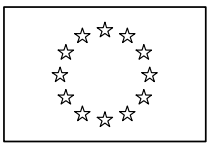

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

First Report on the application of the Tobacco Products Directive

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1. INTRODUCTION

Article 11 of Directive 2001/37/EC of 5 June 2001[1] on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products ("the Directive") requires that the Commission shall regularly report to the European Parliament, the Council and the Economic and Social Committee on the application of the Directive.

This report provides the first assessment of the application of the Directive. It is based on the feedback from Member States, largely in response to a questionnaire sent to all of them (EU25) in June 2004. The report takes into account recent developments and new scientific knowledge and incorporates views of stakeholders in the area of tobacco control. Given the short period of time since the transposition of the Directive, including the delays explained in Chapter 2, such experience is limited both at national and EU level.

However, the Report demonstrates that the positive effects of the regulation of tobacco products are already emerging at EU level. This experience will also be useful in the global context. The WHO Framework Convention on Tobacco Control[2] (FCTC) incorporates many of the concepts central to the Directive.

The report does not include separate sections on tobacco products for oral use or roll-your-own tobacco as the replies from the Member States did not provide any new information and as there was not enough new scientific information on ingredients that encourage addiction or on tobacco products that may have the potential to reduce harm. However, the Commission continues to follow closely scientific developments as regards different aspects of tobacco products and their health effects, including carcinogenic, cardiotoxic and dependence producing effects, and will cover any findings in detail in the next report.

The report highlights areas that should be developed based on the first experience and in the light of new scientific and technical knowledge.

2. TRANSPOSITION

As of 31 October 2004, the Directive was transposed in all Member States with the exception of Estonia[3].

As regards the EU15, there were some delays in the transposition, due by 30 September 2002. The Commission issued a warning letter to those Member States in November 2002. Some Member States cited the legal uncertainty as a result of challenges before the European Court of Justice as a cause for delay. In both two cases[4] the Court maintained the Directive.

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1 OJ L 194, 18.7.01, p. 26.

2 www.who.int/tobacco/framework

3 The Estonian Parliament adopted the act that transposes the Directive on 4 May 2005.

4 European Court of Justice: cases C210-03 and C434-02.

3. APPLICATION

3.1. Maximum tar, nicotine and carbon monoxide yields of cigarettes (Article 3)

All EU15 countries respected the deadline in Article 3 that by 1 January 2004 cigarettes released for free circulation, marketed or manufactured in the Member States should comply with the maximum tar, nicotine and carbon monoxide (CO) yields. In Greece, the tar yield will apply from 1 January 2007. The EU10 did not request transitional periods for this provision. Regarding the yields applied to cigarettes exported to countries outside the EU all Member States comply with the deadline of 1 January 2005 set by the Directive.

3.2. Measurement methods (Article 4) and yield labelling

3.2.1. Testing laboratories

Thirteen countries have notified the approved laboratories to the Commission. A number of Member States, particularly smaller ones, indicated the lack of an appropriate laboratory in the country; their solution is to approve a laboratory in another Member State.

The Commission will consult Member States on questions related to laboratories, in particular on sharing of the laboratory capacity and publish the list of approved laboratories.

3.2.2. Measurement of tar, nicotine and carbon monoxide yields

Nicotine is the single most important substance contained in cigarettes and its regulation is vital. Nicotine is the reason why people continue smoking. The nicotine limit set in the Directive is an important harmonising measure and successfully brings nicotine under regulatory control. The WHO[5] acknowledges that a broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in reducing risks.

The ISO measurement of yields is based on smoking simulated by a machine. New evidence, however, confirms that smokers adjust inhalation with the yield. Hence, despite lower nominal yields from cigarettes, there is only limited evidence that this approach is successful in reducing the toxic burden of a smoker. As a result, the health community[6] has put the use of the ISO standards into question. Although the ISO standards are criticised, there is no international agreement on alternatives.

The Commission does not propose to revise the current standards set out the Directive until solid evidence shows that better methods exist to replace them. The Commission will encourage the scientific and technological development in this area. In particular, the FCTC provides in Article 9 that the Conference of the Parties shall propose guidelines for testing, measuring and regulating the contents and emissions of tobacco products. As soon as more realistic methodologies are internationally agreed the Commission will consider how to adapt the Directive.

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[5] WHO Study Group on Tobacco Product Regulation Recommendation on tobacco product ingredients and emissions WHO 2003 http://www.who.int/tobacco/sactob/recommendations/en/

[6] "Tobacco or Health in the European Union: past, present and future". Report prepared by the ASPECT consortium, 2004.

3.2.3. Reporting the yields

Reporting the yields on the packet has led to concerns that consumers may believe that low yield products are less harmful, and consequently they smoke more of these. While removal of the yield information from packets has been called for, the Commission is of the opinion that the measured yields should continue to be printed on the packets. Also the FCTC provides that information on relevant constituents and emission shall be placed on the package in its Article 11(2).

3.3. Labelling (Article 5)

3.3.1. Implementation

While the implementation of the Article 5 overall is generally satisfactory there have been some difficulties. In addition, some of the EU10 countries applied a transitional period.

As regards the black border around the warnings, the Commission advises that the border should not be considered as a part of the warning area.

Very thin packets pose a special problem: The yield information should be printed parallel to the top edge but this leads to poor readability. Printing the information rotated by 90 degrees improves readability. Although contrary to the provisions of Article 5(6), the Commission has not reacted because this is considered as a temporary solution waiting for the amendment of the Directive.

Member States also reported industry attempts to circumvent the legislation by attempting to hide, obscure or reduce the visibility of the warnings by various means, such as a cardboard sheath ("*etuis en carton"*) to cover the warnings and stickers. A year after the new warnings were introduced such practices have become limited.

3.3.2. Impact on smoking

The evidence indicates that these measures influence smoking behaviour despite the fact that the warnings have been in use for a short time. Studies show that smokers have been more motivated to stop or to reduce smoking. The warnings have been particularly effective among 15-24 year olds.

A Dutch study indicated that some adults smoked less and were more motivated to quit as a result of the warnings. Among 13-18 year olds the effect was strong: 28% said that they smoked less because of the warnings[7]. Another Dutch study found that the inclusion of the quit line number increased calls to the service, in particular from lower income groups[8] that are usually less active. A Belgian study found that bigger, clearer warnings motivated smokers to stop smoking and made cigarette packs less attractive to youngsters[9]. Of Polish male smokers, 3% said they had quit because of the large health warnings, 16% had tried

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[7] Persbericht Defacto (2002) 28% van jonge rokers rookt minder door de nieuwe waarschuwingen op.

[8] Willemsen M, Simons C, Zeeman G(2002). Impact of the new EU health warnings on the Dutch quit line, Tobacco Control, 11:381-2.

[9] Joossens L, Onderzoek naar het effect van gezondheidswaarschuwingen op sigarettenpakjes in België, Vlaams Instituut voor Gezondheidspromotie, Brussel, 2004.

quitting, and 14% claimed to understand health effects of smoking better[10]. In Malta, the demand for smoking cessation enquiries increased threefold following the introduction of the warnings.

3.3.3. Colour images

In line with Article 5 (3) of the Directive, the Commission adopted in September 2003 Decision 2003/641/EC[11], which establishes rules for the use of photographs or other illustrations as health warnings and conditions under which they may be used. In accordance with Article 3 of the Decision, the Commission created a library of images[12] in May 2005.

According to a EuroBarometer survey in the autumn of 2002, 38% of the citizens believe that the addition of colour images to cigarette packages would be useful in persuading people either not to smoke, to smoke less, or to quit[13]. This is also what the Member States in general believe according to the questionnaire. The majority of the Member States intends to study the use the images. The Commission encourages the Member State to use the new pictorial warnings.

3.3.4. Further action

The Commission will consider further development of labelling, such as a wider use of the quit line telephone numbers, once more information is available on the use of new textual and pictorial warnings.

3.4. Ingredients (Article 6)

There have been some difficulties associated to the submission of ingredient information to Member States by the industry. Only 13 Member States have submitted Article 6 information to the Commission.

The format of the information transmitted from the industry to the Member States and further to the Commission varies greatly. National authorities have received information that is either too detailed or too sparse.

In general the data sent to the Member States does not comply fully with the Directive. Article 6 requires the disclosure of all ingredients and their quantities used in the manufacturing of tobacco products. The industry has put forward a template known as the "three model list", providing information according to a "quantity not exceeded" model. This conflicts with the Directive because it does not give a precise quantity and the exact information is not provided by brand.

The Netherlands and Belgium are attempting to establish specific implementing regulations for the submission of tobacco ingredients. The industry has legally challenged the Dutch

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10 World Bank Report, Curbing the epidemic. Governments and the economics of tobacco control, Washington DC, 1999.

11 OJ L 226, 10/09/2003 p.24.

12 C(2005) 1452 to be published in the OJ.

13 European Commission, Health & Consumer protection, Smoking and the environment: actions and attitudes, Special Eurobarometer 183/Wave 58.2, November 2003.

regulation concerning the proposed model[14]. It seems that this legal action is inhibiting similar initiatives in other Member States.

A further important barrier to the full implementation of this article is the lack of capacity to analyse the data received at Member State and EU level.

The Directive has succeeded in generating considerable debate on the disclosure of ingredients and placed the issue high on the European tobacco control agenda A harmonised reporting system and the definition of ingredients need further discussion to facilitate full compliance.

The current reporting system needs to be improved to facilitate processing, assessment and wide dissemination. The core element of ingredient regulation is the full disclosure of information by the tobacco manufacturers. All ingredients and constituents used in the manufacturing of a tobacco product and still present in the finished product must be included. The development of a reporting system should consider existing initiatives, such as the Dutch and Belgian models, and the European Chemicals Bureau's system.

Experts have expressed concerns that the current definition of ingredients is too limited. A way forward could therefore be to adopt the WHO working group definition[15] that "*ingredients include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from packaging into the product."*

It seems clear that Article 6 needs to be developed. The Commission will carry out an analysis of the information collected so far in order to create a basis for any amendments needed and consult the Regulatory Committee established under Article 10.

In response to requests by Member States and the industry, the Commission will develop harmonised data collection methods that are based on a common EU format and improved definitions. The Commission intends to launch a consultation involving Member States and stakeholders on this matter.

3.5. Common list of ingredients (Article 12)

Given the limited progress on Article 6, and in particular due to the lack of full submission of information, the Commission has been unable to develop a proposal for a common list of ingredients. However, the Commission has carried out an in-depth exploration on the feasibility and relevance of a common list of ingredients[16].

This consultation raised issues beyond the availability of data that may put into question the approach as set out in Article 12. The Commission has drawn a number of important conclusions relating to the relevance and utility of a list of ingredients.

A rationale behind an authorised list of ingredients is – inter alia - to be able to regulate additives that are known not to increase the toxicity or addictiveness, or to ban those that are

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14 The Dutch State is summoned by seven tobacco companies.

15 WHO Scientific Advisory Committee on Tobacco Product Regulation. www.who.int/tobacco/sactob/recommendations/en

16 This includes expert meetings on 29 September 2003 and 18 February 2004. Commission supported workshops in March 2004 and in June 2004 in Limerick. In addition, the writing of the report "Tobacco or Health in the European Union: past, present and future" was a consultative process in itself.

only used to attract children. A rationale for a common list in the EU is to avoid a situation where tobacco companies could seek approval in a country with the weakest system.

The successful establishment of a common list depends firstly on ingredient information received from the industry in a relevant and timely way. Following the provision of information, it is necessary to determine those ingredients that increase toxicity or addictiveness of the product. Moreover, scientifically sound criteria are needed for approval or prohibition of ingredients.

Such information will need to be based on accepted tests that measure toxicity and addictiveness of ingredients. However, the Commission was advised that no clear criteria for measuring toxicity and addictiveness currently exist. Methodologies should be validated for their sensitivity, specificity and comparability. This is a demanding task requiring skills and expertise currently not widely available. In particular, methodologies for assessing addictiveness are not well developed and not applicable to routine, large-scale monitoring, the development will take several years.

The Directive requires that industry provides only the available toxicological data. However, this is not adequate to meet the needs of developing ingredient regulation.

Questions arise as to who should be responsible for the burden of proof in general, and specifically who should develop and carry out the testing, and at what level. The Commission is convinced that leading the development such tests would be best left in the public sphere.

There have been calls in many countries, and at European level, for a regulatory body for tobacco products. Given the global nature of tobacco products, the WHO should coordinate regulatory efforts through the FCTC. Article 9 of the FCTC calls for the development of internationally accepted guidelines for testing, measuring and regulating the contents and emissions.