For internal use only – Not a leave-behind document Brussels, October 16, 2023

Tobacco Europe position on Cigarettes' Testing Methods

Machine-measured TNCO yields were never intended to indicate the levels of tar, nicotine and carbon monoxide that an individual smoker will inhale. They are for comparing product performance only.

Tobacco Europe members have always been clear that tobacco products carry risks to health, and that no cigarette is safe. No standardized testing methodology can replicate the smoking behavior of individual smokers. The TNCO yields generated from testing are intended to provide an objective **system of comparison between products** but do not give a precise figure for how much TNCO an individual smoker will inhale when smoking a particular cigarette. A product that generates lower TNCO numbers, through emissions testing, is not necessarily less harmful than one that generates higher numbers. The WHO's TobLabNet is also clear on this matter. The following disclaimer is stated across all their relevant documents:

> 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 between brands in exposure and risk. 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. **Representing differences in machine measurements as differences in exposure or risk is a misuse of testing with WHO TobLabNet standards**.[1] (Emphasis added)

In addition, a factsheet produced by the Netherlands Centre for Health Protection, National Institute for Public Health and the Environment (RIVM) related to the testing methods for TNCO levels in tobacco smoke acknowledges the limitations of machine-smoking methods, stating:

> It is important to note that human smoking behaviour is diverse, and no machine smoking method can represent all sorts of smoking behaviour. Machine smoking measurements are useful for characterizing cigarette emissions for example to compare products for research purposes or market surveillance. However, they are not a valid measure of human exposure and are not intended for this purpose. Consequently, TNCO levels based on machine smoking can give a false impression of human exposure and risk.[2]

[1] *See for example*, Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products (2020), Document reference number: WHO/HEP/HPR /2020.1; WHO TobLabNet Official Method SOP 01 (2012): Standard operating procedure for intense smoking of cigarettes; WHO TobLabNet Official Method SOP 02 (2016): Standard operating procedure for validation of analytical methods of tobacco product contents and emissions; WHO TobLabNet Official Method SOP 03 (2014): Standard Operating Procedure for determination of tobacco specific nitrosamines in mainstream cigarette smoke under ISO and Intense Smoking conditions; WHO TobLabNet Official Method SOP 04 (2014) etc.

[2] *See* National Institute for Public Health and the Environment, Ministry of Health Welfare and Sport (2021) Factsheet on Methods for determining TNCO in tobacco smoke.

For internal use only – Not a leave-behind document Brussels, October 16, 2023

Tobacco Europe members abide by EU legislation and produce cigarettes that comply with mandatory tar, nicotine and carbon monoxide maximum emissions by applying the ISO 3308 standardized methodology (smoking machine regime) for the testing and reporting of smoke constituent yields.

The Directive 2014/40/EU recital 11 states "*For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to the relevant, internationally recognized ISO standards*." The relevant ISO standards are named in the Article 4(1) of the Directive 2014/40/EU as follows: "*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*." Mandatory application of these standards was confirmed in the recent CJEU judgement (case C-160/20) where the Court ruled:

> [T]he maximum emission levels for tar, nicotine and carbon monoxide from cigarettes intended to be placed on the market or manufactured in the Member States, prescribed in Article 3(1) of that directive, must be measured in accordance with the measurement methods arising from ISO standards 4387, 10315, 8454 and 8243, to which Article 4(1) refers.[3]

Currently, these methods exclusively apply the standardized machine smoking regime method ISO 3308.

Member States must recognize the impact involved in the case of an additional machine smoking regime.

There are subtle differences between the currently validated machine-smoking regimes. The ISO 3308 machine-smoking regime, for example, does not block any of the filter ventilation holes that manufacturers use to produce cigarettes that comply with mandatory TNCO limits set by regulators and to offer consumers a choice in cigarette characteristics. The 'Canadian Intense' smoking regime, (also known as the Health Canada Intense method and which is now also validated by ISO - ISO 20778), stipulates that 100 % of the filter ventilation holes should be blocked, arguing that a smoker may block the holes with their fingers or lips. However, neither regime accurately represents 'real-life smoking'.

At this point, it is unclear what benefits would be gained by applying the ISO 20778 intense smoking regime in lieu of - or in addition to - the ISO 3308 method. Instead, serious impacts to tobacco manufacturers would be expected in the following ways:

[3]Judgment of the Court (Grand Chamber) of 22 February 2022; Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport; Request for a preliminary ruling from the Rechtbank Rotterdam; Reference for a preliminary ruling – Directive 2014/40/EU – Manufacture, presentation and sale of tobacco products – Products not complying with the maximum emission levels – Prohibition on placing on the market – Measurement method – Filter cigarettes with small ventilation holes – Measurement of the emissions on the basis of ISO standards – Standards not published in the Official Journal of the European Union – Compliance with the publication requirements laid down in Article 297(1) TFEU read in the light of the principle of legal certainty – Compliance with the principle of transparency; Case C-160/20 (linked here).

- **Reporting on two measurements instead of one will lead to an unnecessary increase in testing burden, as is the case in Canada, where double testing using both original ISO 3308 and 'Canadian Intense' methods are mandated, although no TNCO limits are set.**
- **If TNCO emissions are measured according to the ISO 20778 intense smoking regime, a significant portion of cigarettes will not fulfill the mandatory 10-1-10 mg/cig maximum emissions, which were designed for use alongside the original ISO 3308 method. Some important methodological disadvantages have been found when using the Canadian Intense smoking regime. These include a higher variability in the results for 'tar' compared to when using the ISO method. This occurs as a result of higher burning temperatures altering the water accumulation in the filter. Higher variability in the results means that laboratories can be less accurate in their reporting.[4] As a result, cigarettes that were previously fully compatible with the rules of the EU and their member states, will no longer comply. A sudden *de facto* ban will most certainly lead to an increase of illegal products brought to the EU market by criminals that pay no respect to any regulations or testing requirements (TNCO levels, ISO, CI testing regimes included).**

Given that neither, yields measured using the original ISO 3308 smoking machine method, nor ISO 20778 intense smoking regime, will reflect smokers' exposure to TNCO, the implementation of both is unnecessary.

In January 2020, the EU Commissioner for Health and Food Safety gave a statement in relation to the Canadian Intense smoking regime: "*The general consensus at present is that none of the current machine smoking regimens adequately represent human smoking behaviour. This includes the Canada Intense method. In this respect, there was no sufficient evidence to revise the provisions on measurement methods at the time of the last revision of the Tobacco Products Directive (TPD)*".[5]

This is consistent with EU Commission Report on the application of Directive 2014/40/EU dated 20 May 2021: "*It was agreed that no current smoking regime adequately represents human smoking behaviour*".[6]

RIVM scientists have published research highlighting that the 'Canadian Intense' method for testing TNCO levels in tobacco smoke does not offer any improvement on estimating an individual smokers' exposure. Under their experimental conditions, "*Smokers smoke their cigarettes with consistent, individually characteristic puffing topography. These characteristic human puffing profiles show differences between smokers*". When comparing smokers' behavior to smoking machine regimen, the authors point out, *"[T]he present study shows that the smoking machine with the HCI regime may also*

[4] See Purkis, S. W., et al. (2011). Some consequences of using cigarette machine smoking regimes with different intensities on smoke yields and their variability. *Regul Toxicol Pharmacol* 59(2): 293-309

[5] *See* European Commission document: http://www.europarl.europa.eu/doceo/document/E-9-2019-003775-ASW_EN.pdf

[6] *See* Directorate-General for Health and Food Safety (2021) Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products (linked here)

underestimate actual smokers' exposure, because inter-puff intervals are shorter for human smokers than in the HCI regime"[7]

After a Dutch court delivered a ruling prohibiting the Dutch Government from using the original ISO method for measuring TNCO levels in tobacco smoke, the matter was raised once more to the European Commission by the MEP for the Netherlands Esther De Lange.[8] Ms Kyriakides, on behalf of the European Commission responded, making an important point in addition to echoing the statements above: "***No matter the measurement method, smoking is never safe. A change in the approach to tobacco testing methods would not make tobacco products safe for smokers' health***."[9]

In summary, Tobacco Europe members are of the opinion that one machine smoking regime, namely ISO 3308, should be applied for regulatory reporting and product comparison in the context of Directive 2014/40/EU mandatory emission levels from cigarettes.

[7] *See* Pauwels, C., Boots, A. W., Visser, W. F., Pennings, J. L. A., Talhout, R., Schooten, F. V. and Opperhuizen, A. (2020). Characteristic human individual puffing profiles can generate more TNCO than ISO and Health Canada regimes on smoking machine when the same brand is smoked. *Int J Environ Res Public Health*, 17(9).
[8] *See* Esther de Lange, Dutch court ruling on 'sham cigarettes', Priority question for written answer P-003808/2022
to the Commission Rule 138 (link here)
[9] Answer given by Ms Kyriakides on behalf of the European Commission (linked here).