Translation C-160/20-1

#### Case C-160/20

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

#### **Date lodged:**

24 March 2020

#### **Referring court:**

Rechtbank Rotterdam (Netherlands)

#### Date of the decision to refer:

20 March 2020

## **Applicants:**

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

#### **Defendant:**

Staatssecretaris van Volksgezondheid, Welzijn en Sport

#### Subject of the action in the main proceedings

The main proceedings arise from a request to the Netherlands Voedsel- en Warenautoriteit (Food and Consumer Product Safety Authority; 'the NVWA') to take enforcement action, more particularly by withdrawing from the market filter cigarettes which do not comply with the maximum emission levels for tar, nicotine and carbon monoxide.

### Subject and legal basis of the request for a preliminary ruling

The request for a preliminary ruling concerns the interpretation and the validity of Article 4 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1). Also at issue is the interpretation of Article 24(3) of Directive 2014/40/EU.

The request for a preliminary ruling was made pursuant to Article 19(3)(b) TEU and Article 267 TFEU.

#### **Questions** referred

Question 1: Is the form of the measurement method provided for in Article 4(1) of Directive 2014/14/EU, based on ISO standards which are not freely accessible, in accordance with Article 297(1) TFEU (and Regulation (EU) No 216/2013) and with the underlying principle of transparency?

Question 2: Must the ISO standards 4387, 10315, 8454 and 8243 referred to by Article 4(1) of Directive 2014/14/EU be interpreted and applied in such a way that, in the interpretation and application of Article 4(1) of that directive, emissions of tar, nicotine and carbon monoxide should not be measured (and verified) only by the prescribed method, but that those emissions may or must also be measured (and verified) in a different manner and with a different intensity?

Question 3(a): Is Article 4(1) of Directive 2014/14/EU contrary to the underlying principles of that directive and to Article 4(2) thereof as well as to Article 5(3) of the WHO Framework Convention on Tobacco Control, given that the tobacco industry played a role in determining the ISO standards referred to in Article 4(1) of that directive?

Question 3(b): Is Article 4(1) of Directive 2014/14/EU contrary to the underlying principles of that directive, to Article 114(3) TFEU, to the spirit of the WHO Framework Convention on Tobacco Control and to Articles 24 and 35 of the Charter, in so far as the measurement method prescribed therein does not measure the emissions from filter cigarettes during their intended use since, with that method, no account is taken of the effect of the ventilation holes in the filter which are largely closed off during their intended use by the smoker's lips and fingers?

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

- answer question 1 in the negative?
- answer question 2 in the affirmative?
- answer question 3(a) and/or question 3(b) in the affirmative?

Question 4(b) (If the Court is unable to give an answer to question 4(a)): Does the temporary unavailability of a measurement method give rise to a situation such as that referred to in Article 24(3) of Directive 2014/14/EU?

### Provisions of EU law cited

Treaty on European Union: Article 19(3)(b).

Treaty on the Functioning of the European Union: Article 114(3); Article 267, and Article 297(1).

Charter of Fundamental Rights of the European Union: Articles 24 and 35.

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).

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1): recitals 8 and 59; Articles 1, 3, 4 and 24(3).

#### **Provisions of national law cited**

Netherlands Grondwet (Constitution): Article 22(1).

Wet van 10 maart 1988, houdende maatregelen ter beperking van het tabaksgebruik, in het bijzonder ter bescherming van de niet-roker (Law of 10 March 1988 laying down measures to limit tobacco use, in particular, to protect the non-smoker) (*Staatsblad* 1988, 342; Tabaks- en rookwarenwet): Article 2(1); Article 3(1); Article 14, and Article 17a(1), (2) and (4).

Besluit van 14 oktober 2015, houdende samenvoeging van de algemene maatregelen van bestuur op basis van de Tabakswet tot één besluit (Decree of 14 October 2015, combining the general administrative measures based on the Tobacco Act into a single decree) (*Staatsblad* 2015, 398; Tabaks- en rookwarenbesluit): Article 2.1.

Regeling van de Staatssecretaris van Volksgezondheid, Welzijn en Sport van 10 mei 2016, kenmerk 966398-150196-WJZ, houdende regels inzake de productie, de presentatie en de verkoop van tabaksproducten en aanverwante producten (Regulation of the State Secretary for Health, Welfare and Sport of 10 May 2016, No 966398-150196-WJZ, laying down rules on the production, presentation and sale of tobacco products and related products) (*Staatscourant* 2016, 25446; Tabaks- en rookwarenregeling): Article 2.1.

## Brief summary of the facts and the procedure in the main proceedings

- By letters of 31 July and 2 August 2018, the applicants in the main proceedings requested the NVWA to ensure that filter cigarettes offered for sale to consumers in the Netherlands comply during their intended use with the maximum emission levels for tar, nicotine and carbon monoxide pursuant to Article 3 of Directive 2014/40/EU. In addition, the NVWA was requested to take enforcement action by withdrawing from the market filter cigarettes which do not comply with the maximum emission levels for tar, nicotine and carbon monoxide.
- The enforcement request was based on a study by the Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment) of 13 June 2018, from which it follows that, using the 'Canadian Intense' measurement method, all filter cigarettes sold in the Netherlands significantly exceed the maximum emission levels for tar, nicotine and carbon monoxide laid down in Article 3(1) of Directive 2014/40/EU.
- 3 By a decision of 20 September 2018, the NVWA rejected the enforcement request of the Stichting Rookpreventie Jeugd (Youth Smoking Prevention Foundation).
- 4 By a decision of 31 January 2019 ('the contested decision'), the Staatssecretaris van Volksgezondheid, Welzijn en Sport ('the defendant') declared the objection

- lodged by the Stichting Rookpreventie Jeugd unfounded and the objection lodged by the other applicants inadmissible.
- 5 The applicants lodged an appeal against the contested decision before the Rechtbank Rotterdam (District Court, Rotterdam).

### Main submissions of the parties to the main proceedings

- The <u>applicants</u> contend that the 'Canadian Intense' measurement method must be used when the emissions of tar, nicotine and carbon monoxide from filter cigarettes because that method, unlike the measurement method provided for in Article 4 of Directive 2014/40/EU, measures emissions from filter cigarettes during their intended use.
- The applicants note in that regard that tobacco producers make small holes in cigarette filters and that clean air is drawn through the filter via those holes (so-called filter ventilation). As a result, tar, nicotine and carbon monoxide levels are diluted. During intended use, however, those holes are largely closed by the smoker's fingers and lips meaning that he or she inhales significantly higher levels of tar, nicotine and carbon monoxide than the maximum emission levels laid down in Article 3 of Directive 2014/40/EU. According to the applicants, the measuring method provided for in Article 4 of that directive does not take that into account and therefore does not measure the levels released during the intended use. The filter cigarettes sold in the Netherlands are therefore even more harmful to health and even more addictive than smokers might assume on the basis of the aforementioned directive.
- The <u>defendant</u> rejected the request by a decision of 20 September 2018. In its view, Article 4 of Directive 2014/40/EU leaves no scope for the use of a measurement method other than the method prescribed therein, and, when that measurement method is used, the filter cigarettes sold in the Netherlands comply with the maximum emission levels of Article 3 of that directive.

# Brief summary of the reasons for the referral

- 9 Questions have arisen for the referring court as to the interpretation and validity of Article 4 of Directive 2014/40/EU.
- Article 4(1) of that directive provides that the tar, nicotine and carbon monoxide emissions from cigarettes are to be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide, and that the accuracy of the tar, nicotine and carbon monoxide measurements is to be determined in accordance with ISO standard 8243.
- According to Article 4(2) of that directive, the measurements referred to in paragraph 1 thereof 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.

### First question

The referring court notes that the measurement method provided for in Article 4 of Directive 2014/40/EU is based on ISO standards. Those ISO standards are not publicly accessible, and can be consulted only for a fee. The question which then arises is whether such a method of regulation is in accordance with the publication regime applicable to EU legislation, i.e. publication in the *Official Journal of the European Union* in accordance with Article 297(1) TFEU (and Regulation No 216/2013), and with the principle of transparency.

#### Second question

- Furthermore, the referring court states that it is not clear whether the measurement method laid down in Article 4 of Directive 2014/40/EU is the only measurement method permitted.
- In that regard, it notes that ISO standard 3308, referred to by each of the ISO standards cited in Article 4 of the directive, itself recommends that emissions also be measured using machines which measure a different smoke intensity than that set out in those standards.
- If it were to follow from the ISO standards declared applicable in Article 4 of the directive themselves that the emission levels of tar, nicotine and carbon monoxide should not be measured (and verified) on the basis of the prescribed method alone, but that those emissions may or must also be measured (and verified) in a different manner and at a different intensity, then, in the view of the referring court, the consequence of that could be that Article 4(1) of Directive 2014/40/EU must be applied in such a way that, in order to determine whether the cigarettes placed on the market are in conformity with the permitted maximum emission levels, it is not sufficient to measure (and verify) by means of the smoking machine as referred to in the ISO standards, or that the result of that measurement is in any event inconclusive.

#### Third question

- The referring court also notes that, should the second question be answered in the negative, a third question must be referred to the Court of Justice for a preliminary ruling. By that question, it seeks to ascertain whether the measurement method provided for in Article 4 of the directive is consistent with the purpose and intent of Directive 2014/40/EU as well as with higher legal standards.
- 17 The referring court states that the measurement methods provided for in Article 4(1) of Directive 2014/40/EU were developed with input from the tobacco industry.

- The question which arises in that regard is whether the measurement and validation methods thus set out are contrary to the underlying principles of that directive, with the intent of Article 4(2) of that directive which provides that the measurements are to be verified by laboratories not owned or controlled directly or indirectly by the tobacco industry and to Article 5.3 of the World Health Organization Framework Convention on Tobacco Control, which provides that, in setting and implementing their public health policies, those policies are to be protected from commercial and other vested interests of the tobacco industry.
- The referring court also questions whether, given the fact that ventilation holes are made in the filters of filter cigarettes, the measurement and validation methods referred to in Article 4(1) of Directive 2014/40/EU are in accordance with the objective of that directive as is set out in the recitals and in Article 3 thereof.
- Failing to meet the target of maximum emissions from the intended use of filter cigarettes would, in its view, seriously undermine the objective of a high level of health protection, whereby account should be taken, in particular, of any new developments based on scientific facts, as is set out in recital 8 of Directive 2014/40/EU. In that case, the referring court cannot rule out the possibility that Article 4(1) of that directive is contrary to Article 114(3) TFEU, to the spirit of the World Health Organisation Framework Convention on Tobacco Control, and to Articles 24 and 35 of the Charter.

#### Fourth question

- 21 Should the Court of Justice answer the second question in the affirmative, the question arises, according to the referring court, as to which alternative method may or must be used. It notes that that question also arises if the Court of Justice answers the first question in the negative and/or answers the third question in the affirmative. In that regard, it also notes, however, that it is uncertain whether the Court of Justice can prescribe an alternative method.
- In the event that the Court of Justice cannot answer the question regarding the alternative method which may or must be used, the referring court wishes to ascertain whether the temporary unavailability of a measurement method constitutes a situation such as that referred to in Article 24(3) of Directive 2014/40/EU. Under that provision, a Member State may prohibit a certain category of tobacco or related products on grounds relating to the specific situation in that Member State and provided it is justified by the need to protect public health.