MEMORIAL

in the case C-160/20

1. **Stichting Rookpreventie Jeugd, Amsterdam;**
2. **Mayor and Aldermen of Amsterdam;**
3. **Stichting Inspire2Live, Amsterdam;**
4. **Rode Kruis Ziekenhuis B.V., Beverwijk;**
5. **Stichting ClaudicatioNet, Eindhoven;**
6. **Nederlandse Vereniging voor Verzekeringsgeneeskunde** [Dutch Association for Insurance Medicine]**, Utrecht;**
7. **Accare, Stichting Universitaire and Algemene Kinder- en Jeugdpsychiatrie Noord-Nederland** [North Netherlands General Child and Youth Psychiatry] **(Groningen), Assen;**
8. **Vereniging Praktijkhoudende Huisartsen** [Association of Practicing General Practitioners]**, Amsterdam;**
9. **Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose** [Dutch Association of Physicians for Pulmonary Diseases and Tuberculosis]**, 's Hertogenbosch;**
10. **Nederlandse Federatie van Kankerpatiëntenorganisaties** [Dutch Federation of Cancer Patient Organisations]**, Utrecht;**
11. **Nederlandse Vereniging Arbeids- en Bedrijfsgeneeskunde** [Dutch Association of Occupational and Industrial Medicine]**, Utrecht;**
12. **Nederlandse Vereniging voor Cardiologie** [Dutch Society of Cardiology]**, based in Utrecht;**
13. **Koepel van Artsen Maatschappij en Gezondheid** [Umbrella Organisation of Physicians, Community and Health]**, based in Utrecht;**
14. **Nederlandse Vereniging voor Kindergeneeskunde** [Dutch Association for Paediatrics]**, Utrecht;**
15. **Koninklijke Nederlandse Maatschappij tot bevordering der Tandheelkunde** [Royal Dutch Dentistry Society]**,** Utrecht**;**

plaintiffs in the national proceedings, hereinafter referred to as Rookpreventie Jeugd et al., represented in this case by A.H.J. van den Biesen, attorney practicing in Amsterdam.

against

the State Secretary for Health, Welfare and Sport, defendant

with, as a third party,

the Vereniging Nederlandse Sigaretten- en Kerftabakfabrikanten [Association of Dutch Cigarette and Kerftabak Manufacturers] **(VSK)**

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Background

1. Article 3, paragraph 1 of the Tobacco Products Directive[1] (hereinafter: the Directive) stipulates that:

> "1. The emission levels from cigarettes placed on the market or manufactured in the Member States ('maximum emission levels') shall not be greater than:
>
> (a) 10 mg of tar per cigarette;
> (b) 1 mg nicotine per cigarette;
> (c) 10 mg of carbon monoxide per cigarette."[2]

2. Article 4, paragraph 1 of the Directive stipulates that:

> "1. 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."

   All four of these ISO standards specify the same cigarette-smoking machine, which itself is also standardised in an ISO standard: ISO 3308.

3. The limits of Article 3, paragraph 1 therefore cannot be exceeded. Application of the ISO measurement method prescribed by Article 4, paragraph 1 of the Directive demonstrates that, as a general rule, the tested cigarettes remain below the limits. However, research carried out by RIVM shows[3] that the *actual* emissions are consistently two to three times the legal limits.

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[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 L 127/1, 29.4.2014, p. 1-38.

[2] These are the primary substances related to harm to health; usually abbreviated together as "TNCO"

[3] RIVM, Rijksinstituut voor Volksgezondheid en Milieu [National Institute for Public Health and the Environment], www.rivm.nl

4. In establishing these facts, the District Court relied on RIVM's research, which compared the application of the ISO measurement method outlined in Article 4, paragraph 1 to the application of the Canadian Measurement Method, Canadian Intense (CI), a method that is identical to the standard developed by the World Health Organisation's (WHO) TobLabNet "WHO TobLabNet SOP 01" (SOP 01).[4] [5]

5. SOP 01 and CI use the cigarette-smoking machine mentioned in paragraph 2, ISO 3308. However, the *usage scheme* that was applied differs in two respects from the *usage scheme* outlined in the ISO standards:
    - the applied intensity of a pull and the frequency of inhaling and the interval between two pulls are higher;
    - the ventilation holes in the cigarette filters are taped during measurement.[6]

6. In 2018, RIVM applied the above-mentioned CI/SOP 01 usage scheme and concluded that:

    > "No cigarette contained less tar, nicotine or carbon monoxide than was measured using the ISO method. With the exception of one cigarette, all measured TNCO values are above the legal limits. The results of this study support the conclusion that the prescribed ISO method underestimates the amounts of TNCO a smoker ingests. The committee that developed this method was significantly influenced by the tobacco industry. Therefore, RIVM argues that, instead of the ISO method, an independent measurement method should be included in the law, such as the WHO TobLabNet method. (**Appendix 1**)[7]

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[4] WHO TobLabNet Official Method SOP 01, Standard operating procedure for intense smoking of cigarettes https://apps.who.int/iris/bitstream/handle/10665/75261/9789241503891_eng.pdf;isessionid=E33C6BFA38F1C09F468C08671FF58074?sequence=1

[5] RIVM initially used Canadian Intense and SOP01 interchangeably, and over time began to exclusively refer to the WHO TobLabNet SOP 01 standard.

[6] SOP 01, see para. 12 Cigarette preparation

[7] 12/6/2018, RIVM press release: https://www.rivm.nl/nieuws/rivm-meet-veel-hogere-waarden-van-teer-nicotine-en-koolmonoxide-in-sigaretten; *English version*, https://www.rivm.nl/en/news/rivm-measures-much-higher-levels-of-tar-nicotine-and-carbon-monoxide-in-cigarettes; retrieved 16/7/2020 at 5:45 p.m.

7. The authority in charge of enforcement, the NVWA[8], has not contested the accuracy of the RIVM conclusions, nor does the State Secretary responsible for the NVWA and RIVM, the defendant in the national proceedings.

8. The District Court of Rotterdam referred to an RIVM table that included 11 cigarettes studied by RIVM.[9] The complete overview of the 100 studied cigarette brands that was published by RIVM (**Appendix 2**)[10] makes it clear that 99 of them contain values that are two to three times higher than the legal limits.

9. These higher emission values mean that the risk of cancer (due to tar) and cerebral infarction (due to carbon monoxide) is considerably higher than the legal limits, and that also applies to the addictive effect (nicotine). The increased addictive effect leads to earlier and faster addiction among young people in particular and to stronger addiction for all smokers.

10. With Article 3, paragraph 1, the European legislature did not intend for the TNCO ceilings to be loosely interpreted. On the contrary, the legislature addresses the "high level of health and consumer protection" defined and expressed in milligrams, which the Directive aims to *guarantee*[11]. Rookpreventie Jeugd would also like to point out that this emission level is not a "healthy" level, either; there is no such thing as "healthy smoking".

11. Those limits were lowered in the 1990s from 15-1-15, to 12.5-1.25-12.5, then to 10-10-10 (in the forerunner of the current directive) for emissions of tar, nicotine and carbon monoxide, respectively. The Directive defines emissions as "substances that are released when a tobacco product... *is consumed as intended*...".[12]

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[8] NVWA. Nederlandse Voedsel- en Warenautoriteit [Netherlands Food and Consumer Product Safety Authority], www.nvwa.nl

[9] Judgment by the District Court of Rotterdam dated 20.3.2020, ROT 19/1249, ECLI:NL:RBROT:2020:2382, point 10.2.

[10] RIVM measurement results: SOP 01 measurement compared to ISO
https://www.rivm.nl/sites/default/files/2018-11/Tabel%20resultaten_ratio_kleur_DEF.pdf

[11] See, inter alia, recital (59) of the Preamble to the Directive

[12] Article 2, point 21 of the Directive, italics added

12. Tobacco producers have known for years that, in practice, the smoker ingests two to three times as much TNCO as the maximum values stipulated by Article 3, paragraph 3. VSK, the "third party", told the District Court of Rotterdam, through their Director Strater:

> "We are open to new measurement methods, Canadian Intense is just one. If that becomes the new standard, that is fine. But *then other emission values will also be needed, tailored to the new test"*.[13]

The tobacco industry does not deny the accuracy of RIVM's findings, and VSK is therefore of the opinion that the tobacco industry is even "entitled" to the current substantial exceedance of the legal limits. It is apparently considered normal by the tobacco industry that smokers are currently ingesting two to three times as many harmful substances as is legally permitted, and also that the current addictive strength of the inhaled nicotine, which is two to three times higher, should remain if another measurement method is chosen. This amounts to the tobacco industry's desire to legalise the current exceedences, thereby increasing the legal 10-1-10 limits to 20-2-20 or even 30-3-30.

13. For Rookpreventie Jeugd et al., the aim of these proceedings is for the maximum emission levels outlined in Article 3, paragraph 1 of the Directive (10-1-10) to be effectively enforced and for the measurement method specified in Article 4, paragraph 1, to no longer be considered the decisive measurement method. The ineffectiveness of Article 4, paragraph 1 is at stake in this case.

14. The individual questions[14] posed by the District Court are discussed successively below. Rookpreventie Jeugd et al. requests that the Court of Justice read their responses to each question in relation to the responses they have provided to the other questions.

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[13] Source: the official record of the hearing before the District Court of Rotterdam on 11/11/2019, italics added. J.H.J.M. Strater is the director of the VSK, third interested party in the national proceedings.

[14] Judgment by the District Court of Rotterdam dated 20.3.2020 (see note 9), point 12.

Question 1

15. The regulation outlined in Article 4, paragraph 1 of the Tobacco Products Directive consists - materially speaking - of the contents of the four listed ISO standards. This provision was raised as an objection against Rookpreventie Jeugd when they requested that the limits in Article 3, paragraph 1 be enforced.

16. In Article 4, paragraph 1, only the *numbers* of four ISO standards are printed, which, in itself, is not enough information to enable one to know and appreciate this "law". But ISO standards are not published and can only be obtained from standardisation organizations for a substantial price.[15] Moreover, each ISO standard always refers in its regulations to a handful of other ISO standards, which must also be complied with and purchased separately. To illustrate this, a sort of organogram of ISO standard 4387 (tar) has been attached to this Memorial, which easily lists dozens of offshoot ISO standards to be consulted (**Appendix 3)**.[16]
    ISO 3308, the cigarette-smoking machine that is central in this case, is "prescribed" in the four ISO standards listed in Article 4, paragraph 1, but is invisible in the Directive itself.

17. A proper publication of the *content* of the relevant ISO standards did not occur. The Court of Justice ruled in 2007 that:

> "44 The principle of legal certainty requires that a Community regime must enable the parties concerned to precisely ascertain the extent of the obligations which it imposes on them. Individuals must unequivocally be able to know their rights and obligations and to make provisions accordingly (judgment in Case C-158/06 ROMprojecten [2007] ECR pp. 1-5103, paragraph 25, and the case-law cited therein).[17]

    It is difficult to see how Article 4, paragraph 1 meets these requirements of the principle of legal certainty. This is especially true insofar as the use of ISO-3308 is prescribed in this provision.

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[15] more than 100 euros, per standard

[16] ISO 4387 (tar); can be purchased at: https://www.iso.org/standard/76549.html, retrieved 3/8/2020

[17] Judgment dated 10.3.2009, Heinrich, C-345/06, ECLI:EU:C:2009:140, paragraphs 42 47; see also the judgment dated 11.12.2007, Skoma Lux, C 161/06, ECLI:EU:C:2007:773, paragraph 33.

18. The simple elevation to law of a strictly *private* standard, the creation of which has been completely concealed from public view and whose official "legal history" is not accessible to the public, is contrary to the general principles of the process of European regulation, including the "right of access to the documents of the institutions, bodies, offices and agencies of the Union"[18] as well as the principles of openness and transparency.[19]

19. By way of contrast, the European standardisation bodies produce standards that are created through a procedure regulated by EU regulations in order to meet good governance requirements[20]. The Commission fills *ex ante* a coordinating and supervisory role in that process. There are no such features and guarantees involved in the creation of the private ISO standards.

Response to Question 1

20. Prescribing a measurement method, including cigarette-smoking machine, in Article 4, paragraph 1 of the Directive by simply mentioning ISO standards is contrary to the principle of legal certainty, the principle of openness and transparency and to the citizen's right of access to (legislative) information. This provision is contrary to the provisions of Article 297, paragraph 1 of the TFEU (and Regulation (EU) No. 216/2013) and Article 12, paragraph 2 of Regulation (EU) No. 1049/2001.

[18] Charter of Fundamental Rights of the European Union, Article 42 and Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145/43, 31.5.2001, p. 43-48. See in particular the second paragraph of Article 12 on access to legislative documents.

[19] Article 15, paragraphs 1 and 3 of the TFEU

[20] Regulation (EU) No. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, OJ L 316, 14.11.2012, p. 12-33. See e.g. Articles 3, 4 and 5, 6 on transparency and stakeholder participation, respectively.

Question 2

21. If, in the verification of Article 4, paragraph 2 first sentence, the legally prescribed method is followed, then all assessed cigarettes remain below the limits of Article 3, paragraph 1, see **Appendix 4**[21]. But the reality is completely different. As can be seen above (see paragraphs 4 to 8), this is partly due to the ventilation holes in the cigarette filters. As a result, the cigarette-smoking machine measures highly diluted smoke. Neither the number of holes nor the pattern in which they are produced is regulated in the Directive, not even in the ISO standards. The RIVM study illustrates that the amount of TNCO that the smoker *actually* ingests is considerably higher than ISO measurements indicate. Firstly, the smoker blocks a significant number of holes with their fingers and lips, decreasing the applied dilution and increasing the amount of harmful substances being inhaled. If the smoke is still diluted on inhalation, the smoker compensates for this by inhaling more vigorously and with a higher frequency, thus ingesting a heavier dose, which also causes a more severe type of cancer.[22]

22. In other words, the use of the ISO 3308 cigarette-smoking machine standard, which does not allow for holes to be masked and applies much less intense simulated smoking behaviour, is not suitable for determining whether or not the average smoker inhales more than the TNCO maximum *with intended use*. Applying the ISO measurement method therefore does not provide valid results to answer the question whether the limits of Article 3, paragraph 1 are being respected.

23. The tobacco industry acknowledges this, and at the beginning of these proceedings, they made statements in the media saying that

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[21] TNCO values for cigarettes 2017 - appendix to the Government Information (Public Access) Decree dated 15/3/2019 - Verification by RIVM, carried out in accordance with the ISO method outlined in Article 4, paragraph 1

[22] see, among others: Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma, Miv-Ae Song and 10 others, JNCI Journal of the National Cancer Institute, 22/5/2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6059254/. last retrieved 9/8/2020; also mentioned in the national proceedings: Judgment by the District Court of Rotterdam dated 20.3.2020 (see footnote 9), paragraph 6.2.

"...the EU measurement method [was] never developed to measure 'the actual exposure' of smokers to tar, nicotine and carbon monoxide. "The method is intended to make comparisons between cigarette brands that are smoked in an identical manner. ""[23]

24. The use of *European* standardisation standards does not count as *proof* of conformity, but only as a *presumption* of conformity[24]. That means there may be proof to the contrary. A similar possibility is not explicitly given for the four ISO standards in Article 4, paragraph 1 in the Directive, but the ISO standards themselves leave room for this. In paragraph 9.1, the District Court of Rotterdam quotes the preliminary considerations of ISO 3308, which recommend "that cigarettes also be tested under conditions of a different intensity of machine smoking than those specified in this International Standard".[25]

25. The inclusion of the ISO standards in the Directive makes them part of European law and therefore open to interpretation by the Court.[26] In that case, the Court may or perhaps even must also interpret the ISO standards in Article 4, paragraph 1, including ISO 3308. Rookpreventie Jeugd et al. therefore believe, following in the footsteps of RIVM, that the WHO TobLabNet SOP 01 should at least be used as a control standard.[27]

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[23] Trouw [Newspaper], 31/7/2018, https://www.trouw.nl/nieuws/patienten-en-medici-eisen-verbod on-cheat cigarette~bb9df1_led/

[24] See paragraphs 5, 29, 49 and 50 of the preamble to Regulation (EU) No. 1025/2012 of the European Parliament and of the Council of 25/10/2012, https://eur-lex.europa.eu/legal=content/NL/TXT/PDF/?uri:CELEX:32012R1025&from=NL.

[25] Judgment by the District Court of Rotterdam dated 20/3/2020 (see note 9), paragraph 9.1.

[26] See also the judgment dated 27/10/2016, James Elliot Construction, C-613/14, ECLI:EU:C:2016:821, paragraphs 34-40, http://curia.europa.eu/juris/document/document.jsf?text=&docid=18489l&pagelndex^O&doclang^NL&modeHst&dir=&occ=first&part=l&cid=10872861; that judgment concerns standardisation standards

[27] RIVM goes beyond a control measurement: "The results of this study support the conclusion that the prescribed ISO method underestimates the amounts of TNCO that a smoker ingests (...) Therefore, instead of the ISO method, RIVM advocates inserting an independent measurement method in the law, such as the WHO TobLabNet method," https://www.rivm.nl/nieuws/rivm-meet-veel-hogere-waarden-van-teer-nicotine-en-koolmonoxide-in-sigaretten.

Response to Question 2

26. Article 4, paragraph 1 of the Directive must be interpreted and applied in such a way that the emissions of tar, nicotine and carbon monoxide must not only be measured and verified using the prescribed method, but also that control measurements must be carried out using a valid method.

Question 3a

27. The underlying principle of the Directive is that legislative acts must always be based on a high level of public health protection.[28] This is neither an obligation of conduct nor an obligation of result, but a guaranteed starting point.[29] In that regard, Article 24, paragraphs 2 and 3 of the Directive state that "...the high level of protection of public health established by this Directive" shall be taken into account. Article 3, paragraph 1, translates the guaranteed high level of public health protection into caps on tar, nicotine and carbon monoxide emissions set at 10, 1 and 10 mg per cigarette respectively. "Emissions" refers to substances released during "intended use".[30] In the context of the high level of public health protection, it therefore refers to the amount of these harmful substances that people ingest when they smoke.

28. The ISO method, which has been elevated to legal status in Article 4, paragraph 1, does not provide emissions data at "intended use", which renders effective enforcement of the maximum TNCO values impossible. See more under question 3b, which primarily concerns the role of the tobacco industry and its consequences for the meaning of Article 4, paragraph 1.

29. To say that the tobacco industry played a role in setting the relevant ISO standards is an understatement:

[28] see recitals 8, 36, 43 and 54 in the Preamble to the Directive

[29] see also recital 59 in the Preamble to the Directive

[30] Article 2 of the Directive, under 21

- the tobacco industry has - and has had from the beginning - a predominant influence in the development of the relevant ISO standards (**Appendix 5**)[31]; the Dutch NEN tobacco committee claims in its 2018 Committee Plan to have had a decisive influence on the ISO process. This committee consists exclusively of representatives of the tobacco industry.[32] The "independent" Chairman of the committee worked for Phillip Morris prior to his retirement and was already on this committee at that time;
- The cigarette-smoking machine (ISO 3308) prescribed by the ISO standards in Article 4, paragraph 1, was developed by Coresta, the scientific institute of the tobacco industry. Coresta also developed the tobacco ISO standards.[33]

30. Article 4, paragraph 2 of the Directive defines the qualifications for verification laboratories. RIVM is the only laboratory in the Netherlands certified for this purpose. However, RIVM is not at liberty to actually investigate, on the basis of its expertise, whether the cigarettes sold in the Netherlands meet the high level of public health protection guaranteed by the Directive in Article 3, paragraph 1; RIVM is bound by the four ISO standards, including ISO-3308. Consequently, when applying Article 4, paragraph 1, there is no way for RIVM to escape or oppose direct, let alone indirect, control by the tobacco industry. After all, the verification process itself is, as a whole, directly or indirectly controlled by the tobacco industry with the prescribed ISO measurement method.

31. The fact that following the law leads to a serious underestimation of the amount of TNCO that the smoker ingests (with "intended use") was demonstrated by RIVM in its 2018 study, for which it used its independent expertise and carried out the verification according to the CI / SOP 01 method.[34]These truly independent measurements demonstrate that the 100 verifications that were carried out yielded only one cigarette that fell within the maximum TNCO values. The TNCO values for the rest of the cigarettes tested were two to three times the permitted maximum.

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[31] 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://pubmcd.nebi.nlm.nih.gov/l1387528/

[32] 2019 Committee Plan, https://docplaver.nl/l45999387-Commissieplan-2019-normcommissie-tabak-en-tabaksproducten.html

[33] See Appendix 5 and footnote 31

[34] See introduction above, paragraphs 3 to 5

32. The prescribing of ISO standards in Article 4, paragraph 1 therefore automatically leads to a conflict with Article 4, paragraph 2, second sentence of the Directive: the independence of the verification envisaged in this paragraph 2 is nothing more than illusion from the outset, thanks to compulsion of technical regulations that happen to be completely designed, *nota bene*, by the group being regulated.

33. Question 3a also relates to Article 5.3 of the WHO Framework Convention on Tobacco Control (hereinafter: FCTC), to which both the European Union and all EU Member States are parties.[35] The preamble of this convention states, among other things:

> "*Recognizing also* that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,
> …
> *Recognizing* the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts, ..."

and Article 5, paragraph 3 stipulates that:

> "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

[35] World Health Organisation Framework Convention on Tobacco Control, signed in Geneva on 21 May 2003 ('the WHO Convention'), approved by Council Decision 2004/513/EC of 2 June 2004 (OJ 2004 L 213, p. 8), PB L 213/8 of 15.6.2004, p. 8-11.

tobacco industry in accordance with national law."[36]

34. Establishing maximum emission levels in Article 3, paragraph 1 and making arrangements to monitor tobacco industry compliance in Article 4, paragraphs 1 and 2 are both covered by "setting and implementing their public health policies with respect to tobacco control". The ISO measurement method outlined in Article 4 paragraph 1 is, according to the tobacco industry, also intended to compare cigarette brands, but not to verify that the tobacco industry complies with the limits set out in Article 3, paragraph 1. Given that the design of that measurement method, including the cigarette-smoking machine and its associated usage scheme, originated in the tobacco industry, its inclusion in this Directive should be considered an ultimate violation of Article 5, paragraph 3 of the FCTC. The RIVM study illustrates the significant deviations from the guaranteed high level of public health protection that this ultimate violation leads to.[37]

35. Rookpreventie Jeugd et al. realise that a question could be raised here about the direct effect of Article 5, paragraph 3 of the FCTC, but in this case, that seems to be an academic discussion. After all, the European legislature's choice in favour of ISO standards unfortunately cannot be qualified as "to act to protect these policies...", but is more in line with "to act to *subordinate* these policies to commercial and other vested interests of the tobacco industry". It seems undeniable that this constitutes a serious and complete violation of the EU's obligation to protect its own policies from influence by the tobacco industry. Apart from this, the Directive also seems to be based on the idea that further legislation is not necessarily necessary for Article 5, paragraph 3, since this subject does not appear in recital 7 of the preamble nor in the listing included in Article 1 of the Directive. In any case, the text of Article 5.3 is sufficiently concrete and unconditional to be able to conclude, without further regulation, that this treaty obligation has been violated.

36. When the predecessor of the current directive was established, the FCTC did not exist. That predecessor was repealed by Article 38 of the current directive. When the current directive was drafted, the FCTC had been in force for nearly ten years.

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[36] The English language is one of the authentic languages of the Convention, see Article 38 FCTC

[37] See Background, paragraph 3

Response to Question 3a

37. = Article 4, paragraph 1 is contrary to the basic principle of the Directive that it guarantees a high level of public health protection, since the ISO measurement method is not designed to measure emissions in intended use, nor does it do so.
= The fact that the tobacco industry designed the measurement method, including the corresponding cigarette-smoking machine, of Article 4, paragraph 1
makes the independence of verification envisaged by Article 4, paragraph 2 nothing more than illusion from the outset, which means that Article 4, paragraph 1 conflicts with Article 4, paragraph 2; and
makes its inclusion in the Directive an ultimate violation of Article 5, paragraph 3 of the FCTC.

Question 3b

38. The emissions capped in Article 3, paragraph 1 relate to "substances released when a tobacco product or related product is *used as intended*"[38] RIVM concludes that the ISO method "does not provide an accurate picture of the amount of TNCO actually ingested by smokers"[39] and that a measurement method that much more closely approximates 'intended use' demonstrates that the maximum emissions in Article 3, paragraph 1 are exceeded by 100% to 200%. This hits the heart of the Directive: the guaranteed, high level of protection is not being achieved. The provisions in Article 4, paragraph 1 in fact constitute the opposite of guaranteeing the high level of protection for public health.

39. The Directive, Article 114, paragraph 3 of the TFEU and Article 35 of the Charter consider and reiterate that legislative acts must always ensure a high level of protection of public health. When it comes to the use of cigarettes, that high level of protection is defined in the

[38] Article 2 of the Directive, under 21, italics added
[39] RIVM website, 'Measurement methods for TNCO', paragraph 2, https://www.rivm.nl/tabak/filterventilatie/meetmethoden-voor-tnco.

maximum emissions values for tar, nicotine and carbon monoxide. Application of the ISO standards does not provide a picture of what a smoker is inhaling. Nor are the standards intended to capture emissions under "intended use" conditions. Application of the ISO standards merely gives the appearance that the cigarettes verified using their methods remain below the limits, while in reality they have been found to very seriously exceed those limits. Both SOP 01 and CI were designed to come as close as possible to what the average smoker inhales.

40. The *Dyson* case addressed how the energy efficiency of vacuum cleaners is measured and the question of what the phrase "during use" meant for that measurement. The Court found that the element "during use" when measuring energy consumption was an essential part of the relevant directive. The Court therefore ruled that the Commission was obliged ".... to opt for a method of calculation capable of measuring the energy performance of vacuum cleaners *in conditions as close as possible to actual conditions of use*".[40] In our case, it is clear that ensuring a high level of health protection is the basis of the Directive and that in that context capping TNCO values plays the leading role. These emission caps are an essential part of the Directive, which is demonstrated by the fact that the Commission has not been empowered in the Directive to adopt delegated acts (with the exception of *lowering* the ceilings) on this point. The "emissions" are defined in the Directive in terms of "intended use", which refers to the inhalation of cigarette smoke by humans. Given the definition in the Directive, it is in line with the approach developed by the Court in Dyson to choose a measurement method that comes as close as possible to the intended use. RIVM found that the ISO method seriously underestimates the amount of TNCO the smoker ingests, and concluded that, for example, the WHO TobLabNet standard should be the preferred measurement method.[41]

41. It has already been established that the right to life is at stake in regulating smoking that leads to premature death for more than half of smokers. Since 9 December 1994, the

[40] Judgment dated 11/5/2017, Dyson Ltd v European Commission, C-44/16 P, ECLI:EU:C:2017:357, paragraph 68. http://curia.europa.eu/juris/document/document.jsf?text=&docid=190587&paaeindex=0&doclang-nl&mode=lst&dir=&occ=first&part=&cid=11529674 (italics added)
[41] See **Appendix 1** and

European Court of Human Rights has handed down a long series of judgements in which insufficiently effective action was taken against life-threatening situations and activities.[42] *Öneryildiz v. Turkey* is still a leading precedent for that Court.[43] With regard to the necessary arrangements to be made, the Human Rights Court found, in paragraph 90, that it "must make it compulsory for all those concerned to take practical measures to ensure the effective protection of citizens whose lives might be endangered by the inherent risks". The intended protection must therefore be effective.

42. In short, the Charter stipulates that the scope of the rights in the European Convention on Human Rights[44] sets the bottom limit for the scope of the fundamental rights regulated in the Charter.[45]

43. The FCTC, Article 24 of the Charter and the Directive itself put the importance of young people's health first. This is certainly appropriate to this topic given that two thirds of smokers start smoking well before the age of 19 and that young people become addicted far more quickly than adults. More than half of the number of smokers die prematurely as a result of smoking. That fact is the raison d'être for Rookpreventie Jeugd and the spearhead for the city of Amsterdam's anti-smoking policy. This extra attention being paid to the interests of young people is incompatible with the fact that legally sold cigarettes contain two to three times as many addictive substances as permitted by Article 3, paragraph 1.

Response to Question 3b

44. = Part a) of the response to Question 3a also serves as the answer to Question 3b.
= The identified inconsistency applies not only to the principles of the Directive, but also to Article 114, paragraph 3 of the TFEU, the scope of the WHO Framework Convention on Tobacco Control and Articles 24 and 35 of the Charter. Moreover, this violation also constitutes a violation of Articles 2 and 7 of the Charter.

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[42] López Ostra v. Spain, no. 16798/90, 9 December 1994, Guerra and Others v. Italy, no. 14967/89, 19 February 1998 and Öneryildiz v. Turkey [GC], no. 48939/99, 30 November 2004.
[43] See previous footnote
[44] European Convention for the Protection of Human Rights and Fundamental Freedoms, Articles 3 and 8, in the Charter, Articles 2 and 7, respectively
[45] Charter, Article 52, paragraph 3

Question 4a

45. This question is based on the assumption that the conclusions of the Court of Justice will mean that Article 4, paragraph 1 will no longer be applied, at any rate – in the case of question 2 – not exclusively be applied. It is obvious that the WHO TobLabNet SOP 01 standard must then be chosen, given that the RIVM study, the basis of the national proceedings, is essentially based on the application of the Canadian Intense method, which is identical to the WHO TobLabNet SOP 01 standard. No serious criticisms have been levied against the RIVM study, not even by the tobacco industry. The WHO recently published an Information Sheet that includes the content, background and purpose of SOP 01 (**Appendix 6**).[46]

Response to Question 4a

46. WHO TobLabNet SOP 01.

Question 4b

47. The VSK has combined their explicit non-refuting the accuracy of the RIVM findings with their statement that applying a different measurement method entails adjusting (read: increasing) the maximum values of Article 3, paragraph 1. But that is impossible, given that the limits of Article 3, paragraph 1 are the expression of what the EU legislature has established and guarantees as a high level of protection of public health. It is not possible to see how such a fundamental protection of public health could be, let alone must be weakened if a measurement method that simply complies with the law (Article 2, paragraph 21 of the Directive) were to come into force. In this case, therefore, only the consequences for the ISO method of measurement are at stake.

[46] WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products, https://www.who.into/publications/i/item/WHQ-HEP-HPR-2020.1

48. A negative answer to question 1 and/or question 3a) and/or 3b) should not lead to the invalidation of the entire Directive, but only to a partial invalidation, since the specific measurement method is not a defining element for the fate of the Directive[47] (question 4a addresses the situation that would arise as a consequence).

49. Another relevant point here is that the measurement method of Article 4, paragraph 1 has been considered non-essential by the legislature. Indeed, the Directive explicitly provides the Commission with the power to adopt delegated acts in accordance with Article 27. This power is based on Article 290 of the TFEU[48], which only "supplements or amends certain non-essential elements of the legislative act".[49] On the other hand, it is clear that the Commission does not have the power to raise the limits set out in Article 3, paragraph 1; decreasing them is permitted.[50] These maximum limits are therefore, unlike the measurement method, an essential part of the Directive. This also goes without saying, since the EU legislature has defined the high level of protection of public health by setting maximum levels. This status obviously does not apply to a measurement method.

50. The answers to questions 1 and 3a and 3b as discussed here should therefore, in the opinion of Rookpreventie Jeugd et al., lead to the invalidation of Article 4, paragraph 1.
The answer to question 2 as discussed here does not lead to the invalidation of Article 4, paragraph 1, because in that case, the Court interprets the meaning of the four ISO standards, including ISO 3308, in such a way that a control verification must always be carried out using a measurement method that fits within the Directive's definition of intended use. In the latter case, cigarettes can only be brought to market if both verifications produce results that are below the limits of Article 3, paragraph 1.

51. Thus, the approach expressed in the previous point leads to a situation in which the immediate consequence of answering the questions is that there is no longer a measurement method, or that there is an absence of a control measurement method, respectively. At that point, the Commission will have to, if necessary at the instruction of the Court, exercise its

[47] Judgment dated 11/12/2008, *Commission of the European Communities vs. Département du Loiret and Scott SA*, C-295/07, ECLI:EU:C:2008:707, paragraphs 104-106
[48] See also recital (51) of the preamble to the Directive
[49] Article 290, paragraph 1 of the TFEU
[50] Article 3, paragraph 2 of the Directive

power under Article 4, paragraph 3 of the Directive in order to immediately, or at a time determined by the Court, fill that gap by adopting delegated acts.

Response to Question 4b

52. If the Court's answer to question 4a means that the Directive no longer contains a definition of a primary measurement method, or that a control measurement method is lacking, the Commission will need to adopt the necessary delegated acts pursuant to Article 4, paragraph 3 immediately, or at least at a time to be determined by the Court.

Overview of all responses proposed by Rookpreventie Jeugd et al.

Response 1

53. Prescribing a measurement method, including cigarette-smoking machine, in Article 4, paragraph 1 of the Directive by simply mentioning ISO standards is contrary to the principle of legal certainty, the principle of openness and transparency and to the citizen's right of access to (legislative) information. This provision is contrary to the provisions of Article 297, paragraph 1 of the TFEU (and Regulation (EU) No. 216/2013) and Article 12, paragraph 2 of Regulation (EU) No. 1049/2001.

Response 2

54. Article 4, paragraph 1 of the Directive must be interpreted and applied in such a way that the emissions of tar, nicotine and carbon monoxide must not only be measured and verified using the prescribed method, but also that control measurements must be carried out using a valid method.

Response 3a

55. = Article 4, paragraph 1 is contrary to the basic principle of the Directive that it guarantees a high level of public health protection, since the ISO measurement method is not designed to

measure emissions in intended use, nor does it do so.
= The fact that the tobacco industry designed the measurement method, including the corresponding cigarette-smoking machine, of Article 4, paragraph 1
makes the independence of verification envisaged by Article 4, paragraph 2 nothing more than illusion from the outset, which means that Article 4, paragraph 1 conflicts with Article 4, paragraph 2; and
makes its inclusion in the Directive an ultimate violation of Article 5, paragraph 3 of the FCTC.

Response 3b

56. = Part a) of the answer to question 3a also serves as the answer to question 3b.
= The identified inconsistency applies not only to the principles of the Directive, but also to Article 114, paragraph 3 of the TFEU, the scope of the WHO Framework Convention on Tobacco Control and Articles 24 and 35 of the Charter. Moreover, this violation also constitutes a violation of Articles 2 and 7 of the Charter.

Response 4a

57. WHO TobLabNet SOP 01.

Response 4b

57. If the Court's answer to question 4a means that the Directive no longer contains a definition of a primary measurement method, or that a control measurement method is lacking, the Commission will need to adopt the necessary delegated acts pursuant to Article 4, paragraph 3 immediately, or at least at a time to be determined by the Court.

Amsterdam, 14 August 2020

A.H.J. (Phon) van den Biesen,
Attorney for Rookpreventie Jeugd et al.

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APPENDICES - pages 23-47

1. RIVM Press Release, Dutch + English: https://www.rivm.nl/nieuws/rivm-meet-veel-hogere-waarden-van-teer-nicotine-en-koolmonoxide-in-sigaretten, https://www.rivm.nl/en/news/rivm-measures-much-higher-levels-of-tar-nicotine-and-carbon-monoxide-in-cigarettes, retrieved: 16/7/2020

   Memorial, p. 5, paragraph 6

2. RIVM – TNCO Table of measurement results, https://www.rivm.nl/documenten/tabel-meetresultaten-tnco-op-volgorde-van-ratio-in-teergehalte. retrieved: 2/8/2020

   Memorial, p. 6, paragraph 8

3. "Organogram", created by Rookpreventie Jeugd et al. based on ISO 4387 (tar); purchase via: https://www.iso.org/standard/76549.html, retrieved: 2/8/2020

   Memorial, p. 8, paragraph 16

4. TNCO values for cigarettes 2017 – appendix to the Government Information (Public Access) Decree dated 15/3/2019, received by Rookpreventie Jeugd Act - Verification by RIVM, carried out using the ISO method in Article 4, paragraph 1 and paragraph 2, first sentence

   Memorial, p. 10, paragraph 21

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/

   Memorial, p. 13, paragraph 29

6. 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: 11/8/2020

   Memorial, p. 19, paragraph 45

Appendix 1

RIVM meet veel hogere waarden van teer, nicotine en koolmonoxide in sigaretten

Publicatiedatum 12-06-2018 | 00:00

Teer, nicotine en koolmonoxide (TNCO) gehalten die gemeten worden volgens de Canadian Intense (CI) methode zijn minimaal twee keer zo hoog als de gehalten gemeten met de wettelijke voorgeschreven ISO methode. In sommige gevallen liggen de gehaltes die met de CI methode zijn gemeten zelfs tot meer dan 20 keer hoger dan die gemeten met de ISO methode. Dat blijkt uit onderzoek van het RIVM, dat 100 sigaretten onder de loep nam met behulp van de Canadian Intense methode.

Dit onderzoek is uitgevoerd vanwege de discussie over de meetmethode die wordt gebruikt bij het meten van de waarden van teer, nicotine en koolmonoxide (TNCO) in sigaretten. Deze worden tot nog toe gemeten met de voorgeschreven ISO-meetmethode, in overeenstemming met de Europese tabaksproductenrichtlijn. Deze ISO-methode geeft echter een onderschatting van de werkelijke hoeveelheden TNCO die rokers binnenkrijgen. Dit wordt onder andere veroorzaakt doordat de te meten rook wordt gemengd met lucht die wordt aangezogen door de ventilatiegaatjes die in het filter van de sigaret zijn aangebracht. Een meer realistische methode is de Canadian Intense methode, waarbij deze gaatjes worden afgeplakt.

Met dit onderzoek heeft het RIVM van 100 merkvarianten sigaretten de waarden van teer, nicotine en koolmonoxide met de Canadian Intense methode gemeten. Deze resultaten zijn vergeleken met de TNCO waarden die de producenten en importeurs hebben gerapporteerd, en die zijn gemeten met de voorgeschreven ISO-methode.

De gemeten teergehaltes met de CI methode zijn 2 tot 26 keer hoger dan werd gemeten met de ISO-methode. Voor nicotine en koolmonoxide liggen de gehaltes respectievelijk 2 tot 17 en 2 tot 20 keer hoger met de CI methode. Opvallend is dat de grootste verschillen tussen de twee meetmethoden worden gevonden voor sigaretten waarbij met de ISO-methode relatief lage TNCO waarden worden gemeten. Deze lage TNCO waarden uit de ISO-methode worden vooral veroorzaakt door een hoge mate van filterventilatie. Omdat bij de CI-methode de filtergaatjes worden geblokkeerd, heeft de mate van filterventilatie geen invloed op de meetresultaten. Hierdoor zijn bij deze methode de verschillen in TNCO gehalten tussen merkvarianten kleiner.

Geen enkele sigaret bevatte bij de meting minder teer, nicotine of koolmonoxide dan werd gemeten met de ISO-methode. Op die van één sigaret na, komen alle gemeten TNCO waarden boven de wettelijk vastgestelde maxima uit.

De resultaten van dit onderzoek ondersteunen de conclusie dat de voorgeschreven ISO methode een onderschatting geeft van de hoeveelheden TNCO die een roker binnenkrijgt. De commissie die deze methode opgesteld heeft wordt in grote mate beïnvloed door de tabaksindustrie. Daarom pleit het RIVM ervoor om in plaats van de ISO methode een onafhankelijke meetmethode op te nemen in de wet, zoals die van WHO TobLabNet.

Meer informatie

- Meetresultaten van TNCO

This news in English

- WHO Collaborating Centre for Tobacco Product Regulation and Control (English)
- RIVM measures much higher levels of tar, nicotine and carbon monoxide in cigarettes

Appendix 1

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Ministerie van Volksgezondheid, Welzijn en Sport

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Home › News › RIVM measures much higher levels of tar, nicotine and carbon monoxide in cigarettes

RIVM measures much higher levels of tar, nicotine and carbon monoxide in cigarettes

Publication date 06/12/2018 - 00:00

Tar, nicotine and carbon monoxide (TNCO) levels measured in accordance with the Canadian Intense (CI) method are at least twice as high as the levels measured in accordance with the prescribed ISO method. In some cases, the levels measured with the CI method are even more than 20 times higher than those measured by the ISO method. This is the result of research by RIVM, examining 100 cigarettes using the Canadian Intense method.

This study was conducted because of the discussion about the measurement method used to measure the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes. Up to now, these levels were measured using the prescribed ISO measurement method, in accordance with the European Tobacco Products Directive. However, this ISO method underestimates the actual amounts of TNCO that smokers ingest. This is caused, among other things, by the fact that the measured smoke is mixed with air that is sucked in via the ventilation holes in the filter of the cigarette. A more realistic method is the Canadian Intense method; in this method these holes are taped closed.

In this study, RIVM measured the tar, nicotine and carbon monoxide levels of 100 brands of cigarettes using the Canadian Intense method. These results were compared with the TNCO levels reported by the manufacturers and importers, which were measured using the prescribed ISO method.

The measured tar contents with the CI method are 2 to 26 times higher than was measured bythe ISO method. For nicotine and carbon monoxide, the levels are respectively 2 to 17 and 2 to 20 times higher with the CI method. It is striking that the largest differences between the two measurement methods are reported for cigarettes with relatively low TNCO levels measured using the ISO method. These low TNCO levels from the ISO method are mainly caused by a high degree of filter ventilation. Because the filter holes are blocked in the CI method, the degree of filter ventilation does not affect the measurement results. As a result, the differences in TNCO levels between cigarette brands are smaller with this method.

During the measurement with the CI method, no cigarette contained less tar, nicotine or carbon monoxide than was measured using the ISO method. With the exception of one cigarette, all measured TNCO levels exceed the legal limits.

The results of this research support the conclusion that the prescribed ISO method underestimates the amounts of TNCO that a smoker ingests. The committee that drew up this method is largely influenced by the tobacco industry. RIVM therefore recommends that an independent measurement method, such as that of WHO TobLabNet, be included in the law, instead of the ISO method.

More information

→ TNCO Measurement results

Appendix 2

Merknaam	WHO Intense-methode - Gemeten waarden			ISO-methode - Opgegeven waarden			Ratio WHO Intense/ISO		
	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (CI/ISO)	Nicotine (CI/ISO)	CO (CI/ISO)
Marlboro Prime	26,1	1,7	40,0	1,0	0,1	2,0	26,1	17,2	20,0
Kent HD White	17,4	1,3	28,0	1,0	0,1	2,0	17,4	13,4	14,0
Peter Stuyvesant Silver	15,2	1,2	19,0	1,0	0,1	2,0	15,2	12,3	9,5
Karelia I	9,6	0,9	9,3	1,0	0,1	1,0	9,6	8,6	9,3
Davidoff Blue*	23,6	1,7	30,9	***2,9***	***0,2***	***2,6***	8,3	7,0	12,1
American Spirit Orange	20,5	2,1	18,4	3,0	0,4	4,0	6,8	5,1	4,6
Kent Surround Menthol	25,0	1,7	30,8	4,0	0,4	5,0	6,3	4,3	6,2
Marlboro Silver Blue	24,7	1,5	32,6	4,0	0,3	5,0	6,2	5,0	6,5
Karelia L (Blue)	17,6	1,7	14,1	3,0	0,3	2,0	5,9	5,6	7,1
Kent HD Silver	21,1	1,6	26,2	4,0	0,4	5,0	5,3	3,9	5,2
Peter Stuyvesant Blue*	20,2	1,6	21,7	4,0	***0,4***	5,0	5,1	4,7	4,3
Kent Surround Silver*	22,5	1,7	27,0	***4,5***	***0,5***	***5,5***	5,0	3,7	4,9
Templeton Blue	25,0	1,8	26,2	5,0	0,4	6,0	5,0	4,4	4,4
Belinda Filterkings	29,9	2,2	24,7	6,0	0,5	6,0	5,0	4,3	4,1
Silk Cut Purple	24,9	2,0	23,4	5,0	0,5	5,0	5,0	4,0	4,7
Boston White	23,3	1,6	25,3	5,0	0,3	6,0	4,7	5,5	4,2
Mark Adams No. 1 Gold	27,0	1,9	26,0	6,0	0,5	7,0	4,5	3,8	3,7
Kornet Blue	22,2	1,3	25,5	5,0	0,3	6,0	4,4	4,4	4,3
Riverside Blue	22,1	1,5	24,6	5,0	0,3	6,0	4,4	5,1	4,1
Pueblo Blue	26,4	2,5	27,4	6,0	0,6	6,0	4,4	4,2	4,6
Ruba White	22,0	1,6	25,7	5,0	0,3	6,0	4,4	5,2	4,3
Goldfield White	22,0	1,5	26,8	5,0	0,3	6,0	4,4	5,0	4,5
Davidoff Gold*	28,1	2,2	31,6	***6,9***	***0,5***	***7,1***	4,1	4,0	4,5
Belinda Green	24,1	1,9	25,6	6,0	0,5	6,0	4,0	3,9	4,3
American Spirit Yellow	19,5	1,8	17,0	5,0	0,6	6,0	3,9	3,0	2,8
Belinda Super Kings	36,3	2,7	29,5	10,0	0,8	10,0	3,6	3,4	2,9
Davidoff Menthol*	26,4	1,9	33,6	7,3	***0,6***	***7,7***	3,6	3,1	4,4
Kornet Red	25,0	1,6	27,3	7,0	0,4	9,0	3,6	4,1	3,0
L&M Blue Label	28,1	1,8	27,3	8,0	0,6	9,0	3,5	3,1	3,0
Gauloises Blondes Red*	25,3	2,1	28,8	***7,3***	***0,6***	***7,6***	3,5	3,5	3,8

Appendix 2

Merknaam	WHO Intense-methode - Gemeten waarden			ISO-methode - Opgegeven waarden			Ratio WHO Intense/ISO		
	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (CI/ISO)	Nicotine (CI/ISO)	CO (CI/ISO)
Marlboro Red 100s	34,8	2,6	32,1	10,0	0,7	10,0	3,5	3,8	3,2
Lucky Strike Blue Additive Free	24,2	1,6	23,2	7,0	0,6	8,0	3,5	2,7	2,9
Couture Gold	17,1	1,4	14,4	5,0	0,5	5,0	3,4	2,9	2,9
Lucky Strike Gold	23,8	1,7	22,3	7,0	0,6	9,0	3,4	2,8	2,5
Kornet Green	23,4	1,5	26,2	7,0	0,4	10,0	3,3	3,8	2,6
Boston Red	23,2	1,6	25,4	7,0	0,4	9,0	3,3	4,0	2,8
Ruba Green	23,1	1,5	27,4	7,0	0,4	10,0	3,3	3,8	2,7
Black Devil Black	23,1	1,6	30,4	7,0	0,6	9,0	3,3	2,7	3,4
Lucky Strike Original Red	32,8	2,2	26,6	10,0	0,8	10,0	3,3	2,8	2,7
Vogue Menthe*	22,8	1,9	14,6	7,0	0,7	***5,5***	3,3	2,7	2,7
Riverside Green	22,8	1,5	25,7	7,0	0,4	10,0	3,3	3,6	2,6
Riverside Red	22,6	1,6	24,1	7,0	0,4	9,0	3,2	3,9	2,7
Elixyr Blue	22,6	1,6	25,9	7,0	0,6	8,0	3,2	2,7	3,2
Goldfield Green	22,6	1,5	26,8	7,0	0,4	10,0	3,2	3,7	2,7
Ruba Red	22,5	1,5	26,4	7,0	0,4	9,0	3,2	3,8	2,9
Mohawk Origins Blue	22,4	1,6	31,0	7,0	0,6	8,0	3,2	2,7	3,9
Black Devil Yellow	25,4	1,8	31,6	8,0	0,6	10,0	3,2	2,9	3,2
Mark Adams No. 1 Red	31,3	2,3	25,8	10,0	0,8	10,0	3,1	2,9	2,6
JPS Silver*	22,5	1,7	25,9	***7,2***	***0,6***	***7,3***	3,1	2,9	3,5
L&M Red Label*	31,2	2,0	29,0	10,0	***0,8***	10,0	3,1	2,7	2,9
Glamm Green	21,8	1,6	17,1	7,0	0,6	6,0	3,1	2,7	2,8
Goldfield Red	21,7	1,5	26,0	7,0	0,4	9,0	3,1	3,8	2,9
Davidoff Classic*	29,1	2,4	31,0	***9,5***	***0,7***	***10,4***	3,1	3,3	3,0
Dunhill International	30,5	2,6	29,1	10,0	0,9	10,0	3,0	2,9	2,9
Tiłaan Red	30,4	2,0	28,8	10,0	0,8	10,0	3,0	2,5	2,9
Florint Red	21,1	1,4	25,6	7,0	0,4	9,0	3,0	3,5	2,8
Marlboro True Red	30,1	2,0	27,9	10,0	0,9	10,0	3,0	2,2	2,8
Tivoli Kingsize	30,0	2,7	28,7	10,0	0,9	10,0	3,0	3,0	2,9
Glamm Pinks	21,0	1,5	17,6	7,0	0,6	6,0	3,0	2,5	2,9

Appendix 2

Merknaam	WHO Intense-methode - Gemeten waarden			ISO-methode - Opgegeven waarden			Ratio WHO Intense/ISO		
	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)	Teer (CI/ISO)	Nicotine (CI/ISO)	CO (CI/ISO)
Lambert & Butler Original Silver*	26,8	2,3	23,6	***9,0***	***0,7***	***8,8***	3,0	3,3	2,7
Marlboro Gold	23,9	1,6	23,7	8,0	0,6	9,0	3,0	2,7	2,6
Pall Mall Red 100s	29,8	2,5	31,9	10,0	0,8	10,0	3,0	3,1	3,2
JPS Red*	30,0	2,3	29,9	***10,1***	***0,7***	***9,4***	3,0	3,1	3,2
Lucky Strike Red Additive Free	29,8	2,2	25,7	10,0	0,9	10,0	3,0	2,5	2,6
Marlboro Mix	26,6	2,0	23,4	9,0	0,7	9,0	3,0	2,8	2,6
Marlboro True Blue	23,4	1,6	23,6	8,0	0,7	9,0	2,9	2,4	2,6
Winston Classic	29,2	2,3	27,8	10,0	0,8	10,0	2,9	2,9	2,8
Export Red	28,9	2,3	29,5	10,0	0,8	10,0	2,9	2,9	2,9
Lexington	28,9	2,3	16,1	10,0	1,0	7,0	2,9	2,3	2,3
Elixyr Red	28,7	2,2	28,4	10,0	0,8	10,0	2,9	2,8	2,8
Karelia S	17,2	1,8	14,6	6,0	0,6	5,0	2,9	3,0	2,9
Esse Blue	14,3	1,3	11,7	5,0	0,5	4,0	2,9	2,6	2,9
Bastos Filter*	27,9	2,3	22,3	***9,8***	***0,9***	***7,6***	2,8	2,5	2,9
Gauloises Blondes Blue *	29,2	2,3	29,7	***10,3***	***0,8***	***10,4***	2,8	2,9	2,9
Benson & Hedges Silver	22,6	1,8	25,1	8,0	0,7	9,0	2,8	2,5	2,8
Claridge Red	22,6	1,3	26,6	8,0	0,6	8,0	2,8	2,2	3,3
Benson & Hedges Gold	28,3	2,3	27,9	10,0	0,9	10,0	2,8	2,6	2,8
Camel Blue	22,5	1,7	23,8	8,0	0,6	9,0	2,8	2,8	2,6
Mark Adams No. 1 Green	28,1	1,8	30,5	10,0	0,8	10,0	2,8	2,2	3,0
Camel Original	28,1	2,1	19,1	10,0	0,8	7,0	2,8	2,6	2,7
Pall Mall Blue	19,6	1,6	17,8	7,0	0,6	8,0	2,8	2,6	2,2
Peter Stuyvesant Red	28,0	2,2	24,6	10,0	0,8	10,0	2,8	2,7	2,5
Winston Blue	22,3	1,7	25,9	8,0	0,6	9,0	2,8	2,8	2,9
Mohawk Origins Red	24,6	1,8	30,2	9,0	0,8	10,0	2,7	2,2	3,0
Superkings original black*	28,5	2,6	26,0	***10,5***	***0,8***	***9,8***	2,7	3,0	2,7
Texas Red	19,0	1,4	24,3	7,0	0,4	9,0	2,7	3,4	2,7
Camel Orange	24,4	1,9	23,6	9,0	0,7	10,0	2,7	2,8	2,4
Vogue Blue*	18,9	1,7	14,3	7,0	***0,7***	***5,5***	2,7	2,6	2,6

Merknaam	WHO Intense-methode - Gemeten waarden				ISO-methode - Opgegeven waarden				Ratio WHO Intense/ISO		
	Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)		Teer (mg/sig)	Nicotine (mg/sig)	CO (mg/sig)		Teer (CI/ISO)	Nicotine (CI/ISO)	CO (CI/ISO)
Couture Purple	21,2	1,8	17,3		8,0	0,7	8,0		2,7	2,5	2,2
Chesterfield Red	26,5	1,8	28,2		10,0	0,7	10,0		2,6	2,6	2,8
Pall Mall Red	26,4	2,2	23,5		10,0	0,8	10,0		2,6	2,7	2,4
Gladstone Classic	26,3	1,9	27,5		10,0	0,8	10,0		2,6	2,4	2,8
Camel Filter	26,2	2,2	21,9		10,0	0,8	10,0		2,6	2,7	2,2
Dunhill Masterblend Red	25,5	1,9	23,7		10,0	0,8	10,0		2,5	2,4	2,4
American Spirit Blue	22,8	2,3	19,5		9,0	1,0	9,0		2,5	2,3	2,2
Marlboro Red	24,5	1,7	18,9		10,0	0,7	10,0		2,5	2,4	1,9
Caballero Plain	23,7	1,9	15,8		10,0	0,8	7,0		2,4	2,3	2,3
Marlboro Green	22,9	1,6	19,9		10,0	0,7	10,0		2,3	2,2	2,0
Mantano Plain	22,8	1,7	16,3		10,0	0,8	7,0		2,3	2,1	2,3
Gauloises Brunes*	23,8	1,6	20,6		***10,5***	***0,8***	***9,0***		2,3	2,1	2,3
							Mediaan ratio:		**3,1**	**2,9**	**2,9**
							Laagste ratio:		**2,3**	**2,1**	**1,9**
							Hoogste ratio:		**26,1**	**17,2**	**20,0**

*__Opmerking__: In enkele gevallen zijn er verschillende ISO TNCO waarden opgegeven voor hetzelfde merk. Dit kan bijvoorbeeld komen doordat sigaretten van dat merk in verschillende fabrieken gemaakt worden. In dit geval is de mediaan van de opgegeven waarden in de tabel opgenomen. De waarden waar dit voor geldt zijn schuingedrukt.

De bedrijven waarvan sigaretten zijn onderzocht zijn minimaal twee weken voor publicatie onder embargo op de hoogte gebracht van de onderzoeksresultaten. Tabaksfabrikant JTI heeft op 6 juni 2018 een reactie gestuurd op deze resultaten. Tabaksfabrikanten Imperial Tobacco en BAT hebben op 8 juni reacties gestuurd. De e-mails aan de betrokken bedrijven met de onderzoeksresultaten en de reacties van JTI, Imperial Tobacco en BAT en de antwoorden daarop worden openbaar gemaakt op www.rijksoverheid.nl/onderwerpen/roken/transparant-over-contact-tabaksindustrie.

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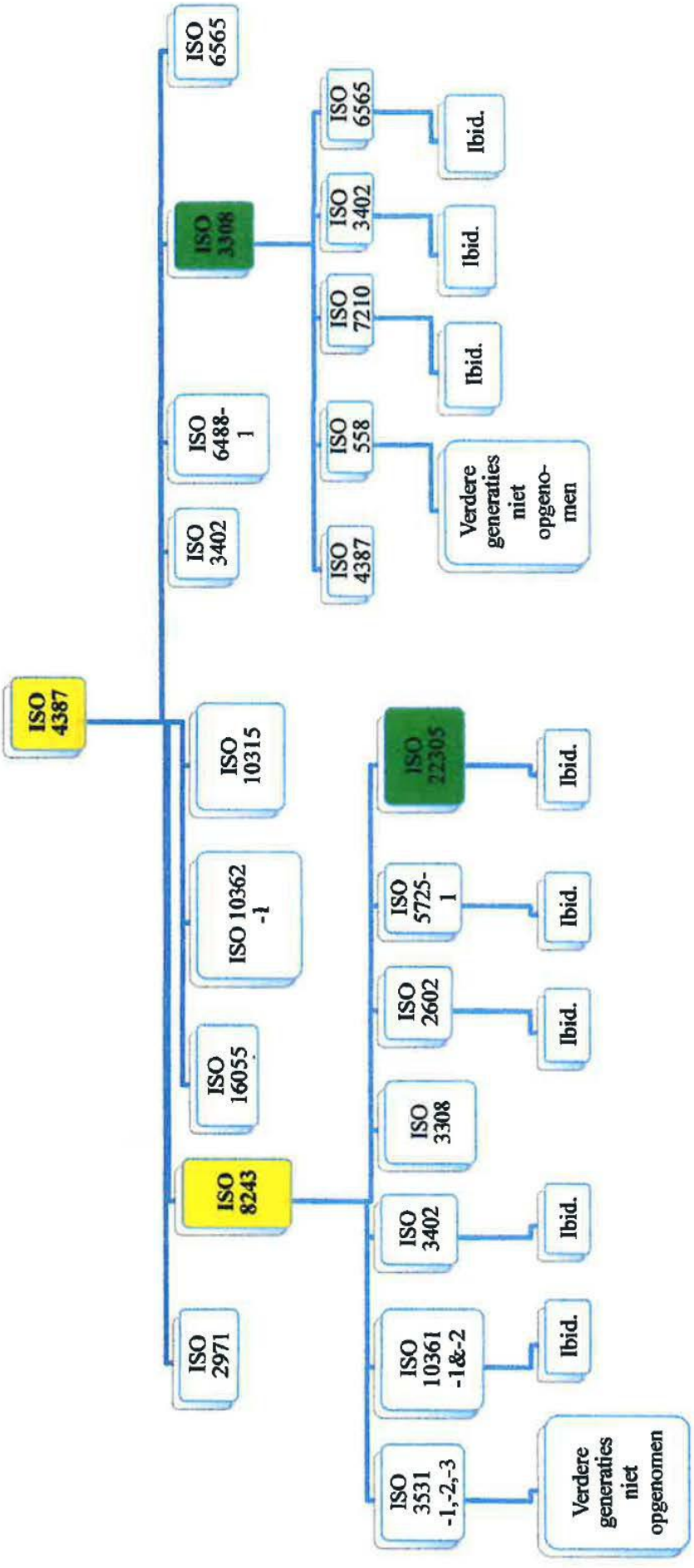
Appendix 3


ISO 4387
ISO 6565
ISO 3308
ISO 6565
Ibid.
ISO 3402
Ibid.
ISO 7210
Ibid.
ISO 558
Verdere generaties niet opgeno-men
ISO 4387
ISO 6488-1
ISO 3402
ISO 10315
ISO 10362-1
ISO 16055
ISO 8243
ISO 22305
Ibid.
ISO 5725-1
Ibid.
ISO 2602
Ibid.
ISO 3308
ISO 3402
Ibid.
ISO 10361-1&-2
Ibid.
ISO 3531-1,-2,-3
Verdere generaties niet opgenomen
ISO 2971

Appendix 4

2019-03-15 TNCO values for cigarettes 2017 -- appendix to Government Information (Public Access) Decree

Overall summary of results monitoring maximum emission standards for cigarettes 2017:

NVWA nr.	Merk/type	Nicotine (mg/sig)	NFDPM (teer) (mg/sig)	CO (mg/sig)
89397987	American Spirit Original Yellow	0,57	5,2	5,7
89397995	American Spirit Original Blue	0,92	8,2	8,0
89398002	American Spirit Original Orange	0,34	3,6	3,9
89398029	Marlboro Red	0,79	9,5	9,0
89398037	Marlboro Menthol	0,72	9,3	10,3
89398045	Pall Mall Red	0,81	9,5	10,5
89398053	Camel Orange	1,25	6,2	9,0
89398061	Camel Filter	0,74	9,2	9,8
89398088	Pall Mall Blue	0,58	6,2	7,3
89398096	Pall mall Alpine	0,64	8,4	9,1
89398118	Peter Stuyvesant Red	0,82	10	10,9
89398126	Peter Stuyvesant Blue	0,36	4,1	5,2
89398134	Peter Stuyvesant Silver	0,10	1	1,7
89398142	Kent HD Silver	0,33	3,8	5,2
89398169	Kent HD White	0,13	1,3	2,0
89398177	Camel Blue	0,68	8,6	10,0
89398185	JPS Silver	0,55	6,5	7,4
89398193	Davidoff Classic	0,88	9,6	10,1
89398207	Davidoff Menthol	0,53	6,1	6,7
89398215	Davidoff Gold	0,71	7,9	8,5
89398223	JPS Red	0,87	11,1	10,9
89398231	Davidoff Blue	0,23	2,6	2,6
89398258	Gauloises Blondes Red	0,56	7,0	7,3
89398266	Gauloises Blondes Blue	0,77	10,4	9,8
89398274	Gauloises Brunes	0,74	10,7	10,1
89398282	Kent Surround Silver	0,29	3,4	4,0
89398304	Kent Surround Menthol	0,20	2,3	3,1
89398312	Lucky Strike Blue Additive Free	0,59	6,9	8,2
89398339	Lucky Strike Original Red	0,88	11,4	11,6
89398347	Mantano	0,83	10,8	7,3
89398355	Dunhill Master Blend Red	0,82	9,5	9,8

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NVWA nr.	Merk/type	Nicotine (mg/sig)	NFDPM (teer) (mg/sig)	CO (mg/sig)
89398371	Lucky strike Gold	0,76	9,7	11,1
89398398	Marlboro Gold	0,58	7,8	8,7
89398401	L & M Blue Label	0,65	8,5	9,3
89398428	L & M Red Label	0,78	10,0	10,5
89398436	Camel Original	0,92	11,7	8,9
89398851	Lucky Strike Ice Gold	0,75	9,9	11,5
89398878	Lucky Strike Ice	0,71	9,5	10,9
89398886	Lucky Strike Red Additive Free	0,85	10,3	10,4
89398894	Kent Great Tobacco Blend with Cooling Sensation	0,57	6,6	8,5
89398908	Belinda Filter	0,55	6,1	6,3
89398916	Marlboro Prime	0,12	1,3	1,6
89398932	Superkings Original Black	0,92	10,1	10,1
89398959	Lambert & Butler Original Silver	0,91	10,0	10,3
89398967	Winston Classic	0,94	10,6	11,4
89398975	Pueblo Blue	0,77	7,2	7,7
89398983	Karelia Slims	0,13	1,7	1,9
89398991	Vogue La Cigarette Verte Originale	0,74	7,4	5,3
89399378	Glamm Green	0,61	7,4	7,0
89399386	Glamm Pinks	0,68	7,6	7,3
89399394	Titaan Red	0,75	10,5	11,1
89399408	Elixyr Groen	0,85	10,4	10,9
89399416	Elixyr Red	0,74	9,0	9,8
89399424	Camel Activate	0,67	8,0	9,1
89399432	Camel Activate White	0,51	5,9	6,6
89399459	Bastos Filter	1,04	10,9	10,1
89399467	Benson & Hedges Gold	0,90	10,0	10,9
89399475	JPS Red	0,81	9,5	9,6
89399483	Belinda Super Kings	0,86	10,8	11,8
89399505	Marlboro Mix	0,68	9,3	9,4
89399513	Esse Blue	0,51	5,3	4,7
89399521	JPS Silver	0,59	6,9	8,5
89399548	Kent	0,54	6,5	8,1
89399556	Caballero	0,81	9,3	6,5

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NVWA nr.	Merk/type	Nicotine (mg/sig)	NFDPM (teer) (mg/sig)	CO (mg/sig)
89399564	Kent HD Silver	0,36	4,2	5,9
89399572	Gauloises	0,88	10,5	10,6
89399599	Marlboro Gold	0,78	9,6	10,3
89399629	Vogue Blue	0,68	7,7	5,9
89399637	Marlboro Red 100	0,79	9,6	9,0
89399645	Gladstone Classic	0,77	10,0	10,3
89399653	Chesterfield Red	0,75	9,8	10,0
89537193	Winston Blue	0,69	8,2	10,3
89537207	Black Devil Black	0,53	6,9	10,0
89537215	Mark 1 New Gold	0,50	6,4	8,0
89537223	Mark 1 Green	0,68	9,8	11,2
89537231	Mark 1 New Red	0,78	10,0	11,2
89537258	Export Classic	0,76	9,2	9,7
89537266	Dunhill International	0,94	10,3	9,9
89537274	Black Devil Yellow	0,61	7,9	10,5
89537282	Belinda Filter Groen	0,49	5,6	5,4
89537304	Belinda Filter Kings	0,55	6,2	6,1
89537312	Kent Surround 100's	0,23	3,1	3,4
89537347	Lexington	1,06	12,1	7,6
89537355	Elixyr Red	0,79	9,4	9,8
89526183	Ruba 24 White	0,46	6,1	7,3
89526191	Ruba Red	0,61	8,2	10,7
89526205	Ruba Green	0,61	8,4	11,5
89526213	American Spirit Orange	0,41	3,6	4,0
89526221	Goldfield Green	0,59	8,1	10,9
89526248	Goldfield Red	0,61	7,8	10,5
89526256	Goldfield White	0,51	6,0	7,3
89526264	Templeton Filter Blue	0,53	6,4	7,3
89526272	Claridge Red	0,51	7,3	10,0
89526299	Kornet Green	0,59	8,1	10,8
89526302	Kornet Red	0,64	8,5	11,6
89526329	Kornet Blue	0,39	5,1	6,7
89526337	Esse Blue	0,61	5,7	4,9

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NVWA nr.	Merk/type	Nicotine (mg/sig)	NFDPM (teer) (mg/sig)	CO (mg/sig)
89392381	Silk Cut Purple	0,59	5,7	6,3
89392403	Pueblo Blue	0,79	7,2	7,6
89392411	Marlboro Silver Blue	0,28	3,1	4,2
89392357	Riverside Red	0,64	8,3	11,2
89392365	Riverside Blue	0,45	5,6	7,1
89392373	Riverside Green	0,57	7,9	10,5
89392586	Boston Red	0,60	8,0	11,0
89392594	Boston White	0,53	6,5	8,1
89393671	Pall Mall Red	0,84	9,8	10,8

Appendix 5

Tobacco Control 2001;**10**:96–104

Whose standard is it, anyway? How the tobacco industry determines the International Organization for Standardization (ISO) standards for tobacco and tobacco products

Stella A Bialous, Derek Yach

Abstract

***Objective*—To describe the extent of the tobacco industry involvement in establishing international standards for tobacco and tobacco products and the industry influence on the International Organization for Standardization (ISO).**

***Methods*—Analysis of tobacco industry documents made public as part of the settlement of the Minnesota Tobacco Trial and the Master Settlement Agreement. Search words included "ISO", "CORESTA", "Barclay", "compensation and machine smoking", "tar and nicotine deliveries", and the name of key players, in different combinations.**

***Results*—It is clear that the tobacco industry, through the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA), play a major role in determining the scientific evidence and suggesting the standards that are eventually adopted as international standards for tobacco and tobacco products in several areas, including the measurement of cigarette tar and nicotine yield.**

***Conclusions*—ISO's tobacco and tobacco products standards are not adequate to guide tobacco products regulatory policies, and no health claims can be made based on ISO's tobacco products standards. There is an urgent need for tobacco control advocates and groups worldwide to be more involved with the work of the ISO, both directly and through their national standardisation organisations.**

(*Tobacco Control* 2001;**10**:96–104)

Keywords: tar and nicotine measurement; International Organization for Standardization; ISO; Cooperation Centre for Scientific Research Relative to Tobacco; CORESTA; regulatory policy

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Standards play a key role in the regulation of consumer products. Regulatory agencies throughout the world use standards to evaluate whether or not a product is in compliance with the desirable consumer safety features, and manufacturers worldwide display the seal of approval of the country's national standardisation office or the International Organization for Standardization (ISO) as a symbol of quality.

The ISO, established in 1947, is a "worldwide non-governmental organisation of national standards bodies from some 130 countries" with a mission to "promote the development of standardisation and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity."[1] ISO standards are used in the development of policies, regulation, and legislation of health and safety matters on a variety of issues.

ISO is made up of its members, which are divided into three categories:
(1) a member body of ISO is the national body "most representative of standardisation in its country", and there is only one member body per country. Member bodies have the right to be represented on a committee;
(2) a correspondent member is an "organisation in a country which does not yet have a fully developed national standards activity". Correspondent members "are entitled to be kept fully informed about the work of interest to them";
(3) subscriber membership, "for countries with very small economies."[1]

Some 2850 technical committees, subcommittees, and working groups carry out the technical work of ISO. Representatives of industry, research institutes, government authorities, non-government organisations, consumer bodies, and international organisations from all over the world participate, directly, in liaison with ISO, or indirectly, through a national member body, in the work of these committees and the development of international standards. (ISO's member bodies are national standards institutions, which in turn have varying degrees of affiliation with their governments, depending on the country.)[1]

The need to develop a standard is usually initiated by an industry sector. Standards result from "consensus agreements reached between all economic players in that industrial sector—suppliers, users, and often government." One of the aims of standards is "to facilitate trade, exchange and technology transfer through... improved health, safety and environmental protection, and reduction of waste."[1] It is important to question if these aims are being met in the case of tobacco and tobacco products standards.

It has been known for decades that the standard ISO measurement to determine tar and nicotine yield (and the slightly different

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US Federal Trade Commission (FTC) method) does not reflect the amount of tar and nicotine delivered to the smoker, a fact that is acknowledged in several published studies, including studies funded by the tobacco industry.[2-6] Both the ISO and the FTC methods, as well as Germany's DIN method, are derived from CORESTA Standard Methods 10 and 12—tar and nicotine determination in cigarette smoke.[7] The methods use a smoking machine to measure the deliveries of these components and were developed to provide a ranking of tar and nicotine yields, and not to determine the health consequences or the amount actually delivered to a smoker. The method specifies the volume and duration of puff over a certain amount of time.[8-10] There are a few differences between these methods that leads to variation in the yield of tar and nicotine measured for the same cigarette brand. Among other differences, the ISO method uses different conditions for smoking, such as temperature, different drafts on the smoking machine, and different cigarette butt length.[11-14]

In addition, cigarette design has been used to "cheat" the smoking machine, providing lower tar and nicotine readings by machine versus human smoking, a fact that has also been widely discussed in the scientific literature. The accompanying misleading labels that claim a cigarette brand is "mild" or "light" and how smokers "compensate" lower yields by changing the manner they smoke, has also been amply discussed, including by the tobacco industry itself.[4-6 8 9 15 16] The FTC, in its proposal to review the cigarette testing methodology, states that the "compensatory smoking behaviour substantially reduces the informative value of the current [tar and nicotine] ratings" and that more accurate information should be provided to consumers.[8]

Like the FTC method, the ISO method can be useful for some ranking in terms of tar and nicotine yield as measured by machine smoking procedures, but it can not be used for consumer information or claims in terms of tar and nicotine actually delivered to the smoker. No health claims can be made based on the ISO/FTC tar and nicotine cigarette yield measurements. Indeed, when the FTC method was adopted, in 1967, it was not to determine "the amount of 'tar' and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by a machine in accordance with the prescribed method."[8] Nonetheless, ISO standards continue to be used in regulatory and policy settings, and public health concerns continue to be inappropriately mentioned as reasons to lower tar and nicotine yield in cigarette smoke as measured by machine smoking methods. In June 2000 the European Union (EU) started the approval process of a directive that determines new, lower limits of tar, nicotine, and carbon monoxide deliveries based on ISO measurements,[17] despite commentaries from health groups pointing to the inadequacy of the ISO method.[18 19] Although the EU recognised that all cigarettes are harmful, including those with lower tar and nicotine yield, it stated that tar, nicotine, and carbon monoxide ceilings, as measured by ISO methods (for lack of another international standard and until a better standard is developed), were necessary to "ensure high levels of public health protection."[17] (As of March 2001 the directive has not yet been through all the steps of the approval process, but it is moving rapidly in that direction.)

Considering the massive amount of evidence showing that ISO standards on tobacco and tobacco products are inadequate for health protection purposes, and indeed they were not meant to serve as a health and safety standard, one is puzzled by the fact that there has been no concerted worldwide effort by government and non-government agencies to develop and propose more appropriate performance standards—that is, standards that will permit a better assessment of the cigarette smoke components delivered to the smoker. Among options to address the issue are: on the one hand, as a precautionary measure, the refusal to consider standards that make no provision for health concerns (such as the current ISO standard) when developing regulatory, health related policies and legislation, thus no longer perpetuating the "low tar, low nicotine" myth; and on the other hand, there is the option of increased participation in the work of ISO. So far, health groups and health agencies have largely underestimated the importance of conveying their views and concerns to ISO's committees and thus have failed to counter the influence of the tobacco industry on ISO. However, change might be forthcoming with an increase worldwide interest in the regulation of tobacco products. The final report[20] from the World Health Organization (WHO) sponsored meeting "Advancing knowledge on regulating tobacco products", held in Oslo, Norway in February 2000 to discuss international regulatory issues, acknowledges the inadequacy of using ISO/FTC measurements to determine the health impact of cigarettes, and recommends that measures of tar and nicotine derived from ISO/FTC methods be removed from cigarette packages because of their misleading influence in a health perspective.[20 21]

The issue of standard measurement of tobacco products components is likely to gain even more international visibility as the negotiations for the Framework Convention for Tobacco Control advance and include the regulation of tobacco products among its protocols. As these initiatives move forward, it is important for public health professionals to understand the purposes of such standards and to use them accordingly.[22 23]

This paper describes the extent of the tobacco industry involvement in establishing international standards for tobacco and tobacco products.

Methods

We analysed the contents of tobacco industry documents made public as part of the settlement of the Minnesota Tobacco Trial and

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the Master Settlement Agreement. We searched both tobacco industry and non-tobacco industry websites that placed these documents on the internet. Search words included "ISO", "CORESTA", "Barclay", "compensation and machine smoking", "tar and nicotine deliveries", and the name of key players, in different combinations.

Results

Industry participation in the development of ISO standards is not exclusive to tobacco, but unlike other products, such as screws and credit cards, the determination of standards by the industry, without the participation of other interested parties, has lead to the development of standards that protect the political and commercial interests of the industry rather than those of the consumer. In the case of ISO technical committee 126—tobacco and tobacco products standards (ISO TC/126, established in 1968), the standards are developed in fact by the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA).

CORESTA

CORESTA began in 1955 as a research organisation of industry tobacco chemists from around the world. Its membership is dominated by the tobacco industry, including both state monopolies and multinational companies.[24–27]

CORESTA's scientific activities aim to advance the interests of the tobacco industry worldwide,[28] and to pre-empt regulations through the development of its own research and standards.[29 30] For example, a letter from Philip Morris (PM) vice president of international operations services, Manuel Bourlas, to CORESTA's secretary general François Jacob in 1992[31] stated:

> "I believe in and continue to support the concept of a collaborative effort in addressing scientific problems related to tobacco as the concept tends to strengthen the industry's position in the scientific world . . .
>
> "I am certain that we could develop a global scientific program which would go beyond the development of measurement techniques while at the same time remain sensitive to proprietary and competitive issues."[31]

CORESTA is one of the many international bodies that work in liaison with ISO.[32] The standards developed under the aegis of ISO/TC 126 are based on the tests and scientific evidence provided by CORESTA. Most individuals involved in the work of ISO/TC 126 are tobacco industry representatives.[33 34] At the 1995 ISO/TC 126 plenary meeting in South Africa, of the 52 individuals present, only seven people identified themselves as representing their national standards body, plus the two people of TC 126 secretariat—the German DIN.[34] As stated in a 1993 letter from PM Europe research and development employee, JB Boder, to Manuel Bourlas, PM senior manager:

> "There are two international organizations controlled by the industry: CORESTA and ISO . . . CORESTA which is 100% controlled by the industry . . . ISO technical committee 126 is made of approximately 80% Industry . . . The best way to work with these two organizations is to do all the technical work within CORESTA and then have it endorsed by ISO."[21]

CORESTA conducts its work on tobacco products standards through one of several mechanisms: suggesting new standards and work items,[33 35 36] revising current standards[32] or responding to ISO's request for research in the establishment of a new standard.[37 38] Draft standards prepared by CORESTA are eventually circulated to the technical committee's member bodies for approval and standards are approved as recommended by CORESTA, with limited opportunity for significant amendments. For example, the minutes of a CORESTA's environmental tobacco smoke (ETS) subgroup meeting in Paris in April 1997 state:

> "The draft international standard ISO/DIS 11454 'Tobacco and tobacco products—determination of vapour-phase nicotine in air—gas chromatography method' was approved and will be published without change, other than editorial, as an international standard. (This standard is technically the same as CORESTA recommended method 14)."[39]

This arrangement is favourably perceived by the tobacco industry. As per a document describing the technical committee 126:

> "It is unnecessary to describe CORESTA in detail. Suffice to say that the relationship with ISO/TC 126 is such that CORESTA does the science and the collaborative testing and produces recommended methods which are subsequently submitted for conversion into International Standards. If a work proposal is accepted by ISO/TC 126 and study is required, it is almost always referred to the appropriate study group in CORESTA. This procedure has worked extraordinarily well in the revision of ISO 3308, 3402, 4387, 8243 and the issue of 10315 and 10362."[33]

The chairperson of technical committee 126 is PI Adams, who used to work for Imperial Tobacco Ltd,[40 41] is credited with the invention of a type of ventilated filter,[42] served as president of CORESTA's technology group,[43] and is listed as an "industry consultant" to the Tobacco Manufacturers Association.[44 45]

In addition to methods for measuring tar and nicotine yield, CORESTA also provides ISO with research to establish standards in other areas such as: methods for determining organochlorine pesticides residues,[46 47] methods for preparation, conditioning, and sampling of fine cut tobaccos and smoking articles,[46] analysis of genetically modified tobacco,[47–50] and determination of nicotine in ETS through gas chromatographic methods.[51 52]

Moreover, CORESTA conducts research in preparation for future standard needs in the areas where there has not yet been enough agreement within the industry that standards are needed. Such areas include ETS components and non-smoker exposure to these components,[51 53] cigar, pipe, and cut tobacco smoking, and roll-your-own (RYO) cigarettes, among others.[46 49 51 54]

CORESTA works with ISO either directly or through one of ISO's member bodies, such as

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the British Standard Institute (BSI) or American National Standards Institute (ANSI).[32 44 53] (At a CORESTA's ETS subgroup meeting in Paris in April 1997 it was stated that ultraviolet absorbance and fluorescence methods described in document ISO/TC 126 N 554, "Environmental tobacco smoke-estimation of the contribution to respirable suspended particles—ultraviolet absorbance and fluorescence methods" would be accepted by ISO as a new work item and that Mike Ogden, from RJ Reynolds (RJR) tobacco research and development department would be confirmed as project leader.[39]) For example, Helmut Reif's (from PM worldwide scientific affairs) monthly report for May 1998,[56] described the "regular meeting of the scientific commission of CORESTA" and stated:

> " . . .a method for ETS determination (quantification by UVPM and FPM) sent via ANSI (M Ogden) to ISO. It was seen necessary to make it clear in a preamble that this method would only be able to determine RSP that stem from any combustion process and therefore cannot be seen as specific for ETS.[56]

CORESTA expanded from a mere scientific entity to become more involved in political issues that concern the industry, such as regulatory policies,[38 57] but there was apprehension that by becoming too politically involved CORESTA's scientific credibility could suffer,[58 59] particularly in the area of pesticides. Nonetheless, the 1983 minutes of the scientific committee states, "thanks to the pesticide subgroup, the industry was in a better position for discussion with the regulatory authorities."[60] And in a 1989 report of a CORESTA board meeting in Rome, where a review of smoking procedures methods was discussed, PM's Manuel Bourlas stated that:

> "The situation today however, is that 'regulatory authorities' DO play an important role in the analytical methods which are used and play an even larger role in 'printed numbers'."[emphasis on original][61]

NON-CORESTA PARTICIPATION IN ISO TC 126

ISO's member bodies are entitled to participate and exercise full voting rights on any technical committee and policy committee of ISO. A member body takes the responsibility for "informing potentially interested parties in their country of relevant international standardisation opportunities and initiatives: and "ensuring that a concerted view of the country's interests is present during international negotiations leading to standards agreements."[1] Despite the stated openness for input from interested parties, CORESTA resists any interference with its proposed standards, and make efforts to keep overall control of the situation and the outcomes of ISO meetings. For example, the minutes of CORESTA's outgoing scientific commission meeting in Japan in 1996 stated:

> "The subgroup routine analytical chemistry has prepared a series of editorial updates of the smoking methods. Shortly before the ISO meeting in Williamsburg in October 1996, the British body (BSI) sent a number of proposals on the same topic and at the meeting it was clear that some non-CORESTA participants, in particular government labs, were eager to have their say, with the support of ISO itself.
>
> "After the meeting of ISO, it is clear that if the CORESTA methods and ISO standards are to remain close or identical, it is not desirable to publish revised CORESTA methods immediately, but to hand out a draft and wait for eventual ISO amendments, then publish a revised version very close to the ISO revised standard."[57]

Further, while addressing the issue of standards for RYO, the same minutes stated: "At the ISO meeting, the matter of participation of non-CORESTA bodies to the experimental work was raised and has to be addressed."[57] The proposed solution to this "outsider" participation was that after methods have been determined by CORESTA, a subgroup will work on the validation of the methods, at which stage "outside bodies such as government labs could then be invited to participate . . ."[57] (The industry was concerned that problems with reaching an agreement over methods for measuring RYO tar and nicotine yield would lead to a cooperation with government laboratories.[46])

CORESTA AND ISO RELATIONS WITH WHO AND OTHER ORGANISATIONS

ISO has official status as a non-governmental organisation with WHO, which provides the tobacco industry, through ISO/TC 126, access to WHO and the United Nations' Food and Agriculture Organization (FAO). (In addition, WHO has an observer status with ISO, and CORESTA has an official "liaison" with FAO.)

In 1990 one of CORESTA's consultants was a Dr Vetorazzi, an asset to the industry as he was "personally acquainted to most of the main players in the WHO/FAO business, due to his former assignment as secretary of the joint working group . . ."[38] and who due to his old contacts "can approach all files of WHO, even the classified ones . . ." while he was working on pesticide issues for CORESTA.[38 58] In 1993, while still working as a CORESTA consultant, Vetorazzi was an invited temporary advisor on the joint FAO/WHO meeting on pesticides residues.[62] (The tobacco industry interest in FAO is, at least partly, out of concern with pesticide use and pesticide residues allowance regulations. CORESTA's involvement with FAO on pesticides residue regulations intensified in 1974.[63] Pesticides residues allowances are a concern of the industry because they are usually based on leaf residues and not on health effects of the residues in the final product—cigarette. This often leads to lower levels allowed than desired by the industry.)

In addition to WHO and FAO, ISO/TC 126 also participates in other multisectoral collaboration of the United Nations agencies on issues of tobacco and health, providing information about the works of ISO/TC 126 to, for example, the United Nations Conference on Trade and Development (UNCTAD).[27 34]

Although CORESTA represents the industry, individual companies also develop their own strategies to protect their commercial interests in the face of standards and

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regulations. An example is PM's "Europe science and technology defensive activities for 1983-1988" that list, among others, objectives and strategies to contact scientists and officials, including at WHO, to "learn about their intentions, to modify their opinions, *to precede* their *interventions* with national government agencies . . ."[64] to extend and deepen PM's position within CORESTA, and:

> "Further deepening of contacts by PM experts with standardizing organisations and with institutions that carry out control measurements on cigarettes, ingredients, or other relevant commodities in order to assure that *PM products are measured* correctly throughout the world, and that they find universal acceptance.
>
> "Strategies: Initiative by PM representatives in *directing* the activities of the International Standards Organization (ISO) and the various national standardizing committees *in the PM sense* as well as actively collaborating in joint experimentations with national testing organisations (e.g. LGC, Canton Chemists, BGA) so as to assure that *PM methodology*, *PM instrumentation*, *PM laboratory practices* find the widest possible acceptance, and that *PM products are tested in a fair way*."[64] [emphasis in original]

In 1990, PM continued to attempt to grow its influence in the works of ISO and CORESTA and wanted these organisations to:

> ". . .provide better support for the Industry (and PM) by taking a more aggressive position in the technical/scientific tobacco environment. Without implying that they should jump into the smoking and health controversy, I think there are many issues which they could handle with good chances of success. For example:
> –Tolerated pesticide residues levels
> –Approved tobacco additives
> –ETS studies
> –Approved packaging materials
> –etc . . ."[24]

PHILIP MORRIS VERSUS BRITISH AMERICAN TOBACCO: THE LOW TAR DEBATE

One of the areas where ISO standards have best served the industry is through providing the impression of legitimacy to industry claims that cigarettes with lower levels of tar and nicotine yield were less harmful.[6 16] A discussion over one particular low tar claim led to one of the largest "insider" battles of the tobacco industry.

Although in the area of standards, the tobacco companies tend to agree, this agreement is not always easily reached. Commercial interests and proprietary issues often create conflict in the work of CORESTA and ISO. One of such disagreements occurred in the early 1980s, over whether or not British American Tobacco (BAT) channel ventilated cigarettes should be submitted to the same analytical tests as non-channel, conventionally ventilated cigarettes. (Channel ventilation was a design that brought additional airflow into the cigarette filter.) Conventionally ventilated filters dilute mainstream smoke through a variety of mechanisms, used alone or in combination, mainly: creation of holes in the filter itself, increased air permeability, and porosity of the paper used to wrap the filter and the tip of the cigarette, all part of the filter itself and with the intent of creating holes in the filter.[65 66] Holes in cigarette filters were invented to "cheat" smoking machines that measure tar and nicotine yield, by allowing air to flow into the machine and diluting the concentration of cigarette smoke components. It has been demonstrated that human smokers compensate for lower delivery by, among other things, blocking those holes.[2 5 6 15] Channel ventilated cigarettes were able to yield even lower tar reading through the standard smoking machine method (ISO/DIS 4387) by bringing additional fresh air in the smoke through its channels. These cigarettes used the:

> ". . .so-called 'Actron' filter which provides ventilation through four peripheral channels which are isolated from the core of the filter. When a human being smokes this cigarette, his lips inevitably block some of the peripheral channels, so that the cigarette delivers significantly greater amounts of tar when smoked by human beings than when tested on a smoking machine."[67]

BAT marketed the new product, Barclay, as an "ultra-light" cigarette with only 1 mg of tar. (The reported 1 mg of tar was actually 5 mg when the channels in the filter were blocked.[68])

PM protested that BAT could not market its products based on a reading by a method not appropriate for channel ventilated filters. It considered channel ventilation a "leakage" (false air entering the cigarette holder) rather than "ventilation" (dilution).[7] BAT's argument was that:

> ". . .*all ventilated cigarettes* produce higher deliveries during human smoking than during machine smoking, and that even though this difference is greater in channel-ventilated cigarettes it is not reason enough to treat these cigarettes differently.[69] [emphasis on original]

The industry documents addressing the BAT/PM disagreement provide insight on how aware the cigarette companies were that by creating a special type of filter they were able to reduce the readings of tar and nicotine without compromising the taste of the cigarette. ISO meetings became the arena for the BAT and PM battle. The debate over adequacy the testing methods for the channel ventilated cigarettes started at an ISO meeting in Paris in September 1985,[70] continued in 1986 in Turkey,[69 71] and 1988 in China.[72 73] By 1989, an agreement was reached between the two companies. It was agreed that CORESTA would work on developing a new testing method that would address issues related to measuring yield in channel ventilated cigarettes (without changing measurements of "conventional" cigarettes), and that both companies would work toward "a smooth and rapid adoption of the new method".[74] It was also agreed that PM would stop litigation in regards to Barclay. It was not a change in the yields of either conventional or channel ventilated cigarettes, but a rather an agreement on how the data would be reported.[74 76]

Measurement methods continued to be a commercial and operational concern for the industry. Indeed, a 1990 PM memo discussing the fact that a few countries have their own measuring standards stated:

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"Tar delivery of cigarettes depends upon the smoking method used, and no one method can be said to be more correct than another.
"As a result of this lack of agreement on a standard smoking method, governmental regulators within each country have arbitrarily defined standard smoking method for their country to provide consumers with a relative ranking of tar delivery of cigarettes and to regulate the advertising of cigarettes. As an example of the magnitude of these different methods, the tar delivery of a full flavoured Marlboro will vary by as much as 2 mg, depending upon the smoking method used. This becomes critical in those countries where we are required to print tar delivery on the packs and the tar delivery is verified by "official" governmental laboratory . . .
"If we accept the 2 mg lower limit as in this Standard [ISO/DIS 4387], we run the risk of losing the ability to advertise a product as 1 mg in those countries that do not have a "regulatory authority" to confirm the data . . .
"If we are successful in developing new ISO methods that are adopted by the EEC countries, it should also be adopted by the other countries that follow ISO standards. I would recommend that PM work towards having the ISO smoking methods adopted by those countries that do not traditionally follow ISO standards. This includes US, Japan, Gulf Coast Countries, the Pacific Rim Countries, South America and anywhere else we either sell or plan to sell cigarettes."[68]

INTERNATIONAL VENTILATION STANDARDS—ISO/TC 205

In addition to consumer products, standards are also utilised to determine air and water quality. For example, the indoor air quality in office buildings is determined according to a set of standards which in turn are used to guide health and safety policies and regulations. In the USA, the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) is the organisation appointed by the American National Standards Institute (ANSI) to address indoor air quality standards. In turn, ISO relies on ANSI/ASHRAE standards to develop international air quality standards.

A less discussed fact is the tobacco industry involvement with ISO's technical committee 205—building environment design, mainly with its working group 4: indoor air quality. Given the priority the industry has given in the past few years to the issue of regulation of indoor smoking, this committee is likely to assume a greater importance in the industry's view. The tobacco industry documents provide ample evidence of the industry's interest and influence on ISO/TC 205 and on ventilation and indoor air quality standards.[39 48 77-80] An in-depth discussion of these documents is beyond the scope of this paper. However, it is noteworthy that in the future, the industry is likely to exert greater pressure on ISO/TC 205. Until the year 2000, the international standard for indoor air quality has been essentially the same as ASHRAE standard 62-1989. (ASHRAE has revised standard 62-1989, which is now standard 62-1999, with addenda 62 c-f approved and others still under review. It provides stricter ventilation standards for separating ETS areas from ETS-free areas. It will be interesting to see if ISO will adopt the revised standard.)[81]

Discussion

The tobacco industry dominates the process of tobacco and tobacco products standard setting to advance its political and commercial needs, therefore pre-empting the passage of regulatory policies that would indeed protect the health of the public. In the area of cigarettes and other tobacco products, the establishment of international standards has failed to protect consumers' health and safety, due largely to the influence of the tobacco industry. One of the areas where the overarching influence of the tobacco industry is most blatant is in the determination of tar and nicotine yield in cigarette smoke. For several decades the tobacco industry has been *de facto* responsible for determining the ISO standards on tobacco and tobacco products. Tar and nicotine measurement based on those standards have been widely used by the industry to promote its products as "mild", "lights" and "ultra-lights", for example, insinuating health benefits from these lower tar and nicotine products, when no health benefits exist.[6 9 15 16] (In 1962, in Canada, the tobacco industry agreed to avoid using tar and nicotine levels in advertising, a deal that fell apart in the mid-seventies, with an increase in the competition for the "light" cigarettes market.[82 83])

It is clear that ISO standards serve only to rank cigarettes according to the tar and nicotine yield when smoked by a machine and that is not reflective of human smoking. ISO standards on tobacco and tobacco products should not be used to measure the health impact these cigarette smoke components have on the smoker as well as on the environment. There is an urgent and long overdue need for public health professionals to push for meaningful changes in the way tobacco related standards are developed, and how they are used. For example, Koslowski and O'Connor suggested a "two stage" compensating test that would provide a more accurate reading of tar and nicotine yield and of tar/nicotine ratios than the existing methods by not only testing cigarettes under more intense smoking conditions (higher volume puff, shorter interval) but also through blocking filter ventilation.[9]

Health advocates in Canada have already convinced the government that current standards on tobacco are deceptive. Both the British Columbia and federal governments modified the ISO methods to produce more realistic readings of the levels of tar and nicotine and other components yields. The Canadian modification provides a range of yields under regular and intense smoking conditions. It is still just a rank of tar and nicotine level as per machine smoke and not a measure of health effects—it may not be possible to estimate precisely a human exposure, as each smoker will smoke in slightly different ways—but it allows for more accurate information to be provided to consumers.[10] This is relevant as legislation regarding package labelling

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displaying levels of tar and nicotine is being considered, both in Canada and elsewhere, and in face of the proposed European directive.[17] The 1999 European directive determines, among other things, that tar levels should not exceed 10 mg and nicotine levels should not exceed 1 mg, by the year 2003, according to ISO measurement methods. This is an update from a 1990 European directive limiting the amount of tar to 15 mg. To comply with the early directive, the industry changed measuring methods without changing the product, as stated in this 1993 memo from PM's M. Bourlas:

> "You already know about the EEC mandate to reduce all deliveries to 15 mg. As we knew this was going to happen as early as 1988, we began to develop a strategy with which to react. The strategy centred around the fact that there existed a number of different testing procedures around the world and it seemed prudent on our part to harmonize them. Speerheaded [sic] by PM Europe, we put together a team represented by 23 different markets (countries) and began the task of standardization. The 3 year effort resulted in a new method (now known as 'new ISO') which reduces the smoke delivery results by about 1 mg at the 16 mg level. The Marlboro sold in the EEC was initially delivering about 15.5 mg, prior to any analytical methodology change. When the new system was implemented, the deliveries were around 14.5 mg, but remember, no product change ever took place . . ."[18]

It is likely that the tobacco industry has already develop strategies to deal with the new European Directive in a manner that will be most beneficial to its interests, such as changing cigarette design. Thus, continuing to make health policy decisions based on current ISO standards is meaningless and is a step back in the tobacco control and consumers' protection movements.

The final report from the WHO's sponsored meeting "Advancing Knowledge on Regulating Tobacco Products" held in Oslo, Norway in February 2000[20, 21] acknowledges that:

> "FTC/ISO methods currently in use were not intended to measure the biological or epidemiological impact of tobacco products. New methods and protocols must be developed to measure the impact of tobacco products on an individual and population basis. ISO should be urged to ensure that its members recognize and adhere to the principle that ISO/FTC measurement and methods are used to monitor performance and not health impacts of tobacco products."[20]

The report recommends:

> "Ban the use of misleading terms such as "light", "mild", and other words or imagery (including certain brand names) which have the aim or effect of implying a reduced health risk attributable to low tar or nicotine measurements on tobacco products and in advertising/promotional material.
>
> "Remove tar and nicotine measures derived from ISO/FTC methods from packages. Warning labels to emphasize the addictiveness of tobacco products.
>
> "Discontinue harm reduction strategies based on naïve interpretation of tar and nicotine yield measurements. This means abandoning the strategy of seeking lower nominal tar yields and instead, finding approaches that genuinely reduce harm to nicotine users."[20]

The issue of standard measurement of tobacco products components is likely to gain even more international visibility as the negotiations for the Framework Convention for Tobacco Control advance and include the regulation of tobacco products among its protocols.

Each government could follow Canada's example, but it would be more effective if health professionals and tobacco control groups attempt to participate in the work of ISO, either directly or through a national standard organisation. It is unlikely that every single ISO member will be able to set its own measurement standards, as the tobacco industry knows which is why it prefers to work through international organisations. As stated in a 1990 PM document:

> "The main disadvantage of arguing with local authorities is that it is very difficult to find technically competent people and/or that we often have to face the anti-smoking lobby and the debate then becomes emotional. On the other hand, if a 'precooked' solution is proposed by a credible international organisation it is often accepted 'as is' because for the fear of going against international trends."[24]

The need for groups other than the tobacco industry to become involved with the work of ISO is even more pressing because, in an attempt to streamline and speed its procedures ISO is considering some procedural changes that will give the tobacco industry greater opportunity to determine international standards:

> "ISO committees will in future, subject to certain conditions, have the option of dispensing with the committee stage—the part of the ISO process during which national positions are debated in order to reach consensus within an ISO committee—and with the final approval stage, during which the texts of final standards are submitted for formal approval by the full ISO membership . . .
>
> "New deliverables representing the consensus between technical experts in an ISO working group or an international consensus achieved in an ISO committee allow publication of new types of documents, called, respectively, Publicly Available Specification (ISO/PAS), and Technical Specification (ISO/TS). ISO will also provide the possibility for adoption of documents developed outside the ISO system by less transparent and consensual procedures. Such documents, whether developed within or outside the ISO system as ISO/PAS or ISO/TS, must be reviewed every three years and at the second review must either be withdrawn or revised to become full ISO International Standards."[1]

The time for health groups to act is now. With the knowledge accumulated it is no longer acceptable that claims of lower levels of tar and nicotine be made based on ISO standards measurement methods.

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What this paper adds

It is widely known by public health professionals that the ISO standard methods to measure tar and nicotine content in cigarettes are inadequate to assess the amount of human exposure to these components, underestimating the actual yields. The tobacco industry has taken advantage of the ranking provided by these standards to mislead the public, using labels such as "mild" and "light" for cigarettes that have lower tar and nicotine contents according to the ISO method, implying a non-existent health benefit.

This analysis of internal tobacco industry documents shows how the industry is *de facto* responsible for setting these standard measurement methods, from the testing development to the approval and publication stages. Based on evidence of industry influence provided by this analysis, this study urges public health authorities to play a larger role in the standard setting arena, and to refuse to use the ISO method as a basis to develop health related regulatory policies. The ISO standard, as is, should not be used to justify policies aiming at protecting the public's health.

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Appendix 6

INFORMATION SHEET ON

WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products

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Reducing tobacco product appeal and use through product regulation:

- Tobacco product regulation is a powerful tool that can help to decrease the appeal and subsequent use of tobacco products.
- Tobacco product regulation should be part of a comprehensive tobacco control programme.
- Tobacco product regulation includes measurement of contents and emissions of tobacco products, their regulation and disclosure to regulatory authorities and the public.
- Examples include bans or the restriction of flavours, bans on product categories e.g. smokeless tobacco or electronic nicotine delivery systems (ENDS), or disclosure of the contents of tobacco and related products, such as nicotine and sugars.
- Testing methods for product regulation should have zero industry involvement (industry-independent).
- The development and validation of testing methods is crucial to regulate tobacco products, including data verification.
- Tobacco product regulation need not be expensive as regulators can charge tobacco manufacturers for costs involved in testing products by independent labs.

Why is tobacco product regulation important?

Despite their devastating health effects, tobacco and related products are designed to appeal to young people, are addictive, openly marketed and either under-regulated or not regulated.[1] Given the number of people that die every year from tobacco-related illness, these products should be regulated. Tobacco-product regulation, which forms part of a comprehensive tobacco control programme, should thus be actively pursued. To achieve this, countries can require tobacco manufacturers to make their products less attractive, toxic and addictive,[1] especially to young people, by amending existing tobacco-control laws to include tobacco product-regulation provisions. Regulatory measures, such as setting product standards or banning product features or categories, aim to reduce tobacco use prevalence and tobacco-related harm. Examples include restriction and/or banning of flavours and sugars in tobacco products, restriction on filter features, such as filter ventilation[2] and setting limits on the levels of emissions generated.[2,3]

It must be noted that no machine smoking regimen can represent all human smoking behaviour; machine smoking testing is useful for characterizing cigarette emissions for design and regulatory purposes, but communication of machine measurements to smokers can result in misunderstanding about differences in exposure and risk between brands; data on smoke emissions 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 and representing differences in machine measurements as differences in exposure or risk is a misuse of testing with WHO TobLabNet standards.

World Health Organization

Appendix 6

What is the significance of these methods for tobacco product regulation?

The importance of tobacco product regulation is reflected in Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC).[4] Article 9 sets out the obligation of Parties in regulating the contents and emissions of tobacco products. Article 10, on the other hand, involves the disclosure of such information by tobacco manufacturers to responsible national authorities for tobacco-product regulation, for regulators to extract relevant information in a meaningful way to inform the public about the toxic constituents of tobacco products and the emissions that they may produce. The associated guidelines for both Articles recommend that Parties prohibit or restrict ingredients that increase palatability of tobacco products (e.g. flavourings) and also set out the requirements for independent testing and measurement of the contents and emissions of tobacco products.[5]

How can measuring tobacco product contents and emissions advance tobacco product regulation?

Regulators can measure and monitor levels of compounds in tobacco products or their emissions to understand the type and amount of chemical substances to which consumers are exposed. This may help formulate policies to reduce the toxicity, attractiveness and addictiveness of tobacco and have the potential to contribute to reduced tobacco use. Following implementation of regulatory policies, these compounds can be measured for compliance purposes and remedial action taken as necessary. Validated laboratory testing methods are needed to measure the contents (e.g. humectants and nicotine) and emissions (e.g. nicotine and carbon monoxide) of tobacco products for regulatory purposes and the cost of routine compliance testing, as well as verification of industry data can be charged to tobacco manufacturers.[6] As a first step, countries can monitor and build intelligence on the products on their markets.

Why is it important for these methods to be developed independently of the tobacco industry?

As tobacco products are manufactured and intricately designed by the tobacco industry, their involvement in developing methods to test these products would be a clear conflict of interest. This is even more crucial given that the tobacco industry has a long history of misleading the public and working against well-intentioned tobacco-control policies.[7] Examples include the use of ventilation holes in cigarettes to manipulate the emissions of tobacco products and promote so-called light and mild tobacco products as an alternative to quitting, while being fully aware that testing of these products, using International Organization for Standardisation (ISO) methods, will result in misleadingly low levels of the measured compounds. Therefore, tobacco industry activities, no matter how they are "dressed up", should always be monitored with caution and scepticism and regulatory test methods should be developed and validated independently of the tobacco industry.

Are ISO tobacco testing methods independent?

The industry exerts considerable influence on the adopted ISO testing methods for tobacco and tobacco products, as they make up by far the largest percentage of national and international technical committees. This led to WHO establishing an alternative global network of independent laboratories, the WHO Tobacco Laboratory Network (TobLabNet), to develop the methods for testing these products rather than adopting those developed under industry control and manipulation. Consequently, this will ensure the generation of independent and reliable information on tobacco products for regulatory purposes, thus building capacity for tobacco product regulation and strengthening implementation of relevant provisions.

Appendix 6

More information on TobLabNet and its activities?

TobLabNet is a WHO technical advisory body, comprised of independent scientists with expertise in the fields of product regulation and laboratory analysis of tobacco contents, emissions and design features. It was established in 2005 and has members from the six regions of WHO. TobLabNet develops and validates methods to test the contents and emissions of tobacco products, supports WHO in building testing capacity in WHO Member States, and runs training workshops in countries under the leadership of WHO. TobLabNet works in unison with WHO TobReg, which provides scientifically sound and evidence-based recommendations to Member States through the WHO Director-General on tobacco product regulation.

Find more detailed information on the role of TobLabNet, how to become a member, how to request method development and/or assistance, etc. here. Find more on how to build laboratory testing capacities here.

What are WHO TobLabNet methods and how are they developed?

WHO TobLabNet methods[8] are laboratory testing methods for tobacco and related products developed by part of WHO's global technical network on tobacco-product regulation. This group is made up of members from government, academic and other independent laboratories. TobLabNet methods are developed and validated independently of the tobacco industry, with no tobacco industry representative present at any of the meetings, nor involved in the development and validation of the methods (unlike ISO committees for example). These independent methods are recommended for use by regulators to test the contents and emissions of tobacco products. For example, TobLabNet validated an intense smoking protocol for generating emissions from cigarettes. The WHO Study Group on Tobacco Product Regulation (TobReg), another technical advisory group of WHO on tobacco product regulation, recommends the use of an intense smoking regime, rather than the US Federal Trade Commission (FTC)/ International Organization for Standardisation (ISO) testing regime.[2]

What is the difference between the ISO and the intense regime?

The ISO regime is less intense than human smoking behaviour, especially in the case of cigarettes with a high degree of filter ventilation. As the main addictive component in cigarette smoke is nicotine, and smokers need a certain amount of nicotine to maintain their addiction, they adapt their smoking behaviour to the nicotine levels present in smoke. One of the main factors determining nicotine levels are ventilation holes in the cigarette filter that dilute smoke. In response, smokers (partly) close the ventilation holes with their fingers and lips, and smoke more intensely. The ventilation holes remain open in the ISO regime, but are closed in the intense regime. Additionally, the intense regime uses larger, longer and deeper puffs.

What are priority contents and emissions of tobacco products and which methods are available?

The priority contents and emissions identified by WHO[9] are important targets for product regulation. There are thousands of compounds in tobacco products and their emissions, of which the 39 most toxic compounds have been prioritised for testing by WHO-selected independent scientists. The WHO FCTC Conference of the Parties (COP) requested TobLabNet to develop testing methods for 12 of these compounds, which were further prioritised and considered the most important for monitoring.[10] Nine of these are the toxicants in cigarette smoke recommended for mandated lowering by TobReg (Acetaldehyde, Acrolein, Formaldehyde, Benzene, 1,3-Butadiene, Carbon monoxide, Benzo[a]pyrene, NNK, NNN),[2] and the other three are priority contents in tobacco, namely nicotine, humectants and ammonia.[3,9] These methods are available to regulators and other interested parties.[11] As many countries still use the ISO method for regulatory purposes and the principles of some of these methods guided the development and validation of TobLabNet methods, ISO methods are referenced in some of the TobLabNet methods. This does NOT mean that the industry had any involvement in developing the methods or interfered with the methods in any way. The reason is that TobLabNet methods are also validated for the very low emission levels from open filter holes, as with those achieved by the ISO method.

Appendix 6

What is next for TobLabNet?

TobLabNet continues its work on developing and validating methods for measuring other compounds on the priority list to make a wider range of methods available to countries. It also continues validating methods for analysis of contents and emissions of other tobacco and related products, such as electronic nicotine delivery systems (ENDS) including e-cigarettes, heated tobacco products, smokeless tobacco, waterpipe tobacco products and other tobacco products. TobLabNet's continuing initiatives include efforts on building country capacity to implement validated methods. E-learning tools are being developed for training purposes on the various methods. Further, WHO continues to work with Member States and leverages the diverse expertise in TobLabNet and TobReg to build tobacco-product regulation capacity around the world.

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