Amended 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) [1]

(2000/C 337 E/30)

(Text with EEA relevance)

COM(2000) 428 final — 1999/0244(COD)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 6 July 2000)

[1] OJ C 150 E, 30.5.2000, p. 43.

INITIAL PROPOSAL	AMENDED PROPOSAL
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	Unchanged
Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,	
Having regard to the proposal from the Commission,	
Having regard to the opinion of the Economic and Social Committee,	
Having regard to the opinion of the Committee of the Regions,	
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 [1] was amended substantially by Directive 92/41/EEC [2]. 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 [3], 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 nternal arket.	(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.

[1] OJ L 359, 8.12.1989 p. 1.

[2] OJ L 158, 11.6.1992 p. 30.

[3] OJ L 137, 30.5.1990 p. 36.

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(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.	(3) Those barriers should be reduced and over time 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, .	(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, taking account in particular of any new development based on scientific facts.
(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.	Unchanged
(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.	(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 could constitute barriers to trade and 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 nternal arket. 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.	(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.	Unchanged

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(11) The size of the nternal arket 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 nternal arket of tobacco products to be carried out at Community rather than national level.	(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.
	(11a) The establishment of world-wide standards for tobacco products is also the subject of negotiations for the creation of a World Health Organisation Framework Convention on Tobacco Control.
(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.	Unchanged
(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.	
	(14a) In recent years, scientific knowledge of the dangers of passive smoking has been increased. It has been proven that smoking in babies' presence is a cause of sudden infant death and that smoking during pregnancy is harmful to the unborn child. Warnings should therefore point to the dangers to others, in particular children.
(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,	(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, as well as the consumers targeted, 80 % of new smokers in the European Union being under 18 years of age.

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(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.	Unchanged
(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.	
	(17a) The Community and the Member States must encourage research and technical progress with a view to establishing methods for accurate and reliable measurement of the tar, nicotine and carbon monoxide yields of cigarettes and other tobacco products. Provisionally, reference should be made to the standards ISO 4387, ISO 10315 and ISO 8454, which are the only internationally recognised standards.
	(17b) There are no internationally recognised standards or tests for quantifying and assessing the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide; therefore, a procedure for development of such standards, in consultation with ISO, is necessary.
(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.	Unchanged
(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	(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, health protection and the objectives of this directive.

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(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.	Unchanged
	(21a) The Community and the Member States must encourage research and technical progress in establishing the exposure to toxins and other harmful substances caused by the use of tobacco products, in order to ensure a high level of health protection through the regulation of such products and to provide meaningful information to consumers. The Community Tobacco Fund provides a means for undertaking such research.
	(21b) The measures to be taken for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].
(22) Council Directive 89/552/EEC [2], as last amended by Directive 97/36/EC of the European Parliament and of the Council [3], prohibits all forms of television advertising for cigarettes and other tobacco products. Directive 98/43/EC of the European Parliament and of the Council [4] regulates direct and indirect advertising of tobacco products, including sponsorship.	Unchanged
(23) The Council Resolution of 26 November 1996 on the reduction of smoking in the European Community [5] 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.	
	(23a) The Commission Communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption [6] makes a large number of proposals as to the action that might be taken at Community level to combat the use of tobacco products; among other things, it encourages the Member States to make use of the opportunities available to them to tax tobacco products more heavily. The price of tobacco products can influence to a large extent whether consumption of such products begins or ceases, particularly as regards youngsters.

[2] OJ L 298, 17.10.1989, p. 23.
[3] OJ L 202, 30.7.1997, p. 60.
[4] OJ L 213, 30.7.1998, p. 9.
[5] OJ C 374, 11.12.1996, p. 4.

[1] OJ L 184, 17.7.1999, p. 23.
[6] COM(96) 609 final.

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	(23b) In particular, as was recommended in this Commission Communication, all necessary steps must be taken to implement an effective information and prevention strategy and to promote research and studies in this area. Such a strategy must be aimed at those sections of the population in Europe that are most at risk, with particular reference to young people and women. Socio-economic direct and indirect costs of active and passive tobacco use should also be regularly evaluated and made available to the public.
(24) The Commission Communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption 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.	(24) This Communication also 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.	Unchanged
(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.	

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(27) In its Recommendation arising out of the Helsinki Consensus Conference on Tobacco, the High Level Cancer Experts Committee recommended [1] 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 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.	(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 II.
HAVE ADOPTED THIS DIRECTIVE:	Unchanged
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.	The objective of this Directive is the progressive 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	Unchanged
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;	

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

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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	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, including paper, filter, inks and adhesives.
Article 3	Unchanged
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;	
	4. Member States may apply this Article in respect of cigarettes other than those released for free circulation or marketed in the Member States from December 2004 but must apply the provisions thereof by December 2006 at the latest.
Article 4	Unchanged
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.	1. The tar, nicotine and carbon monoxide yields referred to in Article 3 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.	The accuracy 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.	2. Member States shall require that the tests referred to in paragraph 1 be carried out or verified by a testing laboratory approved for the purpose by the relevant Member State authorities.

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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.	Unchanged
4. The results of all such tests carried out under the provisions of paragraph 3 shall be disclosed to the relevant national authorities annually.	4. The results of all such tests carried out under the provisions of paragraph 3 shall be disclosed to the relevant national authorities whenever there is a change in the composition of a tobacco product.
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.	5. The Member States and the Commission shall ensure that the results of the tests referred to in this article are disseminated by any appropriate means in order to inform consumers, without prejudice to measures intended to protect the confidentiality of information on manufacturing processes.
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.	Unchanged
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.	1. The maximum authorised tar, nicotine and carbon monoxide yields of cigarettes referred to in Article 3(1) 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 30 % 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.	This percentage shall be raised to 35 % for countries with two official languages and 40 % 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:	Unchanged
— '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.	

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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.	Oral tobacco products, where they are permitted to be placed on the market pursuant to the provisions of Article 10, and smokeless tobacco products shall carry the warning: This tobacco product can damage your health and create addiction. 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.	Unchanged
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:	4. The text of warnings and maximum 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;	— printed in black Helvetica bold type (full shading or 100 % intensity) 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;	Unchanged
— 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.	

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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.	5. The printing of the texts required by this Article on the tax stamps of unit packets shall be prohibited. The texts required pursuant to this Article shall be irremovably printed, 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. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.
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.	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 30 % 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 32 % for countries with two official languages and 35 % 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.	7. The additional warning referred to in the second subparagraph of paragraph 2 shall cover not less than 40 % of the external area of the corresponding surface of the unit packet on which it is printed. This percentage shall be increased to 45 % for countries with two official languages and 50 % 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.	These additional warnings shall be rotated in such a way as to guarantee their regular appearance.
	8. In the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 100 cm^2 in area, the warnings referred to in Article 6(2) shall cover an area of at least 25 cm^2 on each surface. This area shall be increased to 27 cm^2 for countries with two official languages and 30 cm^2 for countries with three official languages.
	9. To ensure product traceability, the tobacco product batch number shall be indicated on each unit packet in any appropriate manner enabling the origin of the product to be identified.
Article 7	Unchanged
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.	1. 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, to be sold in that Member State, by brand name and type. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients and constituents in their tobacco products, and by the toxicological data on those ingredients in burnt and unburned form, and their effects on health taking into account, inter alia their addictiveness.

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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.	This information shall be submitted on a yearly basis, beginning no later than one year after the date referred to in Article 13(1).
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.	2. The Member States and the Commission shall ensure that the information and data referred to in paragraph 1 are disseminated by any appropriate means in order to inform consumers, without prejudice to measures intended to protect the confidentiality of information on manufacturing processes.
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.	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, which shall take account thereof in drawing up the reports referred to in Article 11.
Article 8 **Product descriptions**	Unchanged
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.	1. The use of the terms 'low tar', 'light', 'ultra light', 'mild' or any other similar terms, including indication of the yields, 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.	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 reports referred to in Article 11, together with any proposals for remedial action required to resolve Internal Market disparities which have been identified.
	Article 9 **Committee procedure**
	The measures to be taken for the implementation and adaptation to scientific and technical progress of the Directive concerning: — definitions (Article 2); — measurement methods (Article 5); — warnings to be printed on cigarette packets and their rotation (Article 6); shall be adopted by means of the regulatory procedure referred to in Article 5 of Council Decision 1999/468/EC, having regard to Articles 7 and 8 thereof. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

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Article 9	*Article 10*
Oral tobacco	**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.	Unchanged
Article 10	*Article 11*
Report	**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.	Not later than 31 December 2004, 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, and developments on internationally agreed product standards. For the first report, the Commission will attach particular importance, with a view to improving the operation of the internal market, to: (a) Methodologies for more realistically assessing and regulating toxic exposure and harm; (b) Subsequent reduction of the yields laid down in Article 3(1) and development of standards for products other than cigarettes; (c) Evaluation of tobacco products which may have the potential to reduce harm; (d) Evidence-based improvements in health warnings, in terms of size, position and wording; (e) The question of the criteria used for approving the testing laboratories referred to in Article 5; (f) The possibility of drawing-up a common list of the ingredients referred to in Article 7. In drawing up the report, the Commission shall call upon recognised scientific and technical expertise.
Article 11	*Article 12*
Import, sale and consumption of tobacco products	**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.	Unchanged

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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	*Article 13*
Implementation	**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.	1. Without prejudice to the provisions of Article 14, 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.	Unchanged
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	*Article 14*
Repeal	**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.	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 II.
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.	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 III.
Article 14	*Article 15*
Entry into force	**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*.	Unchanged
Article 15	*Article 16*
Addressees	**Addressees**
This Directive is addressed to the Member States.	Unchanged

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ANNEX I	
Tobacco products other than smokeless and oral tobacco	**List of additional health warnings referred to in Article 6(2)**
Additional health warnings which must be included on the national lists pursuant to the second subparagraph of Article 6(2)	Deleted
1. Smokers die younger	Unchanged
2. Smoking causes heart disease and strokes	
3. Smoking causes cancer	
Additional warnings from amongst which the Member States may choose	Deleted
1. Smoking when pregnant harms your baby	4. Smoking when pregnant harms your baby
2. Protect children: don't make them breathe your smoke	5. Passive smoking harms those around you, especially children
3. Your doctor can help you stop smoking	6. Your doctor can help you stop smoking
4. Smoking is addictive	7. Smoking is addictive
5. Stopping smoking reduces the risk of serious disease	8. Stopping smoking reduces the risk of serious disease
	9. Smoking kills half a million persons each year in the European Union
	10. If you smoke, you are killing yourself
	11. Get help to stop smoking: (Telephone; P.O. Box No.; Internet address; Consult your doctor/pharmacist)
ANNEX II	Deleted
Oral and smokeless tobacco products	
Smokeless (or oral, as appropriate) tobacco can damage your health	

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ANNEX III

Time-limits for transposition and for application of repealed Directives

(referred to in Article 13)

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ANNEX II

Time-limits for transposition and for application of repealed Directives

(referred to in Article 14)

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.

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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

This Directive	Directive 89/622/EEC as amended by Directive 92/41/EEC	Directive 90/239/EEC		Other Acts	
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

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ANNEX III

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

This Directive	Directive 89/622/EEC as amended by Directive 92/41/EEC	Directive 90/239/EEC		Other Acts	
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					New
Article 10	Article 8(a)			Act of Accession for Sweden	Partly new
Article 11					New
Article 12(1)	Article 8(1)	Article 7(1)			Partly new
Article 12(2)	Article 8(2)	Article 7(2)			
Article 13(1)	Article 9(1)	Article 8(1)			Partly new
Article 13(2)	Article 9(2)	Article 8(2)			
Article 13(3)	Article 9(1)	Article 8(3)			
Article 14					New
Article 15					
Article 16	Article 10	Article 9			
Annex I	Annex 1				Partly new