

# decision

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DISTRICT COURT OF ROTTERDAM

Administrative case number: ROT 19/1249

**decision of the three-judge panel of 20 March 2020 requesting a preliminary ruling from the Court of Justice of the European Union in the case between**

1. **Stichting Rookpreventie Jeugd** [Youth Smoking Prevention Foundation], Amsterdam, the Netherlands;
2. **Stichting Inspire2Live** [Inspire2Live Foundation], Amsterdam, the Netherlands;
3. **Rode Kruis Ziekenhuis B.V.** [Red Cross Hospital], Beverwijk, the Netherlands;
4. **Stichting ClaudicatioNet** [nationwide community-based physiotherapy network], Eindhoven, the Netherlands;
5. **Nederlandse Vereniging voor Kindergeneeskunde** [NVK, Dutch Association for Paediatrics], Utrecht, the Netherlands;
6. **Nederlandse Vereniging voor Verzekeringsgeneeskunde** [NVVG, Dutch Association of Insurance Medicine], Utrecht, the Netherlands;
7. **Accare, Stichting Universitaire and Algemene Kinder- en Jeugdpsychiatrie Noord-Nederland** [Accare University and General Center for Child and Adolescent Psychiatry North-Netherlands] (Groningen), Assen, the Netherlands;
9. **Vereniging Praktijkhoudende Huisartsen** [VPH, Association of Practising General Practitioners], Amsterdam, the Netherlands;
10. **Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose** [NVALT, Dutch Association of Physicians for Pulmonary Diseases and Tuberculosis], 's-Hertogenbosch, the Netherlands;
11. **Nederlandse Federatie van Kankerpatiëntenorganisaties** [NFK, Dutch Federation of Cancer Patient Organisations], Utrecht, the Netherlands;
12. **Nederlandse Vereniging Arbeids- en Bedrijfsgeneeskunde** [NVAB, Netherlands Society of Occupational Medicine], Utrecht, the Netherlands;
13. **Nederlandse Vereniging voor Cardiologie** [NVVC, Netherlands Society of Cardiology], Utrecht, the Netherlands;
14. **Koepel van Artsen Maatschappij en Gezondheid** [Association of Public Health Physicians], Utrecht, the Netherlands;
15. **Nederlandse Vereniging voor Kindergeneeskunde** [NVK, Dutch Association for Paediatrics], Utrecht, the Netherlands;
16. **Koninklijke Nederlandse Maatschappij tot bevordering der Tandheelkunde** [KNMT, Royal Dutch Dental Association], Utrecht, the Netherlands;
17. **the College of Mayor and Alderpersons of Amsterdam** [the Municipal Executive],

hereinafter referred to as: the plaintiffs,

and

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

in which the following took part in the proceedings as a third party:

**Vereniging Nederlandse Sigaretten- en Kerftakfabrikanten (VSK)** [Dutch association of fine-cut and smoking tobacco manufacturers], Leidschendam, the Netherlands.

### **Course of the proceedings**

In letters dated 31 July 2018 and 2 August 2018, a number of persons and authorities, including plaintiffs 1 through 15 as well as the City of Amsterdam, requested that the Netherlands Food and Consumer Product Safety Authority (NVWA) ensure that filter cigarettes marketed to consumers in the Netherlands comply with the maximum emission levels for tar, nicotine and carbon monoxide from intended use, arising from Article 3 of Directive 2014/40/EU (**the Directive**). In that context, the NVWA was requested to take enforcement action by removing filter cigarettes that do not comply with the maximum emission levels for tar, nicotine and carbon monoxide from the market (administrative enforcement).

Insofar as it is relevant in the context of this ruling, the NVWA rejected the enforcement request made by the Youth Smoking Prevention Foundation (**the Foundation**) in a decision dated 20 September 2018.

In a decision dated 31 January 2019 (the contested decision), the defendant declared the objection made by plaintiffs 2 through 16 to be inadmissible and the Foundation's objection unfounded.

The plaintiffs have appealed against the contested decision.

The Dutch association of fine-cut and smoking tobacco manufacturers (VSK) filed a request to be considered as a third party. They were given the opportunity to submit their views, but refrained from doing so.

The defendant filed a statement of defence.

The hearing took place on 11 November 2019. The plaintiffs were represented by A.H.J. van den Biesen, LL.M., W. de Kanter, chairman of the Foundation, appeared on behalf of the Youth Smoking Prevention Foundation. In addition, R. Osterwald, LL.M, head of the Department of Public Law at the Legal Affairs Department for the City of Amsterdam and R. Scheffel, employee of the Municipal Public Health Service of Amsterdam, appeared on behalf of the College of Mayor and Alderpersons of Amsterdam (the Municipal Executive); and I.C.M. Nijland, LL.M, S.W.A.M.M. Delauw, LL.M, assisted by P. Rijswijk, all employed by the NVWA, and W.N.N. Klerx, employee of the National Institute for Public Health and the Environment (RIVM), appeared as authorised representatives on behalf of the defendant. J.H.J.M. Sträter, managing director, appeared on behalf of VSK.

Following the closure of the hearing, the District Court decided to reopen the investigation for the purpose of addressing requests for preliminary rulings to the Court of Justice of the European Union (**the Court of Justice**) as referred to in Article 19 (3) preamble and under b of the Treaty on European Union (**TEU**) and Article 267 of the Treaty on the Functioning of the European Union (**TFEU**). The parties were given the opportunity to express their views on a draft version of the requests for preliminary rulings.

## **Considerations**

### Introduction

1. The enforcement request is based on a study by the National Institute for Public Health and the Environment (RIVM) published on 13 June 2018, from which it follows that, using the ‘Canadian Intense’ measurement method, all filter cigarettes sold in the Netherlands by far exceed the maximum emission levels for tar, nicotine and carbon monoxide laid down in Article 3 (1) of the Directive.

According to the plaintiffs, the specified measurement method should be used because, contrary to the measurement method prescribed in Article 4 of the Directive, it measures the emissions of filter cigarettes when used as intended. In this respect, the plaintiffs highlight the fact that tobacco manufacturers make small perforations in the cigarette filters and that, as a result, clean air is pulled in through the filter (known as ‘filter ventilation’), which dilutes the levels of tar, nicotine and carbon monoxide. However, when the cigarettes are used as intended, these ventilation holes are largely closed off by the smoker's fingers and lips, meaning that the levels of tar, nicotine and carbon monoxide ingested by the smoker are significantly higher than the maximum emission levels laid down in Article 3 of the Directive. The measurement method outlined in Article 4 of the Directive does not take filter ventilation into account, and therefore, according to the plaintiffs, does not measure the levels released during intended use. As a result, the filter cigarettes sold in the Netherlands are, according to the plaintiffs, even more harmful to health and more addictive than what smokers can assume under the Directive.

The defendant rejected the request in a decision dated 20 September 2018 because, in their opinion, Article 4 of the Directive does not allow for the use of a different measurement method than the one prescribed therein, and the filter cigarettes sold in the Netherlands comply with the maximum emission levels laid down in Article 3 of the Directive when using that measurement method.

Questions were raised on appeal concerning the interpretation and validity of Article 4 of the Directive. Before those questions can be addressed, the procedural questions that have arisen between the parties will be discussed below, but only to the extent that the answers to these questions could prevent substantive assessment of the grounds for appeal.

## Procedural questions

### *Admissibility*

2.1. Together with the defendant, the District Court is of the opinion that the Foundation is an interested party within the meaning of Article 1:2 (3) of the General Administrative Law Act (Awb). It follows from the Foundation's articles of association that its objective is to prevent or restrict the use of tobacco, in particular by children and young people, and to encourage others to do so, with the ultimate aim of making tobacco use a thing of the past. Its actual activities include maintaining websites aimed at preventing young people from smoking, making media appearances, initiating criminal proceedings against the tobacco industry in the Netherlands and in other countries, and conducting civil proceedings against the State with respect to compliance with Article 5 (3) of the WHO Framework Convention on Tobacco Control. In view of this, the aim of reducing the (actual) emission levels of tar, nicotine and carbon monoxide in filter cigarettes can be considered part of its statutory objectives and actual activities.

2.2. Since the Foundation is an interested party, Article 1:2 of the General Administrative Law Act does not preclude a substantive assessment of its appeal. The question of whether the defendant was justified in declaring the other plaintiffs' objections inadmissible in the contested decision can therefore be left open in the context of this interlocutory ruling.

### *Abuse of rights?*

3.1 VSK argued at the hearing that the submission of an enforcement request to the NVWA constituted an abuse of rights, which would therefore also apply to these proceedings. VSK pointed out that, in light of the decision by The Hague Court of Appeal on 6 December 2018 (ECLI:NL:GDHA:2018:3334), the plaintiffs had previously unsuccessfully launched a complaints procedure in order to enforce criminal proceedings against "the tobacco industry", and that only the European

regulator can decide on a change in the measurement method, meaning that the plaintiffs cannot achieve anything with their enforcement request.

3.2. This argument does not hold water, if only because the administrative courts are not bound by the judgement of the criminal courts. Moreover, in view of the principle of 'nullum crimen, nulla poena sine praevia lege poenali', it does not stand to reason that the binding nature of a provision in a Directive to the detriment of a defendant should be raised in criminal proceedings.

*Competence of the Netherlands Food and Consumer Product Safety Authority?*

4. The District Court finds ex officio that the request for enforcement was addressed to the Netherlands Food and Consumer Product Safety Authority (NVWA) and that the decision dated 20 September 2018 on the Foundation's request came from the NVWA, whereas the defendant decided on the objection lodged against that decision. It follows from Articles 1:5 (1) and 6:4 (1) of the General Administrative Law Act (Awb) that an objection is made by submitting a notice of objection to the administrative body that made the decision, in order to request an appeal against a decision from the administrative body that made the decision. It follows from these provisions that the administrative body that made the primary decision should also decide on the objection to the decision. It therefore follows that the defendant was not competent to decide on the Foundation's objection. However, this does not mean that a substantive assessment of the appeal cannot be made. Since the employees of the NVWA stated at the hearing that the NVWA would have reached a substantively similar decision, the lack of competence in this matter does not in any case independently lead to avoidance of the legal consequences of the contested decision. Nor, therefore, does a lack of competence preclude substantive assessment of the case.

## Substantive assessment

### *Legal framework*

5. The relevant Treaty rules and European and national laws and regulations, with the exception of procedural provisions, are outlined in the Annex to this decision.

### *Assertions of the parties*

6.1. In its request of 31 July 2018, the Foundation asked the NVWA to take enforcement action, citing Article 14 of the Tobacco and Related Products Act (**the Act**) as the grounds for its competence in this matter. On the basis of this provision, the NVWA has been granted the competence to act by imposing administrative coercion in the event of non-compliance with Article 17a (1) and (2) of the Act by producers, importers and distributors of tobacco products. According to the Foundation, Article 17a (1) of the Act has been violated because producers, importers and distributors of tobacco products fail to immediately take the necessary measures to bring their products into line with the requirements outlined in or pursuant to this Act, or to withdraw or recall those products from the market, now that it has been established that, in breach of Article 3 (1) in conjunction with Article 2 (1) of the Act, Article 2.1 of the Tobacco and Related Products Decree (**the Decree**), and Article 2.1 of the Tobacco and Related Products Regulation (**the Regulation**), cigarettes have been marketed that do not meet the requirements with regard to the maximum permitted emissions. The Foundation argues that a correct interpretation and application of Article 3 (1) of the Directive implies that the national legislature, when implementing that paragraph of the article, should not attach any (mandatory) significance to the measurement methods referred to in Article 4 (1) of the Directive, on the basis of which the emission levels must be calculated. According to the Foundation, Article 4 (1) of the Directive does not prescribe a mandatory measurement method, and moreover asserts that ISO

standards, which do not themselves constitute generally binding rules because they have not been published as such, should also not be assigned any significance.

According to the Foundation, the measurement should in any case be based on the actual emissions of tar, nicotine and carbon monoxide in intended use, since the purpose and scope of Article 3 (1) of the Directive, also in the light of Article 5 (3) of the WHO Framework Convention on Tobacco Control, Article 114 (3) of the TFEU, Articles 24 and 35 of the Charter of Fundamental Rights of the European Union (**the Charter**), recital 59 in the preamble to the Directive, and Article 1 of the Directive, as well as provisions from various human rights treaties and conventions concerning the right to health, are otherwise not being fulfilled. Because the national regulator assumes that Article 4 (1) of the Directive does prescribe a mandatory measurement method, and the Directive has been implemented in the Decree and the Regulation with regard to emission levels and measurement methods on a one-to-one basis, the Foundation asserts that national laws and regulations do not offer the protection intended by Article 3 (1) of the Directive and Article 22 (1) of the Constitution. The Foundation has therefore asked the District Court to submit requests for preliminary rulings to the Court of Justice.

6.2. As a factual basis for its argument, the Foundation has argued that the measurement methods required by Article 4 (1) of the Directive were developed with the cooperation of the tobacco industry and do not measure the accurate levels of emissions of tar, nicotine and carbon monoxide during intended use, because tobacco manufacturers have made perforations in the filter which ensure that, when filter cigarettes of the various brands are measured, emissions are between 2 and more than 20 times lower than when the filter is taped shut during measurement. According to RIVM, the filter needs to be taped shut, because the filter is also squeezed closed by the fingers and the lips during intended use, i.e. smoking by the consumer. In this context, the Foundation has submitted, among other things, a publication by RIVM dated 13 June 2018, letters from the defendant to the European Commission (**the Commission**) dated 20 October 2017 and 22 June 2018, and a study by M-A Song et al. entitled ‘Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma’, which was published in the *Journal of the National Cancer Institute* on 22 May 2017. According to the Foundation, the Canadian Intense method should be used for measurement, as follows from



investigations and the aforementioned letters from the defendant to the Commission.

7. The defendant takes the position that Article 4 (1) of the Directive does prescribe a mandatory measurement method by referring to the ISO measurement methods mentioned in that paragraph. Furthermore, the defendant and VSK are of the opinion that it is up to the European legislative bodies to amend the Directive or not to do so, and that it is not possible for the national authorities to deviate from the Directive as implemented in national law.

*Considerations regarding the legal validity of ISO standards in EU legislation*

8.1. Article 3 (1) of the Directive stipulates that the emission levels of cigarettes brought to market or manufactured 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) of the Directive states: “The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide. The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO standard 8243.” Following on from this, Article 2.1 of the Regulation refers to the following standards for examination and verification:

- For tar emission levels: NEN-ISO 4387:2000/A1:2008 Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine;
- For nicotine emission levels: NEN-ISO 10315:2013 Cigarettes – Determination of nicotine in smoke condensates – Gas chromatographic method;
- For carbon monoxide emission levels: NEN-ISO 8454:2007/A1:2009 Cigarettes – Determination of carbon monoxide in the vapour phase of cigarette smoke – NDIR method.
- NEN-ISO 8243:2013 Cigarettes – Sampling.

8.2. The meaning of the maximum emission levels laid down in Article 3 (1) of the Directive is also determined by the measurement method outlined in Article 4 of the Directive. Article 4 of the Directive sets out this measurement method in full on the basis of ISO standards. These ISO standards are not available to the public, but can only be consulted for a fee. Consequently, the content of the protection afforded to citizens by Article 3 (1) of the Directive depends on standards that are not freely accessible. The question arises as to whether such a method of regulation is consistent with the publication regime of European Union legislation, i.e. publication in the Official Journal of the European Union in accordance with Article 297 (1) of the TFEU (and Regulation (EU) No. 216/2013), and with the underlying transparency principle. The District Court sees reason to refer that question to the Court of Justice.

*Is the measurement method outlined in Article 4 of the Directive the exclusive determining factor?*

9.1. In each of the ISO standards mentioned in Article 4 of the Directive, reference is made to ISO 3308 for the measurement of the relevant emission level.

This standard relates to the use of a smoke machine. The introduction (page v) of ISO 3308:2012 reads:

“No machine smoking regime can represent all human smoking behaviour:

- it is recommended that cigarettes also be tested under conditions of a different intensity of machine smoking than those specified in this International Standard;
- machine smoking testing is useful to characterize cigarette emissions for design and regulatory purposes, but communication of machine measurements to smokers can result in misunderstandings about differences in exposure and risk across brands;
- smoke emission data from machine measurements may be used as inputs for product hazard assessment, but they are not intended to be nor are they valid as measures of human exposure or risks. Communicating differences between products in machine measurements as differences in exposure or risk is a misuse of testing using ISO standards.”

This text also appears in ISO 4387:2000/A1:2008, ISO 10315:2013 and ISO 8454:2007/A1:2009.

9.2. In light of this quote, these ISO standards recommend that emissions should also be measured with a different intensity of machine smoking. If it follows from the ISO standards themselves, which were declared applicable in Article 4 of the Directive, that tar, nicotine and carbon monoxide emission levels should not only be measured (and verified) using the prescribed method, but that these emissions could or should also be measured (and verified) using a different method and with a different intensity, then this could mean that Article 4 (1) of the Directive and Article 2.1 of the Regulation should be applied in such a way that, in order to determine whether cigarettes brought to market comply with the maximum emission

levels permitted under Article 3 (1) of the Directive and Article 2.1 (1) of the Decree, it is not sufficient to measure (and verify) using the smoke machine referred to in NEN-ISO 3308, or at least that the result of that measurement is not decisive. At the very least, that would mean that the defendant failed to handle the enforcement request with all due care and did not provide sufficient reasons for rejecting it. If the ‘Canadian Intense’ method could also be used – a measurement method that, according to the Foundation, better approximates the intended use of filter cigarettes – this would result in significantly higher emissions being measured than permitted under Article 3 of the Directive, as follows from the RIVM study discussed in more detail below. This interpretation could mean that manufacturers, importers and distributors of tobacco products were and are obliged to immediately take the necessary measures to bring the product in line with legal requirements, or to withdraw or recall the product from the market, and that if they fail to do so, the NVWA is authorised under Article 14 of the Act to impose administrative coercion, as requested by the Foundation.

9.3. The District Court therefore considers it appropriate to refer a second question to the Court of Justice for a preliminary ruling.

*Is the measurement method outlined in Article 4 of the Directive consistent with the purpose and purport of the Directive and in conformity with higher law?*

10.1. If the Court of Justice finds that the answer to the second question is negative, there are grounds for putting a third question to the Court of Justice for a preliminary ruling in light of the findings outlined below.

10.2. Following their earlier letter dated 20 October 2017 (167856), the defendant wrote the following – insofar as it is of interest here – in their letter dated 22 June 2018 (1369203-178340-VGP) to then European Commissioner Vytenis Andriukaitis:

“Secondly, I would like to inform you about the results of the research by the RIVM. As you know the RIVM published the results of their research on tar, nicotine and carbon monoxide (TNCO) emissions measured by the Canadian Intense (CI) method. These results show that smokers inhale considerably more toxic substances in comparison with measurements following the ISO method. These differences of TNCO emissions between the ISO method and the Canadian Intense method are mainly caused by a high extent of filter ventilation.

In our meeting on the 23rd of April we talked about the possibility to explore an alternative method to measure TNCO levels in cigarettes. I was very pleased by your offer to explore solutions in an expert meeting in Brussels. This expert meeting took place on the 6th of June. Unfortunately, the meeting did not result in a proactive strategy to explore alternatives for the ISO-method on a short notice. One week after this meeting, the RIVM published the results of their research. In my opinion, these results are very alarming.

In the Netherlands, about 20,000 people die every year as a result of smoking related diseases. Therefore I want to do everything in my power to prevent young people start smoking and help smokers quit smoking. I will continue putting this issue on the agenda in meetings in Brussels, in the preparation of the Conference of Parties in Geneva this October and in meetings with my European colleagues. I would like to ask you, given the alarming results of the RIVM research, to concretize your following steps on short-notice in preparation of the evaluation of the Tobacco Productive Directive. In this way, we can explore which extra steps we can take together until the evaluation starts.”

Appendix A to that letter and the letter of 20 October 2017 contains the following table:

**Table 1: TNCO contents, as provided by manufacturers, measured by the ISO method vs. TNCO contents measured by the RIVM by means of the CI method. According to the tobacco product directive (2014/40/EU) cigarette smoke is permitted to contain a maximum of 10 mg/cigarette of tar, 1 mg/cigarette of nicotine, and 10 mg/cigarette of carbon monoxide.**

Brand	Tar (mg/cigarette)			Nicotine (mg/cigarette)			CO (mg/cigarette)		
	ISO	CI	CI/ISO ratio*	ISO	CI	CI/ISO ratio*	ISO	CI	CI/ISO ratio*
1.	1	17	17	0.1	1.2	12	2	27	14
2.	4	23	6	0.4	1.5	4	5	24	5
3.	8	20	3	0.6	1.7	3	9	26	3
4.	10	34	3	0.8	2.0	3	10	26	3
5.	10	34	3	0.8	2.0	3	10	28	3
6.	10	37	4	0.8	2.1	3	10	29	3
7.	10	29	3	0.9	1.8	2	10	25	2
8.	10	30	3	0.8	2.0	3	10	28	3
9.	10	29	3	0.8	1.9	2	10	25	3
10.	10	39	4	0.8	1.9	2	10	24	2
11.	10	34	3	0.8	1.7	2	10	29	3

\* The CI / ISO ratio shows how many times the emission level measured by the CI method is higher than the level measured by the ISO method.

10.3. In the light of the foregoing, the District Court has serious doubts as to whether the use of a smoke machine in accordance with ISO 3308 leads to a measurement of the emission levels of tar, nicotine and carbon monoxide corresponding to the emissions in intended use, during which many of the perforations in the filter are closed off by the fingers and the lips of the smoker. The District Court therefore questions whether, given that ventilation holes have been made in the filter of filter cigarettes, the measurement and validation methods referred to in Article 4 (1) of the Directive are consistent with the objective of the Directive as expressed in the preamble and in Article 3 of the Directive. Failure to achieve the objective of maximum emissions from the intended use of filter cigarettes would seriously jeopardise the objective of attaining a high level of protection for human health, particularly taking into account new data based on scientific evidence, as expressed in recital 8 in the preamble to the Directive. In that case, the District Court cannot exclude [the possibility] that Article 4 (1) of the Directive is contrary to Article 114 (3) of the TFEU, to the spirit of the WHO Framework Convention on Tobacco Control (to which the Union and the Netherlands are parties) and to Articles 24 and 35 of the Charter.

10.4. Furthermore, the Foundation has undisputedly argued that the measurement methods prescribed in Article 4 of the Directive were established with input from the tobacco industry. The District Court has serious doubts about whether the

measurement and validation methods thus prescribed are not contrary to the spirit of Article 4 (2) of the Directive, which requires measurements to be verified by laboratories that are not directly or indirectly owned or controlled by the tobacco industry, and to Article 5 (3) of the WHO Framework Convention on Tobacco Control, which states: “In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”

10.5. The District Court therefore sees reason to pose a third request for a preliminary ruling on this matter, which can be broken down into two sub-questions.

*What are the consequences resulting from answering one or more questions in the affirmative?*

11.1. If the Court of Justice answers the second question in the affirmative, the question arises as to which alternative method can or must be used.

11.2. If the Court of Justice answers the first question in the negative and/or the third question in the affirmative, the question arises as to whether the Directive is therefore entirely without legal force or whether only Article 4 (1) of the Directive is without legal force. In the latter case, the question also arises as to which alternative method can or should be used.

11.3. It follows from Article 114 (3) of the TFEU that the Commission's proposals in the fields of public health, safety, environmental protection and consumer protection will assume a high level of protection as a baseline, particularly taking into account any and all new developments based on scientific data, and that the European Parliament and the Council, each within their respective powers, will also seek to achieve this objective. In the light of what has been outlined above, the question can be posed whether the Commission has taken up this task with sufficient diligence, given that there are letters from the defendant to the Commission – explaining that the ISO standards do not approximate the emission levels during intended use of filter cigarettes, while according to current scientific knowledge the 'Canadian Intense' measurement method better approximates the emission levels during intended use – that have remained unanswered, or at least have not led to any detectable activity.

11.4. The question, therefore, is whether the Court of Justice can prescribe an alternative method or whether it can only instruct the Commission and the European Parliament and the Council to come up with new legislation to rectify the gap in the Directive. Although the Directive is aimed at harmonisation, also in view of the functioning of the internal market (see also the judgement by the Court of Justice dated 10 December 2002 (ECLI:EU:C:2002:741) regarding *British American Tobacco et. al*), in order to bridge the period of time involved in the establishment of new Union legislation, the possibility of temporary national measures could also be considered. For example, Article 17a (4) of the Act, implementing Article 24 (3) of the Directive, allows the defendant to issue a prohibition laid down by ministerial order that bans certain categories of tobacco products meeting the requirements under or pursuant to the Act, where justified by the need to protect public health.



11.5. The District Court therefore sees reason to pose a fourth request for a preliminary ruling, which can be broken down into alternative sub-questions.

The questions referred for a preliminary ruling

12. In light of the findings set out above, the District Court is of the opinion that the following questions should be referred to the Court of Justice for a preliminary ruling, pursuant to Article 19 (3), preamble and under b of the TEU and Article 267 of the TFEU:

Question 1: Is the design of the measurement method in Article 4 (1) of the Directive using ISO standards that are not freely available consistent with Article 297 (1) of the TFEU (and Regulation (EU) No. 216/2013) and the underlying principle of transparency?

Question 2: Must ISO standards 4387, 10315, 8454 and 8243 referred to in Article 4 (1) of the Directive be interpreted and applied to the effect that, for the purposes of interpreting and applying Article 4 (1) of the Directive, tar, nicotine and carbon monoxide emissions are not only to be measured (and verified) by the prescribed method, but may or must also be measured (and verified) by other means and with a different intensity?

Question 3a: Is Article 4 (1) of the Directive contrary to the principles of the Directive and to Article 4 (2) of the Directive and Article 5 (3) of the WHO Framework Convention on Tobacco Control (FCTC), because the tobacco industry played a role in establishing the ISO standards referred to in Article 4 (1) of the Directive?

Question 3b: Is Article 4 (1) of the Directive contrary to the principles of the Directive, to Article 114 (3) of the TFEU, to the spirit of the WHO Framework Convention on Tobacco Control and to Articles 24 and 35 of the Charter, because the measurement method prescribed therein does not measure emissions from filter cigarettes during their intended use, as it does not take into account the effect of ventilation holes in the filter which, in their intended use, are largely closed off by the smoker's lips and fingers?

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

- answers question 1 in the negative?
- answers question 2 in the affirmative?
- answers question 3a and/or question 3b in the affirmative?

Question 4b: If the Court of Justice is unable to provide an answer to question 4a, would that then lead to a situation such as the one referred to in Article 24 (3) of the Directive if a measurement method were temporarily unavailable?

#### Final conclusion

The District Court shall stay any further decisions in this case, pending the answers to the questions referred for preliminary ruling.

## Decision

The District Court requests that the Court of Justice of the European Union give preliminary rulings on the questions referred to in ground 12.

This decision was rendered by A.C. Rop, LLM, presiding judge, and M.G.L. de Vette, LLM and S.A. de Vries, LLM, judges, in the presence of R. Stijnen, LLM, registrar. The decision was rendered on 20 March 2020 and made public by means of publication on the website of the Council for the Judiciary.

registrar

presiding judge

The registrar and the preliminary relief judge were unable to sign the decision.

A copy of this decision was sent to the parties on: 20 March 2020

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The Registrar of the  
District Court of Rotterdam  
Administrative Law Sector  
acting registrar <signature>