Answers to questions put by the Court - Case C-160/20
Youth Smoking Prevention Foundation, Municipality of Amsterdam and 13 others
10 March 2021*

Introductory observations

1. The Youth Smoking Prevention Foundation (SRPJ), the Municipality of Amsterdam and the other 13 claimants[1] in the proceedings before the Rotterdam District Court are concerned with effective and correct enforcement of the provisions of Article 3 of Directive 2014/40/EU (further: the Directive), i.e. the maximum TNCO emission levels, which here constitute the "high level of health protection" that the EU guarantees to its citizens.

2. The enforcement authority[2] used Article 4 of the Directive against the claimants because application of the ISO standards did not reveal any exceedance of the maximum emissions of Article 3.[3] This case is based on the fact that the, in the Netherlands, highly authoritative RIVM[4] has investigated and demonstrated that the ISO method does not measure the "intended use" because the ventilation holes in the filters are polluting the measurements by substantially diluting the smoke samples to be analyzed with clean air and because the ISO smoke machine (ISO 3308) assumes an incorrect because much too low intensity and frequency of inhalation. Measurement methods without these shortcomings approximate real smoking behavior considerably better, according to the RIVM and according to the scientists of WHO TobLabNet.[5]

3. RIVM applied a standard for verification that best approximates the level of "substances released when [cigarettes] are used as intended"[6], and established that the TNCO values found are up to three times higher than the maximums of Article 3 of the Directive. This is a serious violation of a primary objective of this Directive, i.e. to guarantee a high level of health and consumer protection, as well as of the protection required by the Directive for the other fundamental rights at stake here.[7]

4. The foregoing, in brief, forms the context in which, according to claimants, everything at issue in this case should be assessed; this context also applies for the following answers to the questions of the Court of Appeal of 10 February 2021.

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* this is not an official Translation; only the original Ducth version of this document is authentic
[1] All working in the health sector
[2] Dutch Food and Consumer Product Safety Authority (NVWA)
[3] The Parliament (Observationa, p. 28) and the Commission (Observations, p. 30) believe that publication of the ISO standards could be omitted because they would be relevant only to a select group; this is generally an untenable position, but the facts disprove the correctness of that assertion
[4] National Institute for Public Health and the Environment (RIVM)
[5] For the views of WHO TobLabNet, see Annex 6 to the Plaintiffs' Memorial of 14-08-2020: WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products, March 2020, https://www.who.int/publications /i/item/WHO-HEP-HPR-2020.1 , retrieved: 08/11/2020
[6] Definition of "emission", Article 2, No. 21 of the Directive
[7] See (59) of the Preamble to the Directive

Question 1 - Relevance of Elliot and SAKSA - in particular points 40 and 43 and 39 respectively

5. For plaintiffs, the relevance of the passages referred to in *Elliot* and *SAKSA* is, first of all, that they illustrate how substantial and important in this case the differences are between European standards within the meaning of Regulation (EU) No 1025/2012 and the ISO standards.

6. In the first place, the question of who is in control of the standard concerned, ie who "initiated / conceived, managed and monitored" the standard? In the case of a "harmonized standard" under EU law, this is the European Commission. For ISO standards, this is formally the International Standards Organization and for ISO standards in Article 4, paragraph 1, in practice it is the tobacco industry.

7. As a private standardization organization, ISO is a project of the international business community that standardizes certain aspects of their production and their operations based on its own interests. This, natural, focus on self-interest means that - now that it is precisely and especially the tobacco industry that has an interest in tobacco-related standardization - the tobacco industry from the outset has had a strong influence and also continuously exercises that influence on (further) development of tobacco standards.[8] Within ISO, *Technical Committees* (TCs) are charged with developing sector-specific standards.[9] ISO / TC 126 is responsible for *Tobacco and Tobacco products*.[10]

8. Just like the Dutch NEN, the German DIN[11] has been very influential within ISO / TC 126 for decades; this has been the case at least since 1996 through today, partly in the person of Prof. W-H Heller who, since 1990, represents the interests of the German tobacco industry in various positions. Heller has also worked within CORESTA since 2004.[12] Since 2018, he has combined the Chairmanship of ISO / TC 126[13] with, among other things, the membership of the Advisory Board of an important representative of the tobacco industry[14].

9. It is therefore the private ISO that, together with the particularly interested tobacco industry, "initiated / conceived"[15] and also "managed" and "monitored" the tobacco-related

[8] See p. 29 of the Memorandum of 14-08-2020 and Annex 5: S.A. Bialous & D Yach, 'Whose Standard is it, anyway? How the tobacco industry determines the International Organization for Standardization (ISO) standards for tobacco and tobacco products, 'Tobacco Control, 2001/10, https://pubmed.ncbi.nlm.nih.gov/11387528/
[9] https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100439.pdf
[10] https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100439.pdf
[11] Deutsche Institut für Normung e.V.
[12] Coresta is the scientific institute of the tobacco industry, see point 29 Memorial
[13] https://www.din.de/de/din-und-seine-partner/din-e-v/ehrungen/verleihung-der-beuth-denkmuenze-an-herrn-prof-dr-wolf-dieter-heller-705740
[14] Institut für Tabakforschung GmbH/Bundesverband der Tabakwirtschaft und neuartiger Erzeugnisse - https://www.din.de/resource/blob/217412/120679abdb7a69849fd1d0ec4517da62/nal-jahresbericht-data.pdf
[15] With exclusive technical input from CORESTA, see point 29 of the Memorial

ISO standards - long before this directive was adopted. As an aside, SRPJ is currently experiencing what, among other things, this "management" means: by invoking the Dutch Freedom of Information Act SRPJ has asked the Dutch Ministry of Health, Welfare and Sport to issue the documents of the Dutch Tobacco Commission 126 of the Dutch standardization body (NEN)[16] from the period that Dutch civil servants still participated in that committee. This case is now pending before the District Court of The Hague, where both NEN and ISO intervened in order to prevent any issue of documents. They rely on the competitiveness of information related to the preparation of the standards. SRPJ aims to gain insight into the "legislative" history of the ISO tobacco standards. If it is up to ISO and NEN, there can be no question of issuing, in particular draft standards and reports of discussions within the committee, and therefore also no transparency.

10. Standards developed in the context of European standardization are developed from the outset under the supervision and guidance of the Commission. In the case of ISO standards, the international business community involved is the party that initiates, manages and monitors. The ISO standards are thus developed under the predominant influence of the tobacco industry, while it concerns methods for checking whether the tobacco industry complies with the maximum TNCO emission levels from the directive. Revision, amendment and adaptation of ISO standards also falls under the management of the ISO organization. Here too the EU is not involved, or at least there is no EU management and / or explicit delegation in the matter.

11. Another important difference is that European standardization requires a defining link between the basic requirements and the harmonized standards developed for them.[17] The basic requirements in this case are the maximum emission values of Article 3, set to ensure a high level of health protection. This is a public interest that does not necessarily coincide with the private interest of the business community, i.e. the tobacco industry. When determining those values, it must concern substances released during *intended use*.[18] Such a relationship is absent from the standards of the Directive, in fact, the tobacco industry has consistently argued that those standards are not intended or suitable for determining the exposure of smokers.[19] There is therefore no question of "strictly governed by the essential requirements defined by that directive" with ISO standards.

12. Moreover, it becomes clear that, since for the ISO standards supervision and guidance (initiate, manage and monitor) are in the hands of direct stakeholders, the Commission and the European legislator are no more than consumers of (long-existing) products of the ISO,

[16] The Dutch TC 126 now consists exclusively of representatives of the tobacco industry; see point 29 of the Memorial of 14-08-2020

[17] See also, for example, *Elliot*, para. 43, "it is nevertheless a necessary implementation measure which is **strictly governed by the essential requirements** defined by that directive" (emphasis added)

[18] wording from the definition of "emission" in Article 2 (21) of Directive 2014/40 / EU

[19] "VSK therefore wishes to clarify that standardized measurement methods are neither intended nor suitable to accurately measure or approximate the actual emission levels to which individual smokers are exposed, due to the significant differences between smokers, a point raised by the Commission, the ISO standards itself and the World Health Organization is recognized. " (Note VSK, p. 20; see also p. 23 in the Mem. Of 14.8.20)

produced under the direction of the tobacco industry. There is no question of embedding these ISO standards in the European legal order. As a result, the ISO standards lack (European Union) legitimacy, which is reinforced in practice because - for the time being - the ISO standards do not have to comply with, and indeed conflict with, the requirements that apply to harmonized standards, i.e. “transparency”, “openness”, “voluntary application” and “independence from specific interests”.[20] With the present proceedings it becomes clear that ISO and the tobacco industry cannot - nor do they want to - comply with these requirements.

13. The RIVM has also found[21] that the ISO measurement method underestimates the amount of carcinogenic tar, addictive nicotine and carbon monoxide inducing heart and cerebral infarction to a very large extent. As a result, the majority of cigarettes contain two to three times as much TNCO as the European legal maximum. The choice of the European legislator for these ISO measurement methods cannot therefore be regarded as fitting within the margins that public administration has in shaping policy and legislation; on the contrary, it is contrary to the main objective of Directive 2014/40 / EU (high level of health protection) and the other fundamental rights referred to in recital 59 of the preamble to the Directive.

14. The plaintiffs' primary answer to Question 1 of the Court is therefore that *Elliot* and *SAKSA* are relevant because they provide clear leads for comparing ISO standards with European standards and that comparison confirms the plaintiffs' conclusion in the main proceedings that article 4, paragraph 1 of the Directive is non-binding.

15. In the alternative, the following applies. From the overview of differences between European and ISO standards given above, it becomes clear that the latter are (by definition) not embedded in the European legal order. This, while the application of those standards is exclusive and binding. In the *Elliot*-case, these are harmonized standards whose application always only provides a presumption of conformity. The Court held in *Elliott*, in paragraph 40, that a harmonized standard “… forms part of EU law, since it is by reference to the provisions of such a standard that it is established whether or not the presumption laid down in Article 4(2) of Directive 89/106 applies to a given product.” And then the Court considered in paragraph 42: “Although evidence of compliance […] may be provided by means other than proof of compliance with harmonised standards, that cannot call into question the existence of the legal effects of a harmonised standard.” If a harmonized standard, which provides only a presumption of conformity, does indeed have legal effects and is part of EU law, this means that a private standard that has exclusive probative value with the accompanying legal consequences falls *a fortiori* under EU law.

16. This means that the Court is competent and bound to interpret the four ISO standards contained in Article 4 (1) of the Directive. This extends to the content of all other ISO standards including their corresponding *Introduction*, which according to the Article 4

[20] Preamble to recital (2) of Ver. (EU) No. 1025/2012, see also Article 4, Article 15 and Annex II, point 3 under c)
[21] This finding was the reason for this procedure

standards must be fully complied with. Those other standards in turn refer to other ISO standards.

Question 2 - Full publication - Article 10 (6) of Regulation (EU) No 1025/2012

formal
17. The regulation deals with European standardization and defines in Article 2 first "international standard", then "European standard" and then "harmonized standard". The latter is defined as "a *European* standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation" (emphasis added).

18. According to the claimants, the title and text of the regulation therefore provide no basis for the idea that Article 10 (6) also applies to the "international standards" defined separately in the regulation. The opposite would also be inappropriate in this Regulation given the very significant differences between harmonized European and ISO standards discussed above.

material
19. Now that the stipulation of the ISO standards is expressly intended to have legal consequences, it is already from a rule of law point of view necessary to publish the standards in full. Moreover, the principle of transparency and the principle of legal certainty entail this. [22] [23] In fact, these legal consequences do not exist now that the standards have not been published in full.

20. Full publication means that it is not sufficient to publish the four ISO standards included in Article 4 (1). After all, they each refer to other ISO standards which, according to the referring standards, must all be applied in order to guarantee a correct application of the standards referred to in the directive. For example, in each of the four standards reference is made to the smoke machine to be used, which machine is separately standardized in ISO 3308. It is precisely the regime prescribed in ISO 3308 for the use of the machine that is a central point in the criticism of RIVM and WHO TobLabNet on the ISO measuring method. In other words: this ISO standard is also invoked against plaintiffs when their request to enforcement of the maximum emission values of Article 3 of the Directive is rejected. And that applies, claimants must assume, also to the other ISO standards referred to under the four standards in Article 4. It is not up to the plaintiffs to make a choice in this regard, nor is the court equipped to do so. The "organization chart" prepared by the claimants provides - without pretending to be complete - an overview of the relevant other ISO standards that apply here.[24]

[22] See also point 17 on page 8 of the Plaintiffs' Memorandum, including the case law mentioned there: *Heinrich*, 10.03.2009, C-345/06, ECLI: EU: C: 2009: 140, paras. 42 47; see also *Skoma Lux*, 11.12.2007, C 161/06, ECLI: EU: C: 2007: 773, para. 33
[23] See, for example, Emas, Annex II to Reg. (EC) No. 1221/2009 of the Parliament and of the Council of 25.11.2009
[24] See Annex 3 to the Memorial of 14-08-2020

21. Full publication also means that the full text, including the *Introduction*, must be published. After all, it contains a number of restrictions that the drafter of that document imposes on the user of the standard and also the recommendation to test the cigarettes with a different intensity of "inhalation" than that included in ISO 3308.[25] Those limitations and recommendation are part of the Standard to which the guideline refers and the legislator is not free to publish any other document than the one to which the directive refers, let alone a document that does not contain instructions given for the application of the standard.

22. Incidentally, if the EU legislator and / or the European Commission were to make use of the power given in Article 4 (3) for the above, they are not at liberty to provide the ISO standards the force of law including the associated legal consequences. Article 5.3 FCTC opposes this. Since the meaning of Article 5.3 FCTC has already been discussed in detail in this case, this position does not need to be explained in more detail here. For the sake of completeness, claimants point out that in the preamble under (59) it is further recalled that "The application of this Directive should respect Union law and relevant international obligations."[26]

23. In the view of the plaintiffs, the answer to the second question of the Court of Appeal is that the reference in Article 4, paragraph 1 of the Directive to four ISO standards (including the ISO standards that must be applied by virtue of those four) now has no legal consequences. those ISO standards have not been published, and certainly not in full.

final remark

24. Of course, Article 3 of the Directive is and will remain in force, so the enforcement of that norm is still possible, albeit not with the aid of the ISO standards of Article 4 paragraph 1 of the Directive.

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[25] The relevant passage was cited by the District Court of Rotterdam in the judgment of 20-03-2020, point 9.1.

[26] Needless to say: "Article 4. Conduct of organs of a State
1.The conduct of any State organ shall be considered an act of that State under international law, whether the organ exercises legislative, executive, judicial or any other functions, whatever position it holds in the organization of the State, and whatever its character as an organ of the central Government or of a territorial unit of the State. (UN Articles on State Responsibility, para. 1, italics added
https://legal.un.org/ilc/texts/instruments/english/draft_articles/9_6_2001.pdf)