Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	1999/0244(COD)
Tobacco: manufacture, presentation and sale of products (recast of Directives 89/622/EEC, 92/41/EEC, 90/239/EEC) Repealed by 2012/0366(COD) Subject 4.20.03 Drug addiction, alcoholism, smoking 4.60.02 Consumer information, advertising, labelling 4.60.04.02 Consumer security	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	DELE EP Delegation to Conciliation Committee		19/03/2001
		ELDR MAATEN Jules	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		26/01/2000
		ELDR MAATEN Jules	
	ENVI Environment, Public Health, Consumer Policy		26/01/2000
		ELDR MAATEN Jules	
	Former committee for opinion		
	JURI Legal Affairs and Internal Market		01/02/2000
		PPE-DE LECHNER Kurt	
	ITRE Industry, External Trade, Research, Energy		24/02/2000
		PPE-DE LANGEN Werner	
	AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Energy	2347	14/05/2001
	Education, Youth, Culture and Sport	2330	12/02/2001
	Health	2281	29/06/2000
	Health	2219	18/11/1999
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events

16/11/1999	Legislative proposal published	COM(1999)0594	Summary
18/11/1999	Debate in Council	2219	
21/01/2000	Committee referral announced in Parliament, 1st reading		
25/05/2000	Vote in committee, 1st reading		Summary
25/05/2000	Committee report tabled for plenary, 1st reading	A5-0156/2000	
13/06/2000	Debate in Parliament		
14/06/2000	Decision by Parliament, 1st reading	T5-0262/2000	Summary
28/06/2000	Modified legislative proposal published	COM(2000)0428	Summary
31/07/2000	Council position published	09448/1/2000	Summary
08/09/2000	Committee referral announced in Parliament, 2nd reading		
21/11/2000	Vote in committee, 2nd reading		Summary
21/11/2000	Committee recommendation tabled for plenary, 2nd reading	A5-0348/2000	
11/12/2000	Debate in Parliament		
13/12/2000	Decision by Parliament, 2nd reading	T5-0557/2000	Summary
12/02/2001	Parliament's amendments rejected by Council		
27/02/2001	Formal meeting of Conciliation Committee		
27/02/2001	Final decision by Conciliation Committee		Summary
05/04/2001	Joint text approved by Conciliation Committee co-chairs	3614/2001	
27/04/2001	Report tabled for plenary, 3rd reading	A5-0162/2001	
14/05/2001	Debate in Parliament		
14/05/2001	Decision by Council, 3rd reading		
15/05/2001	Decision by Parliament, 3rd reading	T5-0242/2001	Summary
05/06/2001	Final act signed		
05/06/2001	End of procedure in Parliament		
18/07/2001	Final act published in Official Journal		

Technical information

Procedure reference	1999/0244(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
	Repealed by 2012/0366(COD)

Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	CODE/5/14568

Documentation gateway

Legislative proposal		COM(1999)0594 OJ C 150 30.05.2000, p. 0043	16/11/1999	EC	Summary
Economic and Social Committee: opinion, report		CES0365/2000 OJ C 140 18.05.2000, p. 0024	29/03/2000	ESC	
Committee of the Regions: opinion		CDR0032/2000 OJ C 226 08.08.2000, p. 0005	12/04/2000	CofR	
Committee report tabled for plenary, 1st reading/single reading		A5-0156/2000 OJ C 067 01.03.2001, p. 0010	25/05/2000	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0262/2000 OJ C 067 01.03.2001, p. 0063-0150	14/06/2000	EP	Summary
Modified legislative proposal		COM(2000)0428 OJ C 337 28.11.2000, p. 0177 E	28/06/2000	EC	Summary
Council position		09448/1/2000 OJ C 300 20.10.2000, p. 0049	31/07/2000	CSL	Summary
Commission communication on Council's position		SEC(2000)1383	07/09/2000	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0348/2000 OJ C 232 17.08.2001, p. 0010	21/11/2000	EP	
Text adopted by Parliament, 2nd reading		T5-0557/2000 OJ C 232 17.08.2001, p. 0077-0146	13/12/2000	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2001)0029	16/01/2001	EC	Summary
Joint text approved by Conciliation Committee co-chairs		3614/2001	05/04/2001	CSL/EP	
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A5-0162/2001	27/04/2001	EP	
Text adopted by Parliament, 3rd reading		T5-0242/2001 OJ C 034 07.02.2002, p. 0023-0104 E	15/05/2001	EP	Summary
Implementing legislative act		32003D0641 OJ L 226 10.09.2003, p. 0024-0026	05/09/2003	EU	Summary
Follow-up document		COM(2005)0339	27/07/2005	EC	Summary
Follow-up document		COM(2007)0754	27/11/2007	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2001/37
OJ L 194 18.07.2001, p. 0026 Summary

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

PURPOSE : Proposal for a Directive on the approximation of Member States' legislation concerning the manufacture, presentation and sale of tobacco products. CONTENT : This proposal : - Recasts three existing directives regarding tar content in cigarettes, oral tobacco and labelling of tobacco products. The tar yield of cigarettes in the Member States must not exceed 10mg per cigarette as from 31 December 2003 (or three years from date of adoption). A continuing derogation is provided in respect of Greece which must apply the 10mg ceiling by 31 December 2006 (or 6 years from the date of adoption). Compulsory labelling provisions will include the new yield of carbon monoxide. There are new provisions on warning labels regarding size and type. The strong warning on oral tobacco will be changed to a more general one, but this does not apply to legitimate aids to stopping smoking. - Includes provisions to harmonise Member States legislation as regards nicotine and carbon monoxide levels in cigarettes. The nicotine yield of cigarettes in the Member States must not exceed 1mg per cigarette from 31 December 2003, or three years from the date of adoption. In line with the approach taken for tar and nicotine, the Commission proposes a ceiling on carbon monoxide yield of not more than 10mg per cigarette with similar time limits. - Includes provisions for the non-tobacco ingredients. The Commission notes that Member States' legislation regarding additives that may be incorporated into tobacco products differs. The control of additives in the Internal Market is subject to great uncertainty. The proposal envisages that manufacturers and importers submit a list of non-tobacco ingredients, together with a statement giving reasons for the ingredients. Member States should obtain toxicological data on them and require evidence that they are safe for public consumption. Commercial confidentiality will be respected. - Makes provision for the description of tobacco products. The proposal envisages that terms such as ·low tar, 'light' and 'mild' be prohibited, since they give a mistaken impression of the health risks involved. The Member States may expressly authorise these terms, but shall inform the Commission of the conditions of the authorisation. The Commission will inform the European Parliament and the Council in this regard. - Provides for a review mechanism through a reporting procedure to take account in particular of new scientific developments in so far as they affect the establishment and operation of the single market.?

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

The committee adopted the report (codecision procedure, first reading) by Jules MAATEN (ELDR, NL) amending the directive on the manufacture, presentation and sale of tobacco products in order to make it much stricter. The committee called for the size of health warnings on cigarette packets to be increased even more than suggested by the Commission, with a minimum of 40% of the packet size for general warnings and no less than 50% for additional, more specific, warnings. Labelling should in general be stricter and provide more complete health warnings and a list of ingredients should be available on request. MEPs felt that general warnings like "smoking can kill" were not sufficient and should be replaced by warnings such as "smoking kills half a million people each year in the EU", "85% of lung cancers are caused by smoking" and "if you smoke, you are killing yourself". The committee also called for such warnings to be clearly displayed on vending machines. Printing colour photographs or other illustrations depicting the health consequences of smoking should also be allowed. The committee adopted various other amendments on testing (laboratories for carrying out tests on cigarette yields should be independent from the tobacco industry), the traceability of cigarette packets (batch numbers should be indicated on each packet) and research (manufacturers should allocate 2% of the proceeds of the sale of tobacco products to encourage scientific research on the health and addiction aspects of smoking). ?

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

The European Parliament in its first reading adopted the report drafted by Jules MAATEN (ELDR, Netherlands) amending the proposal for the manufacture, presentation and sale of tobacco products. The principal amendments are as follows: -as of 31 December 2003, no ammonia or ammonia compounds shall be added to cigarettes released for free circulation, marketed or manufactured in the Member States. -the tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet so that at least 30% of the corresponding surface is covered. This figure is raised to 35% for countries with two official languages and 40% for countries with three official languages. -the list of ingredients for each product must be freely accessible, for example, from web sites and health experts. -each packet of tobacco products, except for smokeless and oral tobacco products must carry an obligatory warning: "Passive smoking harms those around you, especially children" together with one of a specified list of general warnings. An additional warning from Annex I must also be printed. The list in Annex I is extended by the Parliament. At the end of the warning, a free telephone number of an independent service must be given, which can provide detailed information on the dangers of smoking. Member States must set up such a service, if one does not exist. -the general warning must cover not less than 35% of the external area of the corresponding surface of the packet, raised to 37% where thee are two official languages and 40% where there are three. the additional warning will cover not less than 45% of the external area of the corresponding surface of the packet, rising to 47% for countries with two official languages and 50% for countries with three. -there are additional amendments on the size of the warnings for packaging of pipe tobacco and cigars, as well as special conditions for vending machines. -the report on ingredients from manufacturers and importers of tobacco products must be supplied annually, and the requirements for the contents of the report are more carefully specified. provisions for testing of ingredients and dissemination of data are made, -the use of such terms as 'low tar' and 'light' are prohibited; Member States do not have the power expressly to authorise them. -the contents of the report on the application of this directive are more tightly specified.?

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

In general terms, the European Parliament supports the approach and the main orientations of the Commission's proposal. This is particularly important as regards its acceptance of the Internal Market principles underlying the proposal. The amendments proposed by the Parliament are largely of a technical nature. The Commission accepts the majority in whole or in part, and in some cases subject to drafting modifications. The amendments accepted by the Commission concern the inclusion of new recitals: - to incorporate in the text an amendment underlining that the price of tobacco can influence to a large extent whether the consumption of such products begins or ceases, particularly as regards youngsters; - to foster research for new methods for measuring tar, nicotine and CO yields and and accepting ISO standards provisionally; - to encourage research and technical progress in establishing the exposure to toxins and other harmful substances caused by the use of tobacco products; - to encourage Member States to make use of the opportunities available to them to tax tobacco products more heavily; - to point out that the directive must form part of an overall strategy to combat the use of tobacco products aimed at specially at young people and women; - to develop the international standards on tobacco products within the WHO; Other amendments aim to clarify certain aspects of the proposal. As regards the amendments or parts of the amendments which have not been accepted by the Commission, these are for the following reasons: - their objective and formulation is not sufficently clear; - they would not be consistent with Community law including other Community Directives; - they would upset the balance of interests; - they would be too ambitious at this stage given the level of Community legislation.?

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

The Council adopted - either wholly, partly, or retaining only the substance - 15 amendments proposed by the European Parliament which were taken up in the Commission proposal. It also adopted two other amendments, which had been initially rejected by the Commission and which concerns Article 7 (the use of the term 'low tar', 'light', 'ultra light', 'mild' or any other similar terms which have the aim or the direct or indirect effect of conveying the impression that a particular tobacco product is less harmful than others shall be prohibited), reinforcing that Article by a reference to information yield, as propose by the Commission. In relation to the amendments accepted by the Commission but not taken up in the common position, these relate to: - the reference to the price of tobacco products was not appropriate given the overall structure of the Directive; - the specific reference to the evaluation of tobacco products designed to reduce risk, the Council did not consider that this was essential at this stage since this was to be a priority for study in the first report; - improving the accuracy and reliability of methods for measuring tar, nicotine and carbon monoxide yields, and also on investigating the possiblity of drawing up a common list of other ingredients; - improving the evaluation of the effects of tobacco products in connection with the need to ensure a high level of health protection; - the protection of commercial and intellectual property rights in relation to customer information; - the possiblity of an exemption, even a temporary one, for the application of the new provisions to cigarettes exported outside the Community, the Council considers that this is not justified, particularly given the problems of control which this exemption would have raised; - the annual disclosure of results, this would be less costly and more reliable; - the increase in dimensions requested by the Parliament, both for yield indications and for warnings to be included on packaging, this was seen as being excessive. Furthermore, the Council did not incorporate the Commission's proposal that only the maximum authorised yields laid down in Article 3(1) should be printed on the packets, judging that it was important to inform consumers of the actual yields of cigarettes. The principal changes introduced by the Council include: - the amendment of the preamble in order to ensure better correspondance with the text of the enacting terms, be merging some recitals and deleting others, without substantially altering the contents; - reintroducing a provision taken from Directive 89/622/EEC by providing for the possiblity of naming the body which issued the warning, while specifying that this should be stated outside the frame of the warning notice so as not to reduce its impact; - the introduction of two additional warnings. ?

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

The Common position is less ambitious than the provisions sought by the European Parliament, and relected in the Commission's amended proposal, particularly as regards labelling size. However, it represents a significant improvement in the harmonisation of Internal Market rules compared to the present position, while taking a high level of public health protection into account. It may also be mentioned that the common position is stronger in certain respects than the European Parliament text, for example as regards products manufactured in the Union where the common position provides for no transitional period for products not intended for internal consumption. In addition, the Commission considered it desirable to agree to the common position in view of the opposition of several Member States to a more ambitious approach. It should also be noted that in this regard that one Member State did not support the common position, and that three Member States abstained. In concluson, the common position largely takes over the main elements of the Commission's original proposal, but fails to take full account of the amendments introduced by the European Parliament, and accepted by the Commission in its amended proposal. However, the Commission supports the common position as, as stated before, it represents an improvement in the harmonisation of Internal Market rules.

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

The committee adopted the recommendation for second reading under the codecision procedure by Jules MAATEN (ELDR, NL) amending the Council's common position. It retabled a number of important amendments from first reading which had not been taken up by the Council. One of the main points of disagreement between Council and Parliament at first reading had been the size of the general and additional warnings to be shown on cigarette packets. The relevant article in the common position was now stipulating that the general warning should cover not less than 25% of the external surface area of a packet (or 27% for Member States with two official languages and 30% for those with three official languages). The committee amended the text so that the figures were 30%, 32% and 35% respectively and added a new provision stipulating that the additional warning should be 40% of the external area of a packet (45% for States with two official languages and 50% for

those with three). It also wanted the general warning on packets to consist of one of three messages, which would be rotated in such a way as to guarantee their regular appearance. These messages would read: "Passive smoking harms those around you, especially children", "Smoking kills half a million people each year in the EU" and "Smoking causes cancer and heart disease". The committee also amended the list of additional warnings in the common position, altering the wording slightly in some cases and adding three new slogans, including "Smoking can cause a slow and painful death" and "Smoking can damage sperm and decreases fertility". The report also called for all or a proportion of the space for additional warnings to be used for colour illustrations depicting the health consequences of smoking. It further argued that, where tobacco was sold from vending machines, the warnings should be clearly displayed on such machines, as they were used by very young people who were just starting to smoke. The Member States should ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, was made public and the Commission was urged to submit by 31 December 2004 a proposal for a directive providing for a common list of ingredients authorised for tobacco products, taking into account their addictiveness. The committee urged that a three-year transition period be authorised before the introduction of restrictions on exports to non-EU countries, in order to allow time for measures to be put in place to alleviate the impact on EU manufacturers. Lastly, it modified the common position text which prohibited the use of the terms "low tar", "light", "mild" etc. In the wake of the Court of Justice's October 2000 judgment on the tobacco advertising directive, the committee argued that such terms should be permitted if they were a substantial defining part of a trademark registered and genuinely marketed prior to the adoption of the proposed directive.?

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

The European Parliament approved the text by Mr Jules MAATEN (ELDR, NL) on the common position together with all the main amendments tabled to the common position, in particular as regards the size and wording of warnings on cigarette packets, the use of terms such as 'light' and 'ultra light', the use of colour illustrations on packets depicting the consequences of smoking, lists of permitted ingredients and chemical additives, and export derogations. (Refer to the previous document for a guideline of the amendments tabled by the committee responsible and which were subsequently approved by the House).?

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

The Commission accepts 22 out of the 32 amendments adopted by the Parliament on second reading and consequently modified its proposal. The amendments not accepted by the Commission concern in particular a reference to GMO tobacco, health warnings on vending machines, detailed rules on how manufacturers have to declare tobacco additives, the requirements to propose a common additive list by a fixed date, and while this list is being prepared, a ban on additives that increase addiction. In adopting its position on the amendments proposed by the Parliament, the Commission has taken due account of the judgement of the Court of Justice of the European Communities of 5 October 2000 in case C-376/98, Germany against Parliament and Council. This judgement annulled Directive 98/43/EC on tobacco advertising and clarified the requirements for the adoption of directives under the legal basis provided by Article 95 of the EC Treaty.?

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

After detailed negotiations, the Conciliation Committee reached agreement on the joint text of the directive. The main points of the agreement were as follows: Tobacco products for export: after a transitional period until 2007 at the latest (allowing more time to change product specifications and negotiate internationally agreed standards), exported tobacco products would also have to meet the same strict ceilings for tar (10mg), nicotine (1 mg) and carbon monoxide (10mg) as tobacco products marketed in the EU; List of ingredients: tobacco companies would have to submit on an annual basis a list of ingredients of their products to Member States' authorities, who would then make this information available to the public. Furthermore, it was agreed that, by the end of 2004, the Commission would submit a proposal providing for a common list of ingredients authorised for tobacco products. Another Parliament recommendation that was adopted specified that, pending the establishment of that common list, Member States could prohibit the use of ingredients which increased the addictive properties of tobacco products; Health warnings: it was agreed that all packets of tobacco products would have to carry the following general warnings: "Smoking kills/Smoking can kill" or "Smoking seriously harms you and others around you", rotated in such a way as to guarantee their regular appearance. The packets would also have to carry an additional health warning (with a more exact indication of relevant health risks such as lung cancer or heart disease), taken from a list annexed to the directive. That warning would also have to be rotated on a regular basis. As for the size of the health warnings, the agreement took up Parliament's recommendations and thereby provided for much bigger warnings than originally proposed. The general warnings would have to cover 30% of the front of the packet (32% for countries with 2 official languages and 35% for those with 3 official languages), and the additional warning would have to cover 40% of the back of the packet (45% for 2 languages and 50% for 3 languages); The use of photos and graphics: over and above the written warnings, Member States would be allowed to insist on additional warnings on cigarette packets in the form of colour photos or other illustrations depicting and explaining the health consequences of smoking, in accordance with rules to be adopted by the Commission no later than 31 December 2002; Prohibition of misleading descriptors: with effect from September 2003, the use of terms or brand names (such as "low tar", "ultra light" and "mild") or designs suggesting that a particular tobacco product was less harmful than others would be banned.?

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

The European Parliament voted to endorse the compromise agreement, by Mr Jules MAATEN (ELDR, Nl), on a draft directive on the manufacture, presentation and sale of tobacco products. (Please refer to the previous text). ?

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

PURPOSE: to approximate Member State legislation concerning the manufacture, presentation and sale of tobacco products. COMMUNITY MEASURE: Directive 2001/37/EC of the European Parliament and of the Council on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. CONTENT: The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco procducts, taking as a basis a high level of health protection. Against this background, the Directive contains the following provisions: Cigarettes: from January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States, shall not be greater than 10mg per cigarette for tar; 1 mg per cigarette for nicotine and 10 mg per cigarette for carbon monoxide. Member States may apply the yield limits as from 1 January 2005 but shall in any event do so by 1 January 2007 at the latest. Greece shall have a derogation until 1 January 2007. Measurement methods: the tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of the ISO standards 4387 for tar, 10315 for nicotine and 8454 for carbon monoxide. The accuracy of the tar and nicotine indications on packets shall be verified in accordance with the ISO standard 8243. Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, by 30 September 2002, and whenever the change is made. Labelling: Specfic labelling requirements are laid down in the Directive (please refer to outcome of the Conciliation Committee). In addition to the percentages decided,in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm2, the warnings referred to shall cover an area of at least 22,5 cm2 on each surface. That area shall be increased to 24 cm2 for Member States with two official languages and 26,25 cm2 for Member States with three official languages. There are also provisions relating to the font used in text warnings. Imports: Member States may not, for considerations relating to the limitation of tar, nicotine or carbon monoxide yields of cigarettes, to health warning and other indications or to other requirements of this Directive, prohibit or restrict the import, sale and consumption of tobacco products which they deem necessary in order to protect public health, insofar as such rules do not prejudice the rules laid down in this Directive. ENTRY INTO FORCE: 18.07.2001.?

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

LEGISLATIVE ACT : Commission Decision 2003/641/EC on the use of colour photographs or other illustrations as health warnings on tobacco packages. CONTENT : this Decision establishes rules for the use on tobacco packages of colour photographs or other illustrations to depict and explain the health consequences of smoking. The Decision shall apply to those Member States that decide to use colour photographs or illustrations together with the additional warnings required by Directive 2001/37/EC on the packages of some or all types of tobacco products, except for packages containing tobacco for oral use and other smokeless tobacco. Where Member States require health warnings in the form of colour photographs or other illustrations, these shall be in accordance with the rules established by this Decision. IMPLEMENTATION : where Member States decide to require the use of combined warnings on tobacco packages, they shall adopt and publish the provisions necessary to comply with this Decision. They shall apply those provisions at the earliest from 1 October 2004. Those provisions shall provide for adequate transitional periods in order to allow for the necessary changes in the production and packaging process for tobacco products and for the disposal of stocks, in particular as regards small and medium enterprises.?

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

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 Control2 (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 community6 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.

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

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.