum tar content is therefore not exceeded with the prescribed method (Parliamentary Papers II 2017/18, Appendix 1726). Finally, the NVWA has also considered that the maximum emission levels and the measurement methods for enforcement are linked and cannot be viewed separately. The application of a different measurement method by a court of one EU Member State would clearly harm the proper functioning of the EU internal market for tobacco and related products. In theory, this could lead to 27 different measurement methods, completely nullifying the harmonization achieved by the Directive. The internal market objective follows clearly from recitals 5, 16 and 21 in the preamble to the Directive.

13.12. In that regard, VSK notes that EU legislators are considering a new Tobacco and Related Products Directive, which is expected to be completed and enter into force around 2025. Accordingly, the Commission will review scientific developments and assess whether they require a change to the current measurement methodology and the mechanism of maximum emission levels. This is precisely the forum where any discussions about changes to measurement methods or maximum emission levels should take place. In view of the foregoing, according to VSK , it is not necessary or useful to assess, without taking into account Article 4(1) of the Directive, whether the method actually used to measure the emission levels is in accordance with that directive. According to VSK, the ISO standards also comply with the intended use of cigarettes.

The verdict of the court

14.1 The district court rules as follows.

14.2. The Court of Justice is of the opinion that the ISO standards are accessible to companies, but cannot be "invoked" against "individuals in general" if they themselves have not been published in the Official Journal of the European Union. The concepts of "individuals in general" and "invoking against" are decisive for the interpretation to be given to the answer to the questions referred by the Court. However, the Court has not explained those concepts.
The court will therefore consider below the question of what the Court of Appeal must have meant by these two concepts.

14.3. In the opinion of the court, the term “individuals in general” should be understood as all private individuals with the exception of companies. The Court has previously held that unpublished or incorrectly published EU legislation cannot be invoked against individuals (Skoma Lux, ECLI:EU:C:2007:773, paragraph 51; Heinrich, ECLI:EU:C:2009:140 , point 63 and Polska Telefonia Cyfrowa , EU:C:2011:294, paragraph 30). In the cases Skoma Lux and Polska Telefonia Cyfrowa was a company and in the Heinrich case a citizen who contested a decision of the government. In the present judgment, however, the Court for the first time makes a sharp distinction between companies on the one hand and private individuals in general on the other. According to the Court, the ISO standards mentioned in the Directive but not published can be relied on

against the first category (point 33 in conjunction with point 52) , but explicitly not against the second category (see points 48 and 73). In the Court's answer to question 4a (part 5), however, some room for nuance is given by the use of the word “in case”. According to the court, in the light of the further considerations regarding question 4a of the court, this reluctance can only be understood because of the term “individuals” included in that answer and not “individuals in general”. In particular, it is important that the Court finds in paragraph 73 “that Article 4(1) of Directive 2014/40 cannot be relied on against individuals in general in so far as that provision refers to ISO standards that have not been published in the Official Journal of the European Union.” Since – as stated – companies are deemed to have access to the ISO standards, 'individuals in general' should therefore be understood to mean private individuals who are not companies.

14.4. In the opinion of the court, the Foundation falls under the category of “private individuals in general” because it is neither a company nor part of the government. The fact that as an interest group, in the context of its activities, it does have knowledge of the ISO standards referred to in Article 4, paragraph 1, of the Directive, does not mean that the Foundation should be equated with a company. After all, the people whose interests it represents, young people (smokers, second-hand smokers and potential smokers), have no knowledge of these ISO standards. If VSK's argument were to be followed on this point, it would always have to be assessed on a case-by-case basis whether Article 4(1) of the Directive can be invoked against the private individual concerned who is not a company. The ISO standards could then be invoked against the Foundation because it has taken cognizance of those standards in the context of these proceedings, so that conducting the procedure would immediately be pointless because the Foundation would not be able to achieve what it intended. This shows that this line of reasoning of VSK is untenable. Moreover , that line is not in line with the strict separation that the Court establishes between undertakings (including manufacturers, importers and distributors of tobacco products) and private individuals in general. According to the Court, the mere use by the Court of the word combination "individuals" and "in the event" in point 79 and part 5 of the operative part does not entail that a third category of private persons must be distinguished, in which case it would have to be assessed on a case-by-case basis whether Article 4, first paragraph, of the Directive can be invoked against them . If the Court did have a third category of private individuals in mind, it would have been reasonable to have clarified this in the judgment.

14.5. Superfluously, the court points out in this regard that the italicized headline of the press release no. 29/22 accompanying the judgment of the Court states:

> “However, since that method has not been published in the *Official Journal of the European Union,* it is not binding on the public generally, for example on associations for the protection of consumers’ health”

14.6. According to the defendant and VSK, there are only objections to "private persons in general" if they market filter cigarettes themselves. According to VSK, “objection” corresponds only to obligations. This limited interpretation would lead to the absurd conclusion that the Court devoted a large part of its considerations to a non-existent situation: after all, unlike companies, “individuals in general” do not market filter cigarettes. Only manufacturers, importers and distributors of tobacco products are standard addressees of the emission standards referred to in Article 3(1) of the Directive. For that reason alone, it must therefore be assumed that the Court envisaged that “invoking against” entails that

"individuals in general" are deprived of their right to protection against too high emissions at intended use.

14.7. But also apart from that, the court considers the interpretation advocated by the defendant and VSK, in the context of the judgment as a whole, too limited. After all, the Court points out in paragraph 41 that individuals must be able to know unambiguously their "rights" and obligations. Since individuals in general are not able to take cognizance of the ISO standards, they cannot unambiguously become aware of the rights that arise for them from the obligations that Article 3, first paragraph, of the Directive imposes on companies in connection with the ISO standards. Therefore, Article 4(1) of the Directive cannot be invoked against individuals in general to the extent that this provision refers to ISO standards that have not been published in the *Official Journal of the European Union* (point 73). The Court then leaves it to the court to assess whether the methods actually used for measuring the emission levels of tar, nicotine and carbon monoxide are in accordance with the Directive, without taking into account Article 4(1) thereof (paragraph 74). These considerations of the Court would be meaningless if the limited interpretation advocated by the defendant and VSK were to be followed. It is apparent from paragraph 71 of the judgment that the Court is well aware of the dispute in which the questions referred for a preliminary ruling have arisen. It was clear to the Court that the Foundation does not market filter cigarettes itself, but rather aims to have the filter cigarettes currently sold in the Netherlands withdrawn from the market. In view of this, "invoking" Article 4, paragraph 1, insofar as this provision refers to ISO standards, must be understood here as denying, on account of those ISO standards, an appeal to compliance with the provisions of Article 3, paragraph 1, of the Directive-based emission limit values that have a mandatory character for companies but create rights for private individuals in general. In the opinion of the district court there is only a gradual difference between rights and obligations in the case law of the Court and invoking against can be seen in the light of withholding a right as well as assuming an obligation. In this regard, the court points out that individuals (companies and private individuals in general) may have recourse to EU law that has direct effect if they are deprived of something by the government to which they were entitled if EU law had been correctly transposed or if they be obliged to do something towards the government that they would not have been obliged to do if EU law had been correctly transposed (cf. Van Gend en Loos, ECLI:EU:C:1963:1 and Foster/British Gas, ECLI:EU:C:1990:313, item 16).

14.8. It cannot be understood that in these proceedings there is no invoking in a comparable sense, on the understanding that this is a situation in which a provision of the directive can and cannot be relied on against certain individuals at the same time. For the tobacco industry, after all, the measurement standards as referred to in Article 4, first paragraph, of the Directive, as transposed into national law, are adhered to, while they may not be invoked against private individuals in general. In the contested decision, Article 4(1) of the Directive, at least its national counterpart, must be applied in the measurement of emissions and their verification. However, this objection is not allowed as long as the ISO standards have not been published in the Official Journal. With this objection, the Foundation is deprived of a right that consists of a public interest that it pursues, namely that filter cigarettes, with a view to the public health of young people, when used as intended respect the emission limit values specified in Article 3, first paragraph, of the Directive.

14.9. The court realizes that this interpretation has negative consequences for the legal certainty that the tobacco industry believed it could derive from Article 4(1) of the Directive. However, this is the consequence of a situation such as the present in which individuals (individuals in general) invoke the application of EU law against the government

which must apply/enforce this law against other individuals (companies). The present situation, which is unique in that the measurement and verification methods included in ISO standards and referred to in a directive may be used against a certain group of private persons and not against another group of private persons, and where an interest group representing the latter group, requests the national enforcement authority for enforcement, resembles the doctrine of reverse vertical direct effect (cf. Wells, ECLI:EU:C:2004:12, point 57 and ECLI:NL:RVS:2007:BB9488, point 2.8.8) . Also in such a case, the mere negative consequences for the rights of third parties are considered necessary to be able to guarantee the claims of the other party. This is inherent to the direct effect of EU law. The court notes in this regard that the Court of Justice has delivered a declaratory judgment; this implies that the law, as interpreted by the Court of Justice, has always been that way from the entry into force of the Directive. The court also notes that the fact that the directive (also) has an internal market objective does not make this any different. In principle, private civil society organizations in every Member State will be able to invoke the directly effective provisions of the Directive, whereby Article 4(1) of the Directive will then not be enforceable against them by the national authorities or the national court.

14.10. VSK points out that a direct application of Article 3, first paragraph, of the Directive without applying Article 4, first paragraph, of the Directive, in which case the court or the NVWA would have to apply another known measuring method, is not possible for several reasons. In the first place, VSK takes the position that the court and the NVWA are bound by the national rules that have been established for the implementation of the Directive. The ISO standards referred to in Article 4(1) of the Directive are therefore not directly applicable. In contrast, according to VSK, the ISO-NEN standards referred to in Article 2.1 of the Regulation apply. According to VSK, those ISO-NEN standards are generally accessible to the public and therefore to private individuals in view of national case law. Secondly, only the Commission can establish alternative standards for measuring and verifying the measurement of emission values. Thirdly, the emission values of Article 3(1) are inextricably linked to the standards to which Article 4(1) of the Directive refers.

14.11. The court cannot follow the third position of VSK, because it is at odds with part 5 of the declaratory judgment by the Court as explained by the court above. The court can follow VSK's second point. It will come back to that later. With regard to VSK's first position, the court considers that the Regulation does refer to the emission values of Article 3, paragraph 1, of the Directive, but not to the ISO standards referred to in Article 4, paragraph 1, of the Directive, but to ISO-NEN standards. However, these are translations of the ISO standards to which Article 4(1) of the Directive refers. They also have the same numbers, namely: 4387, 10315, 8454 and 8243. Given the primacy of EU law over national law (e.g. Costa Enel, ECLI:EU:C:1964:66 and ECLI:NL:HR :2015:2722), citizens should be able to rely directly on a directive if it has not been or has not been properly transposed into national law. Union loyalty, as laid down in Article 4(3) of the Treaty on European Union, and the existence of preliminary ruling proceedings (Article 267 of the Treaty on the Functioning of the European Union) further entail that the national court is obliged to redress unacceptable derogations from a directive. In the present case – as VSK also states – the Directive has been correctly transposed into national law. However, since the Court has held that the ISO standards referred to in Article 4(1) of the Directive may not be enforced against private individuals in general as long as they have not been published in the Official Journal of the European Union, the Court of takes the view that the principle of loyalty to the Union and the system of preliminary rulings mean that the transposition into national law, insofar as it refers to ISO-NEN standards, cannot be invoked against private individuals

in general either. This means that the previous judgments of the Supreme Court and of the highest administrative courts about the knowability of NEN standards cannot play a role here.

14.12. Since Article 4(1) of Directive 2014/40 cannot be invoked against individuals in general in so far as this provision refers to ISO standards that have not been published in the Official Journal of the European Union, the Court ordered the district court in paragraph 74 of the judgment to assess whether the methods actually used for measuring the emission levels of tar, nicotine and carbon monoxide are in accordance with Directive 2014/40, without taking into account Article 4(1) thereof. The method actually used for measuring the emission levels of tar, nicotine and carbon monoxide from filter cigarettes sold in the Netherlands is the method as described in the ISO standards. The court is of the opinion that this method is not in accordance with the Directive. It is not in dispute that when using the method as described in the ISO standards, the filter is not completely or partially closed by the equipment used, as happens when a person smokes a cigarette, i.e. through the fingers and/or the the smoker's lips. Manufacturers have consciously responded to this by making small holes in the filter through which extra air is drawn in when measuring using the method as described in the ISO standards, which dilutes the emissions. This therefore does not measure the emission values that are released during intended use of a cigarette.

14.13. The court cannot determine whether the filter cigarettes sold in the Netherlands meet the limit values of Article 2.1 of the Regulation in which Article 3, first paragraph, of the Directive has been implemented, because the measuring method used for those cigarettes does not comply with the Directive and no measuring method is prescribed that does comply with the Directive. However, in view of the RIVM study described in the interim decision, there are strong indications that the cigarettes sold in the Netherlands do not meet the aforementioned limit values. That research was carried out using a measuring method (Canadian intense) that is not prescribed in the Directive. It is not up to the court to determine whether the method used by RIVM complies with the Directive, but it is up to the European Commission to determine a measurement method that does comply with the Directive. Until the European Commission does this and the measurement results of this method yet to be prescribed have been obtained, there is no guarantee that the filter cigarettes sold in the Netherlands comply with the emission limit values of Article 3, first paragraph, of the Directive. In view of the objective pursued by that provision of a high level of protection of public health, as further specified in recital 8 in the preamble to the Directive – “Tobacco products are not ordinary products and, in view of the extremely harmful effects of tobacco on human health, significant importance is attached to the protection of public health, in particular to reduce smoking among young people.” – is the sale of filter cigarettes in the Netherlands for which it has not been established that they comply with the limit values of Article 2.1. of the Regulation in violation of that provision of the Regulation. This means that the NVWA wrongly rejected the request to take enforcement action.

How further?

15. The Foundation's appeal is well-founded and the contested decision in which the defendant upheld the rejection of the enforcement request must be annulled.
The court cannot itself impose an order under administrative coercion, as requested by the Foundation, and will therefore determine that the NVWA will have to make a new decision on the objection within six weeks that purports to enforcement action.

Final Considerations

16. The defendant must reimburse the Foundation for the court fees it has paid.

17. The court orders the defendant to pay the costs incurred by the Foundation on appeal. Based on the Administrative Costs Decree, the court sets these costs for legal assistance provided professionally by a third party at € 6,831 (1 point for submitting the notice of appeal, 2 points for making written comments in the preliminary ruling procedure, 1 point for appearing at a hearing, 0.5 point for appearing at a further hearing with a value per point of € 759 and weighting factor 2 due to the gravity of the case).

Decision

The court:

- declares the appeal to be well-founded insofar as submitted by the Foundation;
- annuls the contested decision;
- determines that the NVWA will take a new decision on the objection within six weeks of publication of this decision;
- declares the appeal unfounded insofar as filed by plaintiffs 2 to 15;
- determines that the defendant will reimburse the Foundation for the court fee paid of € 345;
- orders the defendant to pay the costs of the proceedings of the Foundation to an amount of € 6,831.

This decision is delivered by mr. A.C. Rop, chairman, and mr. M.G.L. de Vette and mr. S.A. de Vries, members, in the presence of mr. R. Stijnen, registrar. The verdict was made public on November 4, 2022.

Registrar President

A copy of this ruling has been sent to the parties at:

Remedy
An appeal can be lodged against this decision with the Trade and Industry Appeals Tribunal within six weeks of the date on which it was sent.