



COMMISSION OF THE EUROPEAN COMMUNITIES

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## **Cigarette yield measurement and some basic steps for laboratory approval**

### **PRACTICAL GUIDE**

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## 1. INTRODUCTION

Discussions on the first report on the application of the Tobacco Products Directive 2001/37 EC<sup>12</sup> in the Tobacco Products Regulatory Committee in September 2005 revealed that Member States wish to have more clarity on questions such as the interpretation of thresholds set by the Directive for tar, nicotine and carbon monoxide and their testing frequency as well as on approval of laboratories to enable future laboratory cooperation.

The Tobacco Products Regulatory Committee set up a working group to deal with these questions. The working group consisted of the experts from five Member States and was chaired by the Commission. The Commission also invited its Joint Research Centre and the Chairman of the European Network of Government Laboratories for Tobacco and Tobacco Products to these meetings. The working group met three times and focused on the issue of testing margins. In addition, best practices for the cooperation and approval of tobacco laboratories were addressed.

This document is not legally binding and it represents the views of the Commission services. The document will be updated according to the future experience and new scientific knowledge. It must be emphasised that, in the last resort, it rests with the European Court of Justice (ECJ) to interpret a Directive.

## 2. TAR, NICOTINE AND CARBON MONOXIDE MEASUREMENT

Article 3(1) of the Tobacco Products Directive 2001/37/EC stipulates that, from 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than 10 mg per cigarette for tar, 1 mg per cigarette for nicotine and 10 mg per cigarette for carbon monoxide (CO).

Article 4(1), first subparagraph, of the Directive specifies that these yields shall be measured on the basis of the ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. Article 4(1), second subparagraph, lays down that the accuracy of the tar and nicotine indications on packets shall be verified in accordance with the ISO standard 8243.

ISO standard 8243 contains confidence intervals for two different sampling methods: at one point in time and over a period of time. The confidence intervals permitted by the standard depend on the method of sampling. The sampling mode at one point in time can either be used to analyse samples from different points of sale in the area under study, or to analyse samples present in a producer's premises (or importer's or distributor's warehouse) at a specific point in time. Sampling over a period of time can be used to analyse tobacco products from a given producer (or importer or distributor), over a period of time (e.g. 6 months or 1 year).

The yields specified in the Directive are to be intended as maximum yields. However, for analytical purposes, ISO standard 8243 provides confidence intervals

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<sup>1</sup> OJ L 194, 18.7.2001, p.26 – 34.

<sup>2</sup> COM (2005) 339, [http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005\\_0339en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0339en01.pdf)

which have been estimated for tar and nicotine at a level of 95%, to be  $\pm 20\%$  for sampling at one point in time, and  $\pm 15\%$  for sampling over a period of time. In addition, the confidence intervals for carbon monoxide have been estimated, at a level of 95%, to be  $\pm 25\%$  for sampling at one point in time, and  $\pm 20\%$  for sampling over a period of time<sup>3</sup>. These confidence intervals include the variations arising from the sampling procedures and from the product itself.

The question is whether the maximum limits laid down by the Directive should be regarded as the maximum value around which the confidence interval can fluctuate, or as the upper limit of the confidence interval.

It is proposed that the maximum limits should be regarded as maximum values around which the confidence interval can fluctuate. However, if the values measured are repeatedly<sup>4</sup> above the limits set by the Directive, Member States should take appropriate enforcement actions. Whenever the values measured are over the upper limit of the confidence interval, enforcement actions should also be taken.

It is acknowledged that smoke emission data from such machine measurements are not valid levels of human exposure. The smoke yield intake by consumers as well as the measurements can be altered by product design or other amendments. Tar, nicotine and carbon monoxide yields data should therefore not be regarded as individual exposure and health risk indicators.

The Directive recognises these shortcomings of the ISO methods, and refers to them as the only internationally recognised standards for the time being. Subsequent research and technological progress should make it possible to develop and use more precise and reliable measurement methods and to develop measurement methods for the other tobacco products, as indicated in the 14<sup>th</sup> recital of the Directive<sup>5</sup>. The Commission is actively following this work.

### **3. SOME BASIC STEPS FOR LABORATORY APPROVAL**

#### **3.1. Measurement and Verification**

The first paragraph of Article 4 is divided in two subparagraphs that distinguish between two exercises:

- the measurement of the yields, by using specified methods (the first subparagraph),
- the verification of the accuracy of the indications on packets (the second subparagraph).

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<sup>3</sup> In the ISO standard 8243 (4<sup>th</sup> edition, September 2006) it is also specified that “these confidence intervals will not be smaller than  $\pm 1$  mg for NFDPM,  $\pm 1,5$  mg for CO and  $\pm 0,1$  mg for nicotine”

<sup>4</sup> ISO standard 8243 (point 5.1 and 5.2) provides a recommendation for sampling frequency over a period of time

<sup>5</sup> OJ L 194, 18.7.2001, p. 27.

The first subparagraph requires that the tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. This should be understood to refer to the process used to obtain information on the level of defined analyte(s), by using a specific measurement method.

The second subparagraph requires that the accuracy of the tar and nicotine indications on packets shall be verified in accordance with ISO standard 8243. In general terms, verification should be understood as checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled. The second subparagraph should be understood to refer to checking that, the values for tar, nicotine and carbon monoxide, based on the above measurements and printed on the packs, are correct and within the limits.

### **3.2. Criteria for the approval of testing laboratories**

Article 4(2) of the Directive requires that the tests shall be *carried out or verified* by laboratories approved and monitored by competent authorities and that Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and methods of monitoring applied.

The list of laboratories approved by the Member States and communicated to the Commission can be consulted on the webpage of the Health and Consumer Protection Directorate General of the Commission:

[http://ec.europa.eu/health/ph\\_determinants/life\\_style/Tobacco/label\\_lab\\_en.htm](http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/label_lab_en.htm) ).

The information received by the Commission shows that a variety of criteria has been used to approve the testing laboratories. Moreover, some Member States have not clearly reported which specific criteria they have used.

On the basis of the information and best practices gathered from the Member States, the following criteria seem to have been considered the most appropriate by Member States for tobacco product testing laboratories:

- have trained and competent staff;
- have equipment capable of taking the necessary measurements;
- follow procedures that are sensitive, selective, accurate, and reproducible by using validated methods of measurements, preferably those standardised by a recognised international body ( e.g. ISO);
- have a mechanism for cooperating and sharing information
- establish and maintain a quality system. Laboratories should be accredited in accordance to EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”. This requirement should be fulfilled within the two years following either the establishment of testing or the publication of this document.

### **3.3. Criteria for the approval of verification laboratories**

While the measuring can be performed by industry laboratories pursuant to art.4.1 first subparagraph, the verification of the results should be carried out by independent laboratories that could be governmental or other laboratories that are not owned or controlled, directly or indirectly, by the tobacco industry or can demonstrate a robust and continuous third party audit. Such verification laboratories have to fulfil the criteria for testing laboratories as it is implied by art. 4.2 first subparagraph.

A good example of criteria for laboratory independence is the Terms of Reference document for the laboratories participating in the WHO Tobacco Laboratory Network (TobLabNet) which is convened by the Tobacco Free Initiative. These criteria are given to ensure that the verification of laboratories' results is absolutely transparent and not in any way compromised. These criteria are the following:

- The laboratory should not be totally or partially owned by a tobacco company.
- Laboratories that receive funds from the tobacco industry in the form of fee-for-service must demonstrate independence from the tobacco industry.
- If a publicly-traded company, the tobacco industry should not have more than 10% share of the total stocks.
- The laboratory should not have any member of the Board of Directors, or someone in a senior management position, who is employed by a tobacco company, which includes consultancy positions, among others. This also includes non-compensated consulting or advising to a tobacco company that may create a conflict by carrying the promise of future work.
- The laboratory may have tobacco companies as customers, but not its sole customers.

Verifying laboratories and public health communities are encouraged to establish and maintain close links in order to achieve the best results in the epidemiological and behavioural research on the effects of tobacco products and their claims on health, beliefs, behaviours and outcomes.

## **4. FOLLOW-UP**

The Tobacco Products Regulatory Committee will be informed on experience from the Member States on the use of the guidance discussed in this document.