Tobacco: manufacture, presentation and sale of products (recast of Directives 89/622/EEC, 92/41 /EEC, 90/239/EEC)

1999/0244(COD) - 27/07/2005 - Follow-up document

This report provides the first assessment of the application of the Directive 2001/37/EC concerning the manufacture, presentation and sale of tobacco products ("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 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 highlights areas that should be developed based on the first experience and in the light of new scientific and technical knowledge.

Measurement methods and yield labelling (Article 4): 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. 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.

Labelling (Article 5): Member States 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.

The evidence indicates that measures on labelling 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. 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.

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. 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.

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.

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. 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.

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. 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.