

ESTA POSITION

PUBLIC CONSULTATION DUTCH MINISTRY OF HEALTH

Amending the “Tabaks- en rookwarenregeling” measurement method volume tobacco

Introduction

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The European Smoking Tobacco Association, ESTA, has several suggestions to improve the proposed amendments to the “tabaks- en rookwaren regeling” on how to determine the amount of volume tobacco for use in the Fine-cut tobacco smoking Method.

Main points that could improve the proposed amendments

The Annex of the draft regulation in its first paragraph details the measurement method for volume tobacco.

- It refers to a **measuring cylinder** without specifying its diameter, length, or the material it is made of. It also does not specify the scale to be used. All these specifications are crucial to ensure that test can be performed accurately, can be reproduced and repeated and can be validated.
- It is also necessary that laboratories can **purchase the cylinder** as well as the metal rod for the measurement method and it would have been helpful if the Health Ministry would indicate possible suppliers and would inform tobacco manufacturers and importers.
- The Annex refers to a monitor tobacco, or **EMT**, but it is unclear which Monitor Tobacco this is and how in the future this monitor tobacco would be available to laboratories, manufacturers, and importers. Again, informing tobacco manufacturers and importers is crucial.
- The Annex includes a “conversion” table, and to avoid any misunderstanding, we would like to propose the following alternative table, but with the caveat that it needs scientific underpinning:

volume percentage (%) compared to EMT		To use volume tobacco (mg) in one stick
From	including	
	110%	750
111%	120%	710
121%	130%	650
131%	140%	600
141%	150%	560
151%	160%	520
161%	170%	480
171%	180%	450
181%	190%	430
191%	200%	410
201%	210%	380
211%	220%	370
221%	230%	350



- The Annex refers to the amount of tobacco required in the test as “ongeveer”, i.e. **approximately 10 grams**. We would suggest that this should simply read 10 grams, together with a tolerance as usually applied **for laboratory tests**.
- The Explanatory Memorandum (EM) refers to NEN and ISO Standards and Methods, but unfortunately a reference to **ISO 15592-2** on conditioning is absent. It is necessary to specify in the regulation the conditioning of the EMT and test volume tobacco, which should follow the ISO Standard 15592-2.
- Finally on the volume tobacco subjected to the test, we would like to caution that volume tobacco once placed on the market may undergo “**physical**” **changes** due to shelf life, transport conditions and other factors which may influence any results when compared to recently manufactured volume tobacco. The draft Regulation should therefore allow for such **variation**.
- The Regulation sets the **entry into force** deadline at 31/12/2020, with a sell-through period until 01/04/2021. The Explanatory Memorandum explains that these 9 months should be sufficient time for the industry to prepare. Unfortunately, this preparation time is not 9 months, but after the PC and final publication will be significantly shorter. The draft regulation does not allow any validation studies of the Measurement Method to be undertaken to ensure that the method is robust enough, meeting scientific standards on repeatability and reproducibility and therefore can be legally enforced.
- Only after such a **validation study** can manufacturers and importers test their products and determine whether these need to be **adapted** to be compliant with the emission levels set in Dutch law. If such adaptations are necessary, time will be needed to do so and follow the administrative **notification procedures** as set by law as well. These procedures take much time, time which is not foreseen in the draft Regulation.
- We would like to inform the Dutch Ministry of Health that **ISO** is currently reviewing the ISO Standard for Smoking Tobacco and that the Working Group undertaking this review is developing a Method to ensure that the ISO Method can more easily be applied to volume/expanded fine-cut tobacco. This review will include a validation study of the measuring method for volume tobacco to which ISO Member Organisation’s laboratories around the world will be invited to participate.
- As a final remark we would like to point out that the Ministry has **not engaged industry scientific experts** when developing this draft regulation. As this is not a policy matter, but rather a technical implementation of a testing regime which ESTA in any case supports, the draft regulation would have benefitted from expertise and experience which is clearly available, and in our view, indispensable as our comments above show.

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