COMMISSION OF THE EUROPEAN COMMUNITIES

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

Second Report on the Application of the Tobacco Products Directive

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 (hereafter 'the Directive') requires the Commission to regularly report to the European Parliament, the Council and the Economic and Social Committee on the application of the Directive. The first report on the application of the Directive was adopted on 27 July 2005.

This report contains the second assessment of application of the Directive. It is largely based on the work done and information given by Member States in the Tobacco Products Regulatory Committee, as provided for under Article 10 of the Directive, during the last two years. The report incorporates views of stakeholders in the field of tobacco control as well as of the European Parliament and Member States. It also 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.

2. DEFINITIONS (ARTICLE 2)

The current definition of ingredients in Article 2(5) 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.

However, the WHO definition of the contents of tobacco products as well as the legislation of some countries outside the EU (e.g. Canada) include the tobacco leaf itself. During 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.

Further 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.

[1] OJ L 194, 18.7.2001, p. 26.

3. MAXIMUM TAR, NICOTINE AND CARBON MONOXIDE YIELDS OF CIGARETTES (ARTICLE 3)

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[2].

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.

4. MEASUREMENT METHODS (ARTICLE 4) 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[3].

4.1. Measurement of tar, nicotine and carbon monoxide yields

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). In the non-binding practical guide on "Cigarette yield measurement and some basic steps for laboratory approval"[4], published by the Commission's Directorate-General for Health and Consumer Protection (DG SANCO), the working group proposed that the maximum limits calculated according ISO 8243 should be regarded as maximum values around which the confidence interval can fluctuate.

The Directive contains the possibility of adapting the methods to scientific and technical progress via the Tobacco Products Regulatory Committee. In April 2007, the Commission consulted the Regulatory Committee on the pros and cons of different existing smoking regimes (ISO, Massachusetts, Canadian intense, compensatory method). No definitive conclusion was drawn, although Member States widely wished to continue using the current ISO smoking regime on an obligatory basis until solid evidence shows that better methods exist to replace them[5].

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2 Maximum limits for TNCO became applicable in the 14 Member States (EU15 except Greece) as from 1 January 2004. In the new 10 Member States as from their accession on 1 May 2004 and in Romania and Bulgaria as from their accession on 1 January 2007. For Greece the limits also became applicable on 1 January 2007 after the temporary derogation expired.

3 The list of approved laboratories is available here: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/label_labo_en.htm

4 The document is published here: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/best_practices_en.pdf

5 All presently used measurement methods are based on machine testing which is not suitable for assessing human exposure to smoke. One possibility for human exposure assessment would be to use biomarkers, but more research is still needed on this issue.

4.2. Laboratories

On the basis of the information and best practices gathered from Member States, the abovementioned working group suggested a number of criteria for testing and verification laboratories. These were also included in the practical guide on "Cigarette yield measurement and some basic steps for laboratory approval"[4].

4.3. GoToLab Network

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[6]. The Commission consulted the Regulatory Committee in 2006 on how to better link the Regulatory Committee and the GoToLab Network. Member States and representatives of the GoToLab Network both expressed strong support for enhanced cooperation.

Further action

A functioning and appropriately resourced laboratory network forms the basis for more detailed joint work by Member States and the Commission on tobacco products ingredients and emissions. Therefore, the Commission is committed to promoting cooperation among independent tobacco laboratories[7] within the EU in order to create the operational basis for a shared analysis and assessment of tobacco ingredients and/or smoke emissions. In order to improve the functioning of the Directive it would also be useful to extend the Commission's regulatory powers to cover the development of criteria for approving laboratories and other measures to improve laboratory cooperation and mutual recognition in the context of the next modification of the Directive.

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. The Commission actively follows scientific and technological developments in this area and will come back to this question once there is more common international understanding and agreement on the methods. The Commission considers it important that the standards used in the EU are in line with international developments.

5. LABELLING (ARTICLE 5)

5.1. Textual warnings

The implementation of textual warnings has generally been satisfactory even though Member States reported some difficulties in approach with regard to products other than cigarettes (e.g. rolling tobacco and novel tobacco products). In addition, the Commission received a few complaints about implementation of Article 5(6)(e), which requires warnings to be printed in all official languages of the Member State

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6 Laboratories from 5 Member States attended the first meeting, namely France, Germany, United Kingdom, the Netherlands and Sweden. The Rules of Procedure are available on the GoToLab website along with the list of GoToLab members: http://www.jrc.ec.europa.eu/project/gotolab/index.html

7 For independence criteria see the Practical Guide on "Cigarette yield measurement and some basic steps for laboratory approval", p.5: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/best_practices_en.pdf

where the product is placed on the market. It is important to note that this is a formal requirement in all Member States having more than one official language, and that there are no derogations or territorial exceptions (e.g. for airports). The Commission is currently looking into these issues in its role as a guardian of the Treaty.

5.2. Colour images

Article 5(3) of the Directive empowers the Commission to adopt additional warnings in the form of colour photographs or other illustrations (pictorials). The decision to introduce pictorials is left to Member States.

The Commission adopted the library of 42 selected source documents[8] and technical specifications for printing combined pictorial and written warnings on packages of various proportions[9]. DG SANCO also communicated to Member States its view that the place of marketing (country of destination) is what determines application of the pictorial warning requirements, not the place of manufacturing. It also encouraged Member States on several occasions to swiftly introduce pictorial warnings on all tobacco products, and emphasised that Member States may already complement the combined warnings with quit-line telephone numbers, Internet addresses or other visual elements informing about the support available to those who want to stop smoking. Such references should be placed within the area reserved for combined warnings[10].

Based on this preparatory work, Belgium was the first EU Member State to introduce combined warnings in November 2006 and, as of 10 June 2007, they feature on all cigarette packets sold in Belgium. Implementation has been quite smooth so far. The next country to follow suit will be Romania, where pictorials will become mandatory in July 2008. In the UK, the warnings are planned to appear on cigarette packets from autumn 2008 and on other tobacco products the following year. According to the information available to the Commission, Finland and Latvia have also taken a decision to require the use of pictorial warnings, while further Member States are considering introducing the warnings in the near future. The Commission has also concluded copyright agreements with New Zealand and Switzerland, to allow them to use the EC pictorial library.

The Dutch government commissioned a study to review the published evidence from Canada, Brazil, Australia and New Zealand as regards the effectiveness of pictorial warnings. The study concludes that pictorials are more effective than text warnings alone when it comes to improving knowledge about the health effects of smoking and increasing the intention to quit smoking[11].

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8 Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages, OJ L 226, 10.9.2003, p. 24.

9 These additional specifications were established by Annex III to Commission Decision C(2006) 1502 final of 12 April 2006 amending the Commission Decision of May 2005.The new rules are illustrated by an informal guidance document containing demonstrative adaptations of the warnings for one-language and three-language countries.

10 Article 4(5) of Commission Decision 2003/641/EC.

11 Research voor Beleid. Kleurenfoto's op tabaksverpakkingen - Ervaringen in andere landen. Een onderzoek in opdracht van het ministerie van VWS, Leiden, 22 januari 2007. http://www.research.nl/index.cfm/28,4072,c,html/VGP-2745670B.pdf

There are strong voices in Member States and the European Parliament that say the labelling on TNCO yields is misleading for consumers and should be taken off the packs. A number of Member States also pleaded for combined warnings to be made mandatory on all tobacco packets, which would facilitate their introduction in all EU countries. There were also strong voices in Member States and the European Parliament for making the cessation information mandatory as well as for increasing the size of the warnings and placing pictorials on both sides of the package.

Further action

The Commission considers all these proposals to be promising and will explore them in more detail for future changes to the Directive. The upcoming guidelines on packaging and labelling under the WHO's Framework Convention on Tobacco Control will be a supplementary source of information.

The Commission is currently examining the possibilities with regard to an increased size for the warnings, mandatory pictorial warnings on both sides of the package and the replacement of the maximum limits of TNCO by information on help-lines and/or other substances in tobacco products (e.g. labelling of the use of GMOs).

6. INGREDIENTS (ARTICLE 6)

6.1. Reporting on tobacco product ingredients

The Regulatory Committee set up a working group consisting of several experts from the Member States, chaired by the Commission, 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[12]. Although not legally binding under the current framework, the Member States, manufacturers and importers are expected to use the formats. Electronic submission of data would be the desirable form. Currently, a group of Member States is developing an electronic databank of tobacco product ingredients. This project was recommended for co-funding from the Community's Public Health Programme 2007.

6.2. Administrative agreement with the Joint Research Centre

To assist the Commission and the Member States with the work on tobacco product ingredients, DG SANCO 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[13]. A prolongation with similar amounts for a total of three years is foreseen.

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12 The practical guide "Reporting on tobacco ingredients" is available here: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf

13 DG JRC will mainly focus on analysing the tobacco ingredient data sets, and coordinate the work of the GoToLab Network, provide scientific assistance for the regulatory process, assist DG SANCO in its work as a key facilitator for the FCTC working group on tobacco product regulation, check and

The JRC set up an expert group to develop guiding questions for the data analyses of tobacco product ingredients and to establish, in line with international developments in this area, an initial priority list of ingredients for further analysis. The group will also discuss issues relating to addictiveness and attractiveness.

6.3. REACH Regulation

The work on ingredients under the Directive is closely linked to developments under the REACH Regulation[14] which covers the chemical ingredients of tobacco products just like any other chemical substance. It will be necessary to summarise and to take into account the information on tobacco ingredients made available under REACH in order to avoid overlaps with the on-going work in the context of the Directive[15].

Further action

The Commission is committed to putting into practice all the activities listed in the Commission statement on REACH[16].

A number of Member States as well as the 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 not allow any additives in tobacco products unless manufacturers proved their safety.

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summarise information on tobacco product ingredients covered by REACH and review the scientific data on addictiveness.

14 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1.

15 On the information to be submitted see in particular Articles 10–13 of the REACH Regulation.

16 See the Commission's statement on tobacco ingredients on the Council website: http://register.consilium.europa.eu/pdf/en/06/st16/st16908-ad01.en06.pdf (REACH is item 30, the tobacco declaration starts on p. 16). Together with the other declarations made on the REACH Regulation, it is included in the minutes of the meeting of the Environment Council of 18 December 2006 at which REACH was adopted (reference 16908/06 Add 1).

7. PRODUCT DESCRIPTORS (ARTICLE 7)

Until now, 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.

8. TOBACCO FOR ORAL USE (ARTICLE 8)

Article 8 of the Directive prohibits the marketing of oral tobacco, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

8.1. Scientific opinion

In order to obtain a better understanding of the health effects of various smokeless tobacco products and their role in smoking cessation and initiation, DG SANCO requested an opinion from its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[17].

On 21 June 2007, the SCENIHR approved a preliminary report for public consultation on the health effects of smokeless tobacco products[18]. Interested parties and stakeholders were invited to comment through online consultation. The final report is expected at the beginning of 2008.

8.2. Implementation of the ban on oral tobacco

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, is difficult[19].

Further 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.

9. ADAPTATIONS (ARTICLES 9 AND 10)

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

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17 The mandate is available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_004.pdf

18 The preliminary opinion is currently available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_06_en.htm

19 In its judgment of 18 May 2006 in case C-343/05 (Commission v Finland) the Court of Justice found that Finland had, as regards the Province of Åland, failed to transpose the prohibition on placing on the market of snus and its observance on vessels registered in Finland. In October 2007 the Commission decided to bring Finland in the Court of Justice for non-compliance of the above judgment.

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.

Further 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[20]*, 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.*

10. COMMON LIST OF INGREDIENTS (ARTICLE 12)

Given the still limited progress on Article 6 the Commission was not in a position 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.

Further 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 pyrolysis.

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.

11. IMPORT, SALE AND CONSUMPTION OF TOBACCO PRODUCTS (ARTICLE 13)

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. These types of products are usually accompanied by attractive, modern packages and trendy brand names attractive to young people.

According to Article 13 of the Directive, Members States can keep or introduce more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order to protect public health. However, the rules must comply with the EC Treaty.

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[20] The review of the Directive will need to take into account any possible change which follows the outcome of the negotiations on the "Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products".

Further 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. The Commission will assess the measures under Directive 98/34 following the notification by Member State.

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.

The Commission will take into account any possible change which follows the outcome of the negotiations on the "Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products".

12. EMERGING ISSUES

12.1. Roll-your-own (RYO) cigarettes

Several Member States have underlined that the sales, and accordingly the consumption, of roll-your-own cigarettes are dramatically increasing, 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.

Some Member States apply the maximum limits of the TNCO yields for cigarettes (10:1:10) also to RYOs; in other Member States no such requirement is established, as until now no internationally accepted measurement method existed.

Recently an ISO method 15592 part 3 was validated for RYO cigarettes.

Further 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.

12.2. New tobacco and nicotine products

12.2.1. The emerging market

When it was adopted in 2001, the Directive intended to cover tobacco products that were on the market. Since then, the tobacco products market has increasingly diversified. 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.

12.2.2. The regulatory challenge

The emergence of new types of tobacco and nicotine-related products raises the issue of whether the present regulatory framework for tobacco products and the existing pharmaceutical and general food legislation[21] make it possible to tackle effectively all these kind of products.

Further 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 look at the relationship of the tobacco products regulatory framework with the novel foods and pharmaceutical legislation.

13. 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. In its Article 19 on product liability, the Framework Convention on Tobacco Control, to which the Community is a Party, asks all Parties to consider taking legislative action or promoting their existing laws to deal with criminal and civil liability, including compensation where appropriate.

Further 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.

[21] Directive 2001/83/EC, OJ L 311, 28.11.2001; Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, pp. 1–24.