COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.11.1999
COM(1999) 594 final

1999/0244 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

(recast version)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

The purpose of this proposal for a directive is to recast three existing Internal Market directives dealing with the tar content of cigarettes, oral tobacco, and labelling of tobacco products and to update and complete these provisions in the light of new developments based on scientific facts in the context of the completion of the Internal Market, taking as a basis a high level of public health protection.

2. LEGAL BASIS

This proposal is based on Article 95 of the Treaty, taking as a basis a high level of public health protection. Account is also taken of public health issues raised by the Member States, and scientific authorities, which have been brought to the attention of the Commission (Article 95 paragraph 8).

3. TAR

This proposal seeks to continue the reduction in tar levels of cigarettes already introduced by Council Directive 90/239/EEC[1], and requires that the tar yield of cigarettes put into free circulation, marketed or manufactured in the Member States shall not exceed 10mg per cigarette as from 31 December 2003 (or 3 years from date of adoption). In this respect, it should be noted that the higher the tar content of smoked tobacco, the greater the risk of lung cancer. However, smokers must be aware that all cigarettes are harmful to health; it is therefore more desirable for them to stop smoking rather than to switch to low-tar cigarettes, which still contain other noxious and harmful substances. Nevertheless, the existence of a reduced Community ceiling for tar yields ensures a higher level of public health protection than would otherwise be the case, and creates a common rule applicable across the Internal Market.

A continuing derogation is provided in respect of the Hellenic Republic to take account of particular socio-economic difficulties, leading to the application of the 10mg ceiling by that Member State by 31 December 2006 (or 6 years from the date of adoption).

4. NICOTINE

In reply to questionnaires sent by the Commission Services to the Member States, (details of which were set out in the Commission Report to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on progress achieved in relation to public health protection from the harmful effects of tobacco consumption[2]), it has been established that several Member States have existing national legislation imposing a ceiling for nicotine yield from cigarettes,

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1 OJ L 137, 30.5.1990, p. 36.

2 COM(1999) 407 final.

whereas several others have replied calling for such a ceiling to be introduced at Community level. This situation of variable legislative requirements within the Internal Market is clearly problematic where a product so widely traded is concerned, and which additionally carries such major negative health consequences for its consumers (The World Health Organisation estimates tobacco related deaths to exceed 500,000 annually in the European Union). The effectiveness of national nicotine ceilings is weak in the absence of any Community rules. This legislative weakness is particularly significant as nicotine is an addictive substance contained in tobacco products, which leads to dependency in smokers, reducing their ability to stop consuming. This proposal therefore requires that the nicotine yield of cigarettes put into free circulation, marketed or manufactured in the Member States shall not exceed 1mg per cigarette from 31 December 2003 (or 3 years from date of adoption).

5. CARBON MONOXIDE

In the Recommendation adopted by the Commission's High Level Cancer Experts Committee in Helsinki in October 1996 (see the Annex to the Commission's Communication on the present and proposed Community role in combating tobacco consumption[3]), it is recommended that in addition to reducing the existing ceiling for tar yield in cigarettes, and to creating a ceiling for nicotine yield in cigarettes, a similar measure should be taken as regards carbon monoxide yield in cigarettes. Such a measure is considered justified in the light of scientific evidence linking carbon monoxide in cigarettes with the incidence and onset of cardiovascular disease in smokers[4]. It should be noted that while cancer is clearly identified as one of the consequences of smoking tobacco, so also is cardiovascular disease. Moreover, carbon monoxide is capable of crossing the placental barrier and affecting the oxygen intake of foetuses in the womb. It thus contributes to low birth weight babies and foetal abnormality[5]. Although no Member States currently impose ceilings on carbon monoxide yields, this has been introduced in several third countries. Reporting requirements do, however, exist in some Member States. It may also be noted that both Sweden and Finland had limits on carbon monoxide yield or requirements to state the content for cigarettes until their accession. In line with the approach taken for tar and nicotine, and in order to ensure a high level of public health protection, it is considered necessary to introduce a ceiling for carbon monoxide yields in cigarettes proportionate to the ceilings already mentioned at paragraph 2 and 3 above. This ceiling would require a carbon monoxide yield of not more than 10mg per cigarette from 31 December 2003 (or 3 years from date of adoption).

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3 COM(96) 609 final.

4 US Department of Health and Human Services. The Health Consequences of Smoking: Cardiovascular Disease. A report of the Surgeon General, Rockville, Maryland 1984.

5 US Dep: Health and Human Services: Reducing the Health Consequences of Smoking; 1989.

6. MEASUREMENT STANDARDS

The measurement systems proposed for each of the above-mentioned ceilings are those set down by the International Standards Organisation (ISO) and update those currently indicated in existing Community directives 89/622/EEC[6], 90/239/EEC[7], and 92/41/EEC[8] (the tar and labelling directives).

7. OTHER NOXIOUS SUBSTANCES

In addition to measuring the yields in cigarettes of tar, nicotine and carbon monoxide, it is proposed that Member States may also require tobacco manufacturers or importers to carry out any other such tests as may be laid down by the appropriate national authorities in order to assess the yield of other substances produced by their tobacco products on a brand by brand basis. The purpose of this provision is to allow Member States to monitor specific substances present in burnt or unburned form in tobacco products, and which may be significant in public health terms, such as the yield of and the presence of specific chemical compounds. The proposal provides that information and toxicological data supplied under these provisions shall be protected by the Member States in respect of trade secrecy.

8. LABELLING

Existing Community provisions on labelling[9] are essentially of two sorts: firstly, yields of tar and nicotine in cigarettes are already required to be shown on cigarette packaging; secondly, a series of warning labels have been laid down to alert consumers to the health effects of tobacco use, and these warnings are printed on all tobacco product packaging.

9. _____

It is proposed in respect of the first point mentioned above, to maintain the indication of the yields of tar and nicotine and to add the indication of the yield of carbon monoxide. In this way, the consumer can be better informed of three important noxious constituents of cigarettes. Cigarettes are the only tobacco products which are currently covered by this requirement to declare yields and this will also continue to be the case in the present proposal. In fact, no standard measurement system has yet been developed internationally for measuring tar, nicotine and carbon monoxide yields in tobacco products other than cigarettes, although some work has been done in respect of roll-your-own tobacco and cigars, which indicate that such products may, in fact, have more significant quantities of tar, nicotine and carbon monoxide than manufactured cigarettes. It is not, however, feasible at present to impose indication of yields for tobacco products other than cigarettes in the absence of an internationally recognised measurement system.

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6 OJ L 359, 8.12.1989 p. 1.
7 OJ L 137, 30.5.1990 p. 36.
8 OJ L 158, 11.6.1992 p. 30.
9 Directive 89/622/EEC (OJ L 359, 8.12.1989 p. 1) as amended by Directive 92/41/EEC (OJ L 158, 11.6.1992 p. 30).

10. _____

As regards the second point mentioned in paragraph 8 above, that of health warning messages, it is envisaged in this proposal both to take account of experience in the application of existing Community provisions[10], and new and relevant scientific data which concerns the areas covered in the warning messages and the nature and composition of the smoking population in the European Community, in order to improve the presentation, impact, visibility, comprehension and content of health warnings for consumers of tobacco products.

11. _____

Thus, as regards the printing requirements for such warnings, it is proposed to use black type on a white background, surrounded by a black border; this is intended to avoid rather common difficulties encountered in the application of current Community rules in respect of printing of the warnings on a non-contrasting background.

12. _____

The size of warnings would be increased in the present proposal to include both a standard warning (chosen from a list of two) on the front side, and on the reverse face of the packaging an additional warning (chosen from a list of five), and in the case of cigarettes, the indication of the tar, nicotine and carbon monoxide yields.

13. _____

The content of the health warnings has been revised in this proposal to draw the attention of consumers to the links between smoking and certain diseases, and the particular danger of tobacco consumption in the case of pregnancy. Attention is also drawn to the addictive nature of smoking.

14. **ORAL TOBACCO AND SMOKELESS TOBACCO**

In respect of oral tobacco, it may be noted that in its Act of Accession, Sweden is excluded from the law on placing on the market of oral tobacco[11]. This proposal will leave that exemption unchanged. In respect, however, of the health warnings to be indicated on such products and in respect of other smokeless tobacco products (eg. nasal snuff), scientific opinion no longer supports a strong warning as is currently set out in Directive 92/41/EEC ('Causes Cancer'). It is therefore proposed to replace this warning with a more general one. This will better reflect the established health risks for such products, consumed in very small amounts on the Community market, while not referring to the distinct products, which are the subject

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10 Evaluation of warning texts on cigarette packets. Dept. of Human Sciences, Stockholm 1997.

11 defined as 'all products for oral use,' except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of these forms – particularly those presented in sachet portions or porous sachets – or in a form resembling a food product (definition currently in Directive 92/41/EEC).

of an existing directive forbidding placing on the market, where a high risk of certain oral cancers has been established and where such products may serve as a gateway drug to facilitate commencement of smoking through the introduction of subjects to nicotine addiction[12].

15. _____

The products referred to in paragraph 14 above do not concern legitimate smoking cessation products, which may contain nicotine, and which are subject to pharmaceutical approval procedures in the European Community (eg. nicotine patches, inhalers, gums).

16. **FURTHER PRODUCT INFORMATION**

The Commission Report on smoking prevention[13], referred to earlier, identifies a significant area of difference in Member State laws and regulations governing additives which may be incorporated in tobacco products. Several Member States currently have what could be described as strict provisions in this regards; others apply ipso facto these provisions; others again have no national regulation of additives. Finally, one Member State applies rules adopted in the United States of America. The control of additives in the Internal Market is therefore subject to extraordinary uncertainty, given the large number of consumers involved and the fact that tobacco products are increasingly manufactured in one state but consumed in another, leading to control difficulties. This proposal therefore envisages that all manufacturers and importers of tobacco products shall submit a list of non-tobacco ingredients and constituents, including additives and quantities thereof, used in the manufacture of their tobacco products by brand. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients and constituents in their products. For the purposes of enabling an evaluation of the health impact of such non-tobacco components, it is furthermore proposed that Member States obtain toxicological data on these non-tobacco ingredients and constituents in burnt and unburned form and require manufacturers and importers to demonstrate that the said ingredients are safe for the health of the consumer when used as intended in their tobacco products.

17. _____

In order to ensure the commercial confidentiality of information relating to the manufacture of individual brands of tobacco products, it is envisaged that the Member States provide such information supplied with appropriate protection.

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12 - Long-term use of smokeless tobacco, G. Bolinder, Stockholm 1997.
- Snuff induced changes associated with the use of loose and portion bag packed Swedish moist snuff, Malmo, 1991.
- Smokeless tobacco, American Cancer Society, 1988.
- Health consequences of using smokeless tobacco, US Dept. of Health and Human Sciences, 1986

13 Commission Report of 8 September 1999 (COM(1999) 407 final).

18. PRODUCT DESCRIPTIONS

At present, the description of certain tobacco products can give rise to misapprehensions on the part of consumers who may believe that some such are less dangerous to health than others. This concerns, in particular, the use of such terms as 'low tar,' 'light,' 'ultra light,' 'mild' and so on. Smokers who may otherwise have tried to stop smoking may be attracted to such products in the mistaken belief that they are healthier, whereas in fact they still represent a major risk to their health, particularly because in order to receive a given dose of nicotine, it is necessary to inhale more deeply. This proposal envisages that such terms should be prohibited unless expressly authorised by the Member States, which shall inform the Commission of the conditions for such authorisation. The Commission shall inform the European Parliament and the Council.

19. INTERNATIONAL RECOMMENDATIONS

These measures are in line with Recommendations made by the Commission's Advisory Committee for Cancer Prevention[14], and those of the World Health Assembly of the WHO[15]. The measures proposed also take account of the Commission's Consumers Committee opinion on a socially responsible Community tobacco policy adopted on 14 June 1998.

20. REVIEW AND REPORTING

It is clear that scientific data on tobacco and on its consumption is in constant development. In addition, the technical elements regarding manufacture of such products need to be kept under review in respect, for example, of measurement systems for tar, nicotine and carbon monoxide yields, additives and non-tobacco ingredients, as well as in respect of new or modified products placed on the market, while ensuring a high level of public health protection and taking into account new scientific facts, and consumer protection and information. A review and information exchange procedure is therefore important in order to ensure a smooth operation of the Internal Market. Therefore in order to ensure transparency and rapid circulation of information with a view to the harmonious working of the Internal Market, it is proposed that the Commission reports every two years to the Council, the European Parliament, and to the Economic and Social Committee on the application of this proposed text, and if necessary make further proposals to adapt it to developments in the field of tobacco products, and taking account of any new development based on scientific facts, using as a basis a high level of public health protection (Article 95).

The Commission could, in any event, also consult the relevant Scientific Committee on matters pertaining to the areas covered by this text.

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[14] Final Annex to COM(96) 609.

[15] Tobacco or Health, a status report, Geneva, 1997 p. 49.

21. CONCLUSION

This draft proposal for a directive is intended to recast existing directives regarding tar content in cigarettes, oral tobacco, and labelling of tobacco products. The modifications and additions proposed in relation to the texts of the directives in force are identified by the underlined text and by the word “new” in the correlation table. It also includes provisions to harmonise laws, regulations and administrative provisions of the Member States as regards nicotine and carbon monoxide levels in cigarettes, the description of tobacco products and use of non-tobacco ingredients. It finally provides for a review mechanism through a reporting procedure to take account in particular of new scientific developments in so far as the above affect the establishment and operation of the Internal Market.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

(recast version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use[4] was amended substantially by Directive 92/41/EEC[5]. Since further amendments are to be made to those Directives, as well as to Council Directive 90/239/EEC of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes[6], all those Directives should be recast in the interests of clarity.

(2) There are substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation, and sale of tobacco products. Such manufacture, presentation and sale transcend the borders of the Member States and the differences in question are likely to give rise to barriers to the movement between Member States of tobacco products, as well as distort competition, thereby impeding the functioning of the internal market.

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1 OJ C
2 OJ C
3 OJ C
4 OJ L 359, 8.12.1989 p. 1.
5 OJ L 158, 11.6.1992 p. 30.
6 OJ L 137, 30.5.1990 p. 36.

(3) Those barriers should be eliminated and, to this end, the rules relating to the manufacture, presentation and sale of tobacco products should be approximated, whilst leaving Member States the possibility of introducing, under certain conditions, such requirements as they consider necessary in order to guarantee the protection of the health of individuals.

(4) In accordance with Article 95(3) of the Treaty, the Commission is obliged, in its proposals under Article 95(1) concerning health, safety, environmental protection and consumer protection, to take as a base a high level of protection.

(5) Directive 90/239/EEC established maximum limits for the tar yield of cigarettes marketed in the Member States with effect from 31 December 1992. The carcinogenic nature of tar makes it necessary further to reduce the levels of tar in cigarettes.

(6) Directive 89/622/EEC established a general warning to be carried on the unit packaging of all tobacco products, together with additional warnings exclusively for cigarettes and, from 1992, extended the requirement for additional warnings to other tobacco products.

(7) Directive 89/622/EEC prohibited the sale in the Member States of certain types of tobacco for oral use. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden a derogation from the provisions of that Directive in this regard.

(8) Cigarettes have been shown to produce amounts of carbon monoxide which are hazardous to human health and capable of contributing to heart disease and other ailments. Differences in rules concerning carbon monoxide are liable to constitute barriers to trade and to impede the smooth operation of the Internal Market.

(9) There are differences between the laws, regulations and administrative provisions of the Member States on the limitation of the maximum nicotine yield of cigarettes. Such differences are liable to constitute barriers to trade and to impede the smooth operation of the internal market. Member States and scientific authorities have raised specific problems of public health in a field which has already been the subject of prior harmonisation measures, which the Commission has examined.

(10) Those obstacles should accordingly be eliminated and to that end the release for free circulation, marketing and free movement of cigarettes should be made subject to common rules concerning maximum nicotine and carbon monoxide levels.

(11) The size of the internal market in tobacco products and the increasing tendency of tobacco manufacturers to concentrate production for the whole of the Community in only a small number of production plants within the Member States, calls for legislative action to achieve the smooth operation of the internal market of tobacco products to be carried out at Community rather than national level.

(12) In applying this Directive provision should be made for establishing time-limits which allow, on the one hand, completion to a maximum degree of efficiency of the process of conversion already begun by Directive 90/239/EEC, and, on the other, consumers and manufacturers to adapt to products with a lower tar, nicotine and carbon monoxide yield.

(13) In Directive 90/239/EEC Greece was granted a derogation from the time-limits for the implementation of maximum tar yields. That derogation is still in force.

(14) Tobacco products have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt. The consumer has the right to be informed of the presence of these substances when purchasing or consuming the product and to have such information conveyed in a clear, legible and comprehensible manner. One of the most effective methods of presenting this information is through the medium of warning labels on tobacco product packaging.

(15) Experience of the application of the labelling provisions of Directive 89/622/EEC has shown that the requirements laid down therein are insufficient to meet their objective, particularly given the hazardous, including addictive, nature of tobacco products, and the complexity and amount of information to be supplied.

(16) The presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products. It is necessary that the existing legislation be strengthened and clarified. A high level of health protection should be ensured.

(17) These obstacles should accordingly be eliminated and, to that end, the release for free circulation, marketing and free movement of tobacco products should be subject to clearer and strengthened rules on warnings and yields.

(18) A number of the Member States have neither existing legislation nor voluntary agreements in place on the ingredients and additives used in the manufacture of tobacco products. Several Member States in which such legislation or voluntary agreements exist receive no information from tobacco manufacturers on the quantities of such ingredients and additives present in particular tobacco products on a brand name by brand name basis.

(19) This lack of information together with the lack of toxicological data prevents the relevant authorities in the Member States from assessing in any meaningful manner the toxicity of and hazards posed to the health of the consumer by tobacco products. This is inconsistent with the obligation placed on the Community to ensure a high level of protection for human health.

(20) The Community and the Member States have an obligation to ensure that the commercial and intellectual property rights of the tobacco manufacturers are protected under national and international law. Provision should therefore be made for confidential treatment of product data in so far as this is compatible with the public interest.

(21) Technical and scientific progress in the field of tobacco products calls for regular re-evaluation of the provisions and application in the Member States of this Directive. Therefore, a procedure for regular reports by the Commission is provided for.

(22) Council Directive 89/552/EEC[7], as last amended by Directive 97/36/EC of the European Parliament and of the Council[8], prohibits all forms of television advertising for cigarettes and other tobacco products. Directive 98/43/EC of the European Parliament and of the Council[9] regulates direct and indirect advertising of tobacco products, including sponsorship.

(23) The Council Resolution of 26 November 1996 on the reduction of smoking in the European Community[10] called upon the Commission to take particular account, in its policies in various fields in so far as they have relevance to tobacco or tobacco products, of the detrimental effect of smoking on the health and quality of life of citizens of the Community. The same Council Resolution called upon the Commission to examine further the possible measures which might be taken by the Community and the Member States directed towards the reduction of smoking.

(24) The Commission Communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption[11] called for further review of maximum permitted tar and nicotine limits. The Communication advocated a review of existing warning label requirements and called for action on the definition of the description "low tar" considering that such descriptions may mislead consumers by understating the dangers to health of such products. The Communication noted the lack of any Community legislation to evaluate or regulate the toxicity and health consequences arising from the use of additives in tobacco products. There is Community legislation on additives and ingredients in a wide range of other products which may have health consequences for the consumer.

(25) The use of terms such as 'low tar' on cigarette packaging can mislead the consumer into believing that such products are inherently safer than other types of cigarettes. National rules on the definition of such cigarettes are not reflected in Community law, leading to potential internal market obstacles, and to a gap in measures to ensure a high level of public health protection in this context. Certain smokers ingest higher levels of tar than those indicated on 'low tar' cigarette packets because of the nature of their smoking behaviour.

(26) The European Parliament Report of 4 November 1997 on the Commission Communication calls for any substance added to tobacco to be non-toxic and proven not to have any harmful effects on health in burnt or unburned form. The Report supports initiatives aimed at making the health warnings more prominent and clearly legible, printed in black on white.

(27) In its Recommendation arising out of the Helsinki Consensus Conference on Tobacco, the High Level Cancer Experts Committee recommended[12] that the Community should take action to regulate the toxicity and harmful effects on health of the ingredients, including additives, in cigarettes and considered that a nicotine limit should be introduced for cigarettes as soon as possible. The Committee recommended that the labelling provisions for cigarettes should be strengthened and made more prominent

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7 OJ L 298, 17.10.1989, p. 23.
8 OJ L 202, 30.7.1997, p. 60.
9 OJ L 213, 30.7.1998, p. 9.
10 OJ C 374, 11.12.1996, p. 4.
11 COM(96) 609 final.
12 Final Annex to COM(96) 609.

and that accurate information about smoking and its health consequences be given to the consumer.

(28) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition and for application of the Directives set out in Annex III.

HAVE ADOPTED THIS DIRECTIVE:

Article 1 - Object

The objective of this Directive is the approximation of the laws, regulations and administrative provisions of the Member States concerning the tar yields of cigarettes and the warnings regarding health to appear on packets of tobacco products, together with the approximation of the laws, regulations and administrative provisions of the Member States concerning carbon monoxide and nicotine yields and the ingredients of tobacco products, taking as a base a high level of health protection.

Article 2 - Definitions

For the purposes of this Directive:

(1) '*Tobacco products'* means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco;

(2) *'Tar'* means the raw anhydrous nicotine-free condensate of smoke;

(3) '*Nicotine'* means nicotinic alkaloids;

(4) '*Tobacco for oral use'* means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of these forms - particularly those presented in sachet portions or porous sachets - or in a form resembling a food product;

(5) *'Ingredient'* means any substance except for natural tobacco leaf or its plant parts used as an additive in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form.

Article 3 – Cigarettes: tar, nicotine and carbon monoxide levels

1. The tar yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than 10 mg per cigarette as of 31 December 2003;

2. The nicotine yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than 1.0 mg per cigarette as of 31 December 2003;

3. The carbon monoxide yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than 10 mg per cigarette as of 31 December 2003.

Article 4 - Derogation

For Greece, as a temporary derogation, the limit value of tar yields and date of implementation shall be 10 mg of tar as of 31 December 2006.

This derogation may not be used to justify controls at the Community's internal frontiers.

Article 5 – Measurement methods

1. The tar, nicotine and carbon monoxide yields referred to in Article 3, which must be indicated on cigarette packets, shall be measured on the basis of ISO methods 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

   The accuracy of the indications on the packets shall be verified in accordance with ISO standard 8243.

2. Member States may require that the tests referred to in paragraph 1 be carried out by a testing laboratory approved for the purpose by the relevant Member State authorities.

3. Member States may also require tobacco manufacturers or importers to carry out any other such tests as may be laid down by the appropriate national authorities in order to assess the yields of other substances produced by their tobacco products on a brand name by brand name basis. They may also require that such tests be carried out in approved testing laboratories as laid down in paragraph 2.

4. The results of all such tests carried out under the provisions of paragraph 3 shall be disclosed to the relevant national authorities annually.

5. The Member States shall take such steps as are necessary to protect the trade secrecy of all data and information submitted pursuant to the requirements of this Article.

6. The Member States shall supply all data and information submitted pursuant to this Article to the Commission not later than 31 May of each year.

Article 6 – Labelling

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered.

   This percentage shall be raised to 12% for countries with two official languages and 15% for countries with three official languages.

2. Each unit packet of tobacco products, except for smokeless and oral tobacco products, shall carry one of the following general warnings:

   – "Smoking kills."

   – "Smoking can kill".

Each unit packet of tobacco products, except for oral and smokeless tobacco products, shall carry an additional warning taken exclusively from Annex I.

Oral tobacco products, where they are permitted to be placed on the market pursuant to the provisions of Article 9, and smokeless tobacco products shall carry the warning in Annex II. This warning shall be placed on the most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on this surface in order to accommodate language requirements.

3. The general warning referred to in the first subparagraph of paragraph 2 shall be printed on the most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on this surface in order to accommodate language requirements.

The warning referred to in the second subparagraph of paragraph 2 shall be printed on the other most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on these surfaces in order to accommodate language requirements.

4. The text of warnings and yield indications required under this Article, shall be:

– printed in black Helvetica bold type on a white background. In order to accommodate language requirements, the Member States shall have the right to determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;

– in lower case type except for the first letter of the message;

– centred in the area in which the text is required to be printed, parallel to the top edge of the packet;

– surrounded by a black border not less than 3mm in width and not more than 4mm in width which does not in any way interfere with the text of the warning or information given;

– in the official language or languages of the Member State where the product is placed on the market.

5. The printing of the texts required by this Article on the underside or on the tax stamps of unit packets shall be prohibited. The texts required pursuant to this Article shall be irremovably fixed, indelible and shall not in any way be hidden, obscured or interrupted by other written or pictorial matter, nor by the opening of the packet.

6. The general warning required pursuant to the first subparagraph of paragraph 2 and the warning for smokeless and oral tobacco products referred to in the third subparagraph of paragraph 2 shall cover not less than 25% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. This percentage shall be increased to 27% for countries with two official languages and 30% for countries with three official languages.

7. The additional warning referred to in the second subparagraph of paragraph 2 shall cover not less than 25% of the external area of the corresponding surface of the unit packet on which it is printed. This percentage shall be increased to 27% for countries with two official languages and 30% for countries with three official languages.

These additional warnings shall be rotated in such a way as to guarantee the successive appearance of each warning on an equal quantity of unit packets. A tolerance of 5% shall be permitted.

Article 7 – Further product information

1. Not later than 31 December 2003, Member States shall require all manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of their tobacco products by brand name. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients and constituents in their tobacco products.

Member States shall also require manufacturers and importers to provide all data on these non-tobacco ingredients in burnt and unburned form, and to demonstrate that the said ingredients are safe for the health of the consumer when used as intended in their tobacco products. This information, together with that referred to in the first subparagraph shall be submitted for the first time on 1 January 2004 and on an annual basis thereafter.

2. The Member States shall take such steps as are necessary to protect the trade secrecy of all such data and information submitted pursuant to the requirements set out in paragraph 1.

3. The Member States shall supply all toxicological data and information submitted pursuant to this Article to the Commission no later than 31 May of each year.

Article 8 – Product descriptions

1. The use of the terms '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, unless such terms have been expressly authorised by the Member States where the products in question have been marketed or manufactured.

2. The Member States which authorise the use of such terms shall notify the Commission thereof, together with the conditions applied to such authorisation. The Commission shall present this information in the report referred to in Article 10.

Article 9 – Oral tobacco

The Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to the provisions of Article 151 of the Act of Accession of Austria, Finland and Sweden.

Article 10 – Report

Not later than 31 December 2005, and every two years thereafter, the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on the application of this Directive and, if necessary, make further proposals to adapt it to developments in the field of tobacco products, to the extent necessary for the establishment and operation of the internal market, and taking account of any new development based on scientific facts.

Article 11 - Import, sale and consumption of tobacco products

1. Member States may not, for considerations of limitation of the tar, nicotine or carbon monoxide yields of cigarettes, labelling, or other requirements of this Directive prohibit or restrict the import, sale and consumption of tobacco products which comply with this Directive.

2. This Directive shall not otherwise affect the right of the Member States to adopt, in accordance with the Treaty, more stringent rules concerning the import, sale and consumption of tobacco products they deem necessary in order to protect public health.

Article 12 - Implementation

1. Without prejudice to the provisions of Article 13, as regards time-limits for transposition, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

   When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Products existing at the date of entry into force of this Directive which do not comply with this Directive may continue to be marketed for two years thereafter.

3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 13 - Repeal

Directives 89/622/EEC, 90/239/EEC and 92/41/EEC are repealed, without prejudice to the obligations of the Member States concerning the time-limits for transposition and application set out in Annex III.

References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

Article 14 - Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities.*

Article 15 - Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Tobacco products other than smokeless and oral tobacco

Additional health warnings which must be included on the national lists pursuant to the second subparagraph of Article 6(2)

1. Smokers die younger

2. Smoking causes heart disease and strokes

3. Smoking causes cancer

Additional warnings from amongst which the Member States may choose

1. Smoking when pregnant harms your baby

2. Protect children: don’t make them breathe your smoke

3. Your doctor can help you stop smoking

4. Smoking is addictive

5. Stopping smoking reduces the risk of serious disease

ANNEX II

Oral and smokeless tobacco products

Smokeless (or oral, as appropriate) tobacco can damage your health

ANNEX III

Time-limits for transposition and for application of repealed Directives

(referred to in Article 13)

Directive		Time-limits for transposition	Time-limits for application
89/622/EEC	(OJ L 359, 8.12.1989, p. 1)	1 July 1990	31 December 1991
			31 December 1992
			31 December 1993
90/239/EEC	(OJ L 137, 30.5.1990, p. 36)	18 November 1991	31 December 1992[1]
			31 December 1997[2]
			31 December 1992[3]
			31 December 1998[4]
			31 December 2000[5]
			31 December 2006[6]
92/41/EEC	(OJ L 158, 11.6.1992, p. 30)	1 July 1992	1 July 1992
			1 January 1994
			31 December 1994

1 For all the Member States except Greece.
2 Ibid.
3 Derogation applying to Greece only.
4 Ibid.
5 Ibid.
6 Ibid.

ANNEX IV
CORRELATION TABLE

This Directive	Directive 89/622/EEC as amended by Directive 92/41/EEC	Directive 90/239/EEC		Other Acts	
Article 1	Article 1	Article 1			Partly new
Article 2 points 1, 2 and 3	Article 2(1), (2) and (3)	Article 2(1)			
Article 2, point 4	Article 2(4)				
Article 2, point 5					New
Article 3 (1)		Article 2(2)			Partly new
Article 3(2)					New
Article 3(3)					New
Article 4		Article 2(3)			Partly new
Article 5(1)	Article 3(1) and (2)	Articles 3 and 4			Partly new
Article 5(2) to (6)					New
Article 6(1)	Article 3(3)				Partly new
Article 6(2) first subparagraph	Article 4(1)				Partly new
Article 6(2) second subparagraph	Article 4(2a)(a)				Partly new
Article 6(2) third subparagraph	Article 4(1) and (2a)(c)				Partly new
Article 6(3)	Article 4(1) and (2a)(a)				Partly new
Article 6(4)	Article 4(4)				New (except for final indent)
Article 6(5)	Articles 4(4) and 4(5)				Partly new
Article 6(6)	Article 4(4)				Partly new
Article 6(7) first subparagraph	Article 4(4)				Partly new
Article 6(7) second subparagraph	Article 4(2) second indent				
Article 7					New
Article 8					New
Article 9	Article 8(a)			Act of Accession for Sweden	Partly new
Article 10					New
Article 11(1)	Article 8(1)	Article 7(1)			Partly new
Article 11(2)	Article 8(2)	Article 7(2)			
Article 12(1)	Article 9(1)	Article 8(1)			Partly new
Article 12(2)	Article 9(2)	Article 8(2)			
Article 12(3)	Article 9(1)	Article 8(3)			
Article 13					New
Article 14					
Article 15	Article 10	Article 9			
Annex I	Annex 1				Partly new
Annex II	Annex 2				Partly new

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

TITLE OF PROPOSAL

Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (Text with EEA relevance).

THE PROPOSAL

1. Taking account of the principle of subsidiarity and proportionality, this draft proposal for a directive is intended to recast three existing Internal Market directives dealing with the tar content of cigarettes, oral tobacco and labelling of tobacco products, and to update and complete these provisions in the light of new developments based on scientific facts in the context of the completion of the Internal Market, taking as basis a high level of public health protection.

   Its main aims are to continue the reduction in tar levels of cigarettes already introduced by Council Directive 90/239/EEC, to introduce Community ceilings for nicotine and for carbon monoxide in cigarettes to require a declaration of non-tobacco ingredients (additives) in products, and to authorize the use of certain product descriptors.

   In particular, the proposed measures do not go beyond what is necessary to achieve the objectives of the Treaty, in particular Article 95 thereof, respecting in full the principles set out in the protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

   – The sectors of business affected by the proposal will principally be cigarette manufacturers and importers. Some provisions also apply to tobacco products other than cigarettes, which however represent less than 10% of total tobacco consumption.

   – The overall volume of sales of manufactured tobacco products is concentrated mainly on large multinational firms as regards cigarette production. Those small and medium-sized firms active in the market concentrate principally on non-cigarette products (e.g. snuff, pipe tobacco, rolling tobaccos).

   – The small and medium-sized firms active in the marketplace are not geographically concentrated in any one region of the Community.

3. What will business have to do to comply with the proposal?

In the case of many provisions (tar, nicotine and carbon monoxide ceilings), an extension is proposed on requirements in existing directives. Use of ISO measurement standards is provided for.

In the case of additives, a declaration of non-tobacco ingredients and data thereon will have to be supplied to Member States. Such information can of course be sought from the manufacturers of the additives concerned. On product descriptions, only some firms, which use such terms for their products will be concerned. Authorization will in these cases need to be sought from Member State authorities.

In some cases, voluntary agreements between Member State authorities and industry are already in place or proposed.

4. What economic effects is the proposal likely to have?

– The economic effects of the proposal on employment are considered to be positive, since the text will harmonize and approximate internal market rules, leading to greater clarity and security for market operators. At the moment, for example, each Member State applies a different legislative regime for tobacco additives, a situation which will be clarified and simplified in this proposal. On a more general note, it may be useful to quote a World Bank report of 1999[1]:

> "Statements that tobacco controls will mean massive job losses are usually based on studies funded by the tobacco industry that estimate the number of jobs attributable to tobacco in each sector, the incomes associated with these jobs, tax revenues generated by tobacco sales, and the contribution of tobacco to the country's trade balance wherever this is relevant. These studies also estimate the multiplier effect of money earned in tobacco farming and manufacturing in stimulating activity elsewhere in the economy. However, the methods used for these studies have been criticized. First, they assess the gross contribution of tobacco to employment and the economy. Rarely, if ever, do they take account of the fact that if people stop spending money on tobacco, they usually spend it on other things instead, thus generating alternative jobs to compensate. Second, their methods overstate the impact of any intervention that reduces demand because their estimates of certain variables, such as trends in smoking and trends in the mechanization of cigarette production, tend to be static.
>
> Independent studies of the impact of tobacco on individual economies reach different conclusions. Rather than consider the gross economic contribution of tobacco to the economy, the independent studies estimate its *net* contribution, that is, the benefit to the economy of all tobacco-related activity *after* taking into account the compensating effect of alternative jobs that would be generated by the money not spent on tobacco. The conclusions of these studies are that tobacco control policies would have little or no negative effect on total employment, except in a very few tobacco producing countries.

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[1] Curbing the epidemic World Bank Washington 1999.

A study in the United Kingdom found that jobs would increase by more than 100 000 full-time equivalents in 1990 if former smokers spent their money on luxury items, and if any decline in tax revenues brought about by nontax measures to reduce demand were offset by taxing other goods and services. A study in the United States found that the number of jobs would rise by 20 000 between 1993 and 2000 if all domestic consumption was eliminated. While there would be net job losses in the tobacco-growing region of the United States, the national total would rise because of the money freed up from tobacco purchases and injected into other areas of the economy. Of course, industry transitions can be difficult and may create social and political problems in the short term. But economies go through many such transitions, and this one would not be exceptional."

– As regards investment and the creation of new business, the proposal will increase legal certainty and clarity of regulations across the Internal Market, and thus should contribute to facilitating investment and creation of businesses in the sector concerned while ensuring a high level of public health protection (Article 95 of the Treaty).

– Similarly, the competitive position of business will be significantly improved if rules at the Internal Market level are clarified, and harmonized. Economies of scale will be easier to achieve in these circumstances.

5. The proposal does not contain specific requirements for the situation of small and medium-sized firms, as these facilities were not contained in the earlier directives which are now being recast (89/622/EEC, 90/239/EEC, 92/41/EEC). As the new provisions proposed are largely an extension of these existing provisions, no major justification for specific requirements for SME's appears necessary.

CONSULTATION

6. A detailed consultation has taken place with business sectors likely to be concerned, with governmental authorities, with international organisations and with non-governmental organizations.

In particular, consultations took place with le Groupement des industries européennes du Tabac, the Confederation of European Community Cigarette Manufacturers Ltd, SEITA, Philip Morris, Imperial Tobacco, RJ. Reynolds, Rothmans, European Cigar Manufacturers Association, the European Smoking Tobacco Association.

Discussions took place with Member State ministries (UK, IRL, LUX, NL, F, ESP, IT, SW, FIN, B). As regards N.G.O.'s, discussions took place with the World Health Organization, the International Standards Organisation, the International Agency for Cancer Research, the International Union Against Cancer.

Several of the main tobacco companies query the legal basis of the Commission's proposal, arguing that the measures are not proper to Article 95. This ignores the fact that the three directives to be recast are Internal Market measures.

Support was expressed by companies for improved health warnings as a means of informing consumers. However, they wish to address this reinforcement of consumer information as part of a detailed dialogue with Member States and the Commission, rather than by means of an amendment to the directive.

As regards additives, the companies remark that the existing legislative situations (i.e. of 15 different sets of national rules) is adequate, and that effective controls are in place. This contradicts the factual situation described in the Commission's enquiry on this subject (see Commission Report of 8 September 1999, COM(99) 407 final, p.16 *et al*).

Strong support for the proposed measure has been expressed both by Member State authorities (Council Conclusions due for adoption on 18.11.99) and by non-governmental authorities, and by the European Parliament in a recent Report (OJ C 14, 19.1.1998, p. 197).