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

1999/0244(COD) - 27/11/2007 - Follow-up document

This report contains the second assessment regarding the application of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. It is largely based on information provided by Member States in the Tobacco Products Regulatory Committee over the last two years. The report incorporates views of tobacco stakeholders as well as that of the European Parliament and Member States. The report outlines potential areas for changes to the Directive in order to allow for a proper discussion with Member States and the European Parliament before the Commission considers submitting a formal proposal to amend the Directive.

Definitions:

The current definition of ingredients covers any substance or constituent used in the manufacture or preparation of a tobacco product and still present in the finished product even if in altered form, including paper, filter, inks and adhesives. It does not cover the tobacco leaf itself or other natural or unprocessed tobacco plant parts. In recent years, the Commission has received several questions regarding radioactive and other substances in tobacco products and their health effects – Radon (Rn), Polonium (Po-210), Cadmium (Cd), etc. These questions are all related to tobacco leaves. This has led to discussion about whether the tobacco leaf and its compounds (natural and/or artificial) should be covered by the definition and thus be regulated by the Directive.

- ***Action*****:** The Commission will study whether it is appropriate to include the tobacco leaf and other natural or unprocessed tobacco plant parts in the definition of ingredients.

Maximum Tar, Nicotine And Carbon Monoxide Yields Of Cigarettes:

Article 3(1) of the Directive lays down the maximum yields for tar, nicotine and carbon monoxide (TNCO) of cigarettes released for free circulation in the EU. The limits are now applied in all 27 Member States. Article 3(2) of the Directive makes the same maximum yields applicable to cigarettes manufactured within, but exported from, the European Community, at the latest by 1 January 2007. No Member State has approached the Commission to extend the transitional period and the Commission does not envisage modifying the Directive in this respect.

Measurement Methods And Yield Labelling:

Discussions concerning the first report on application of the Directive revealed that Member States wished to have more clarity on questions such as the interpretation of thresholds set by the Directive for TNCO testing and on approval of laboratories to enable further laboratory cooperation. The Tobacco Products Regulatory Committee established under the Directive set up a working group consisting of experts from several Member States, the Commission's Joint Research Centre and the Chairman of the European Network of Government Laboratories for Tobacco and Tobacco Products (GoToLab). This Committee proposed that the maximum limits calculated according ISO 8243 should be regarded as maximum values around which the confidence interval can fluctuate. Although the possibility exists to modify existing arrangements no definitive plans have been drawn up. Member States have, however, expressed their wish

to continue using the current ISO smoking regime on an obligatory basis until solid evidence shows that better methods exist to replace them.

GoToLab Network: The GoToLab was established as a network of European governmental laboratories for tobacco and tobacco products in January 2002 in order to facilitate the exchange of experience of tobacco laboratories in the EU.

- *Action*: The Commission is committed to promoting cooperation among independent tobacco laboratories within the EU in order to create the operational basis for a shared analysis and assessment of tobacco ingredients and/or smoke emissions. Although the ISO standards are criticised, there is as yet no international agreement on alternatives. The Commission, therefore, does not propose to revise the current standards at this point in time. Furthermore, the Commission considers it important that the standards used in the EU are in line with international developments.

Ingredients:

A working group consisting of several experts from the Member States, chaired by the Commission, has been set up the purpose of which is to develop harmonised reporting formats for tobacco product ingredients which would enable a better analysis and comparison of the information delivered by tobacco manufacturers. Two sets of formats were developed: one requiring all the ingredient information manufacturers have to make available to national regulators and one requiring the information that has to be given to the public. Although not legally binding under the current framework, the Member States, manufacturers and importers are expected to use the formats. In addition to this development, the Commission has signed an administrative arrangement with the Commission's Joint Research Centre (JRC) in 2006. This arrangement, involving a financial amount of €558 502, will run for one year. A prolongation with similar amounts for a total of three years is foreseen. The adoption of the REACH Regulation has also had an impact on the tobacco sector. The work on ingredients under the Directive is closely linked to developments under the REACH Regulation which covers the chemical ingredients of tobacco products just like any other chemical substance.

- *Action*: The Commission is committed to putting into practice all the activities listed in the Commission statement on REACH. A number of Member States, and industry, wish to make the reporting formats on ingredients compulsory. In this respect extending the Commission's regulatory powers by amending Article 9 of the Directive should be considered. The introduction of fines By Member State for non-delivery of information by the industry as well as a possible extension of reporting requirements, e.g. the inclusion of the Hoffmann list of analytes, could be considered.

The European Parliament asked the Commission for further amendments to the Directive in its resolution on the Green Paper "Towards a Europe free from tobacco smoke: policy options at EU level" (adopted by the European Parliament on 24 October), such as the development of a full compendium of tobacco additives and substances in tobacco smoke, and making publicly available all existing toxicological data on the additives and ingredients in tobacco smoke. These proposals will be positively and thoroughly studied. An even more stringent approach would be to prohibit the use of any additives in tobacco products unless and until their safety has been proven.

Product Descriptors:

As yet, the Commission has not received any formal complaints about implementation of this Article. It will continue monitoring the developments under this provision and make appropriate proposals if necessary.

Tobacco For Oral Use:

The ban on tobacco for oral use in Article 8 has, in general, been transposed in Member States. However, controlling smuggling and illegal sale, particularly through the Internet, has proved to be problematic.

- ***Action*****:** The final scientific opinion on the health effects of smokeless tobacco products will form the scientific basis for any future risk management decision of the Commission on this issue.

Adaptations:

The Directive gives the Commission regulatory powers to adapt the measurement methods for TNCO yields, to adapt health warnings and to introduce markings for identification and tracing purposes. It does not enable the Commission to make the reporting formats mandatory, to adopt a list of criteria for the authorisation of laboratories, to adopt measures to improve laboratory cooperation or to amend the common list of ingredients provided under Article 12 of the Directive, once established. The effective implementation of the Directive could be better ensured if the Commission could adopt such measures.

- ***Action*****:** In order to improve the functioning of the Directive it would be useful to extend the Commission's regulatory powers to cover the development of criteria for the approval of laboratories, mutual recognition and measures intended to facilitate cooperation among the tobacco testing and verification laboratories, the introduction and amendment of the reporting formats for ingredients and, in future, the establishment and amendment of a common list of ingredients.

Common List Of Ingredients:

The Commission was unable to develop a proposal for a common list of ingredients. Any meaningful work on specific ingredients requires human and financial resources that are currently not yet available.

- ***Action*****:** Development in this area depends on the progress of work outlined under Article 6. In the abovementioned resolution the European Parliament asked the Commission for further amendments to the Directive as regards ingredients, such as a ban on all additives for which manufacturers and importers do not deliver complete data sets, an immediate ban on all addiction-enhancing additives and on all additives shown by existing toxicological data to be carcinogenic, mutagenic or toxic to reproduction as such or upon paralysis. The Commission will study these suggestions. It will also consider co-financing research on the toxicity and in particular addictiveness of tobacco ingredients and/or smoke emissions under the Research Framework Programme. Other steps might follow.

Import, Sale And Consumption Of Tobacco Products:

Several Member States have drawn the Commission's attention to the increasing and expanding marketing of cigarettes with candy flavourings. The sweet-flavoured cigarettes appeal specifically to young people, and thus might increase smoking initiation.

- ***Action*****:** The Commission will encourage MS to monitor any development in the import, sale and consumption of tobacco products and to take appropriate measures to protect their citizens in accordance with Article 13. In order to decrease the smoking initiation and to protect EU consumers on equal basis in all Member States the introduction of generic (black & white) standardised packaging for all tobacco products could be explored as a possibility to reduce the attractiveness.

Emerging Issues:

Roll-your-own (RYO): Several Member States have underlined that the sales, and accordingly the consumption, of roll-your-own cigarettes is increasing dramatically, especially among young people. The main reason for this development is seen in the lower taxes on RYOs than on cigarettes, which results in lower retail prices.

- ***Action*****:** Validated and internationally recognised measurement methods for RYO could be adopted by using the comitology procedure. The Commission intends to look at the taxation of RYO tobacco at the next revision of the Tobacco Taxation Legal Framework.

New tobacco and nicotine products: The market for new nicotine products has diversified considerably since the adoption of the Directive. In addition to the development of new types of tobacco and nicotine products, some traditional tobacco products and patterns of use are becoming more popular.

- ***Action*****:** The Commission will study the regulatory challenges outlined above with a view to at least ensuring that new tobacco and/or nicotine products marketed are regulated properly at EC level to serve the public health and internal market objectives. The Commission will also examine the relationship of the tobacco products regulatory framework with the novel foods and pharmaceutical legislation.

Product Liability:

The European Parliament asked the Commission to apply product liability in respect of manufacturers and to introduce manufacturer liability for the financing of all health costs arising from tobacco consumption.

- ***Action:*** The Commission will commission a study on the best ways forward to strengthen product liability of tobacco manufacturers and importers in the EU as well as their liability for financing the health costs arising from tobacco consumption. This study will form the basis for further action.