

# PROPOSED REGULATION OF SMOKELESS TOBACCO PRODUCTS WITHIN THE EU

## PART 2

### Proposed Amendments to the EU's Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products

The following document is an amended version of the **EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products** to demonstrate how the proposed regulations described in Part 1 could be included into the Directive. Proposed deletions from the current Directive are in red, proposed replacements/additional sections are in blue.

#### Summary of changes:

##### Article 2. Definitions

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 those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product; - DELETE and replace with:
4. 'smokeless tobacco' means all products that are not smoked, are used orally or inhaled through the nose and meet the constituent limits defined in Annex IV.

##### Article 4. Measurement methods

1. TO BE ADDED after 2<sup>nd</sup> paragraph. For smokeless tobacco products, yields of nicotine and product pH shall be measured. Standardised measurement methods (e.g. ISO) should be developed as a priority.

##### Article 5. Labelling

4. Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products shall carry the following warning: - DELETE and replace with:
4. Smokeless tobacco products permitted under Article 8 shall carry the following warning:
10. TO BE ADDED: Smokeless tobacco products shall be labelled on each unit packet with a best-before date. Each unit packet shall have a declaration of ingredients in a similar manner to EU food labelling requirements. Ingredients that are used in manufacture of each product shall be listed in descending order of weight with flavourings listed as a group.

##### Article 6. Further product information

5. TO BE ADDED: In addition to the requirements stated above, Member States shall require manufacturers and importers of smokeless tobacco products described in Article 8, to report nicotine content and product pH.

##### Article 7. Product descriptions

With effect from 30 September 2003, and without prejudice to Article 5(1), DELETE and replace with:

With the exception of smokeless tobacco products (which in the opinion of regulatory authorities are deemed to be less hazardous) described in Article 8,

#### Article 8. Tobacco for oral use

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden DELETE and replace with:

#### **Smokeless Tobacco Products**

Member States shall require that only smokeless tobacco products that comply with the constituent limits and reporting requirements in Annex IV be permitted to be placed on the market.

#### Article 12. Common list of ingredients

TO BE ADDED after 1<sup>st</sup> paragraph: For smokeless tobacco products, only ingredients permitted for food must be used. Guidance for use is proposed in Annex V.

#### Annexes

TO BE ADDED: **Annex IV Constituent limits for smokeless tobacco products**

TO BE ADDED: **Annex V Ingredients for use in smokeless tobacco products**

**DIRECTIVE 2001/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 5 June 2001****on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products**

THE EUROPEAN PARLIAMENT AND THE  
COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 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 (4), in the light of the joint text approved by the Conciliation Committee on 5 April 2001,

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(5) was amended substantially by Directive 92/41/EEC (6). Since further amendments are to be made to that Directive, 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(7), those Directives should be recast in the interests of clarity.
- 2) There are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation, and sale of tobacco products which impede the functioning of the internal market.
- 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, while 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 individuals.

- (4) In accordance with Article 95(3) of the Treaty, a high level of protection in terms of health, safety, environmental protection and consumer protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts; in view of the particularly harmful effects of tobacco, health protection should be given priority in this context.
- (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 to reduce further 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) Several Member States have indicated that, if measures establishing maximum carbon monoxide yields for cigarettes are not adopted at Community level, they will adopt such measures at national level. Differences in rules concerning carbon monoxide are likely to constitute barriers to trade and to impede the smooth operation of the internal market. In addition, 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.
- (8) A revision of the regulatory framework needs to evaluate evidence-based claims for tobacco products designed and /or marketed to 'reduce risk', or for which harm reduction is claimed by the manufacturers.
- (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 manufacture of cigarettes should be made subject to common rules not only concerning tar but also concerning maximum nicotine and carbon monoxide levels.
- (11) This Directive will also have consequences for tobacco products which are exported from the European community. The export regime is part of the common commercial policy. Health requirements are, pursuant to Article 152(1) of the Treaty and the case law of the Court of Justice of the European Communities, to form a constituent part of the Community's other policies. Rules should be adopted in order to ensure that the internal market provisions are not undermined.
- (12) The provisions of this Directive are without prejudice to Community legislation governing the use and labelling of genetically modified organisms.
- (13) Internationally applicable standards for tobacco products are one of the subjects of the negotiations for the drafting of World Health Organisation Framework Convention on Tobacco Control.
- (14) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are the only internationally recognised standards, it being understood that subsequent research and technological progress to be promoted should make it possible to develop and use more precise and reliable measurement methods for cigarette yields and to develop measurement methods for the other tobacco products.
- (15) There are no internationally agreed standards or tests for quantifying and assessing the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide. A procedure for development of such standards, in consultation with the International Standards Organisation, is therefore necessary.
- (16) In Directive 90/239/EEC, in view of particular socioeconomic problems, Greece was granted a derogation from the time limits for the implementation of maximum tar yields. That derogation should be maintained for the period stipulated.
- (17) The application of tar, nicotine and carbon monoxide ceilings to exported cigarettes should be subject to transitional arrangements in order to allow more time to change product specifications and to allow for the establishment of internationally agreed standards.
- (18) Transitional periods should also be provided for in relation to other provisions of this Directive in order to allow the necessary modifications in production to take place and for disposal of stocks, particularly for products other than cigarettes. Use of irremovable labels should be allowed to facilitate the introduction of the labelling requirements of this Directive.
- (19) 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, and should therefore be eliminated. It is necessary to that end that the existing legislation be strengthened and clarified, while ensuring a high level of health protection.
- (20) Provision should be made for batches of tobacco products to be marked so that those products are traceable for the purposes of monitoring compliance with this Directive.
- (21) The direct and indirect socioeconomic costs of active and passive tobacco use should be regularly evaluated and made available to the public in the context of the appropriate Community programmes.
- (22) The situation varies in the different Member States regarding the ingredients and additives used in the manufacture of tobacco products. A number of Member States have neither existing legislation nor voluntary agreements in place on those substances. 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. An approximation of the measures applicable in this field should be introduced, resulting in greater transparency.
- (23) The 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.
- (24) Member States should be able to adopt more stringent rules concerning tobacco products which they deem necessary to protect public health, in so far as the rules in the Directive are not prejudiced, and subject to the provisions of the Treaty.
- (25) Pending the establishment of the common list of ingredients referred to in Article 12, Member States may provide for the prohibition of the use of ingredients which have the effect of increasing the addictive properties of tobacco products, since the use of such ingredients may undermine the limits on nicotine levels laid down in this Directive.

- (26) Tobacco products have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt. In recent years it has also been shown that passive smoking is dangerous in particular to unborn children and infants and that it can cause or aggravate respiratory problems in persons inhaling smoke. Moreover, 80% of new smokers in the community are below the age of 18. The greatest possible transparency of product information should be ensured, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the tobacco manufacturers.
- (27) The use on tobacco product packaging of certain texts, such as 'low-tar', or 'light', 'ultra-light', 'mild', names, pictures and figurative or other signs, may mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption. Smoking behaviour and addiction, and not only the content of certain substances contained in the product before consumption, also determine the level of inhaled substances. This fact is not reflected in the use of such terms and so may undermine the labelling requirements set in this Directive. In order to ensure the proper functioning of the internal market, and given the development of proposed international rules, the prohibition of such use should be provided for at Community level, giving sufficient time for introduction of this rule.
- (28) 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.
- (29) Technical and scientific progress in the field of tobacco products calls for regular re-evaluation of the provisions and the application of this Directive in Member States. To that end provision should be made for a procedure for the Commission to draw up regular reports supported by scientific and technical data. Certain data ought to be examined with particular attention in this context.
- (30) In connection with the fixing of maximum yields, it ought to be considered whether, on the one hand, it is advisable at a later date to reduce yields fixed and in particular how, if at all, they are connected and, on the other hand, whether standards on these matters should be developed for products other than cigarettes, in particular rolling tobacco.
- (31) As regards tobacco products other than cigarettes,
- standards and measurement methodologies need to be developed at Community level, and to this end the Commission should be requested to submit appropriate proposals.
- (32) As regards the other ingredients, including additives, the drawing up of a common list ought to be considered, with a view to subsequent harmonisation.
- (33) 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 in tobacco products to be carried out at Community rather than national level.
- (34) The functioning of the common organisation of the market in raw tobacco is to be the subject of a Commission report to the European Parliament and Council in 2002(1). The commission has indicated that such report will also examine the issue of integration of public health considerations, including the standards established in this Directive, in other Community policies, as required under Article 152 of the Treaty.
- (35) 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.
- (36) The measures necessary 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 (2).
- (37) This Directive should be without prejudice to the time limits within which the Member States must transpose and apply the Directives set out in Annex II,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Aim**

The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products, taking as a basis 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, whether genetically modified or not;
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 those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product; - DELETE and replace with:
4. 'smokeless tobacco' means all products that are not smoked, are used orally or inhaled through the nose and meet the constituent limits defined in Annex IV.
5. 'ingredient' means any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives.

*Article 3***Cigarettes: maximum tar, nicotine and carbon monoxide yields**

1. From 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be great than:
  - 10 mg per cigarette for tar,
  - 1 mg per cigarette for nicotine,
  - 10 mg per cigarette for carbon monoxide.
2. By way of derogation from the date referred to in paragraph 1, as regards cigarettes manufactured within, but exported from, the European Community, Member States may apply the yield limits laid down in this Article as from 1 January 2005 but shall in any event do so by 1 January 2007 at the latest.
3. For Greece, as a temporary derogation, the date of application of the maximum tar yield of cigarettes manufactured and marketed within its territory, as referred to in paragraph 1, shall be 1 January 2007.

*Article 4***Measurement methods**

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

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

For smokeless tobacco products, yields of nicotine and product pH shall be measured. Standardised methods (e.g. ISO) for these measurements should be developed as a priority.

2. The tests referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, by 30 September 2002, and whenever any change is made.

3. Member States may also require tobacco manufacturers or importers to carry out any other tests as may be laid down by the competent national authorities in order to assess the yield of other substances produced by their tobacco products on a brand-name-by-brand-name basis and type-by-type-basis and in order to assess the effects of those other substances on health, taking into account, *inter alia*, their addictiveness. Member States may also require that such tests be carried out or verified in approved testing laboratories as laid down in paragraph 2.

4. The results of tests carried out in accordance with paragraph 3 shall be submitted to the relevant national authorities on an annual basis. Member States may provide for less frequent disclosure of test results in cases where the product specifications have not varied. Member States shall be informed of changes in such product specifications

Member States shall ensure the dissemination, by any appropriate means, of information submitted in accordance with this Article with a view to informing consumers and in so doing shall take account, where appropriate, of any information which constitutes a trade secret.

5. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which shall take account thereof when drawing up the report referred to in Article 11.

*Article 5***Labelling**

1. The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Article 4 shall be printed on one side of the cigarettes packet in the office 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.

That percentage shall be raised to 12% for Member States with two official languages and to 15% for Member States with three official languages.

2. Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products must carry the following warnings:

(a) general warnings:

1. 'Smoking kills/Smoking can kill,' or
2. 'Smoking seriously harms you and others around you.'

The general warnings indicated above shall be rotated in such a way as to guarantee their regular appearance. The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product; and

(b) an additional warning taken from the list set out in Annex I.

The additional warning referred to above shall be rotated in such a way as to guarantee their regular appearance.

That warning shall be printed on the other most visible surface of the unit packet, and on any outside packaging with the exception of additional transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warnings on those surfaces in order to accommodate language requirements.

3. The Commission shall, as soon as practicable and in any event not later than 31 December 2002, in accordance with the procedure laid down in Article 10(2), adopt rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking, with a view to ensuring that internal market provisions are not undermined.

Where Member States require additional warnings in the form of colour photographs or other illustrations, these shall be in accordance with the abovementioned rules.

4. Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products shall carry the following warning: - DELETE and replace with:

4. Smokeless tobacco products permitted under Article 8 shall carry the following warning:

'This tobacco product can damage your health and is addictive'.

This warning shall be printed on one of the most visible surfaces of the unit packet and on any outside packaging, with the exception of additional

transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warning on that surface in order to accommodate language requirements.

5. The general warning required pursuant to paragraph 2(a) and the warning for smokeless and oral tobacco products referred to in paragraph 4 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. That proportion shall be increased to 32% for Member States with two official languages and 35% for Member States with three official languages. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 45% for Member States with two official languages and 50% for Member States with three official languages.

However, in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm, the warnings referred to in paragraph 2 shall cover a area of at least 22.5cm on each surface. That area shall be increased to 24cm for Member States with two official languages and 26.25 cm for Member States with three official languages.

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

(a) printed in black Helvetica bold type on a white back-ground. In order to accommodate language requirements, 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:

(b) in lower-case type, except for the first letter of the message and where required by grammar usage;

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

(d) for products other than those referred to in paragraph 4, surrounded by a black border not less than 3mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given;

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

7. The printing of the texts required by this Article on the tax stamps of unit packets shall be prohibited. The texts shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or 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.

8. Member States may stipulate that the warnings referred to in paragraphs 2 and 4 are to be accompanied by a reference, outside the box for warnings, to the issuing authority.

9. To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

The technical measures to apply this provision shall be adopted in accordance with the procedure laid down in Article 10(2).

10. Smokeless tobacco products shall be labelled on each unit packet with a best-before date. Each unit packet shall have a declaration of ingredients in a similar manner with EU food labelling requirements. Ingredients that are used in the manufacture of each product shall be listed in descending order of weight with flavourings listed as a group.

#### Article 6

##### Further product information

1. Member States shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.

This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category the list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, *inter alia*, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product.

The information referred to in the first subparagraph shall be provided on a yearly basis and for the first time by 31 December 2002 at the latest.

2. Member States shall ensure the dissemination of the information provided in accordance with this article by any appropriate means, with a view to informing consumers. Due account shall nevertheless be taken of protection of any information on specific product formulae which constitutes a trade secret.

3. Member States shall ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.

4. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which

shall take account thereof when drawing up the report referred to in Article 11.

5. In addition to the requirements stated above, Member States shall require manufacturers and importers of smokeless tobacco products described in Article 8, to report nicotine content and product pH.

#### Article 7

##### Product descriptions

With the exception of smokeless tobacco products (which in the opinion of regulatory authorities are deemed to be less hazardous) described in Article 8, with effect from 30 September 2003, and without prejudice to Article 5(1), (DELETE) texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products

#### Article 8

##### Tobacco for oral use

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden DELETE and replace with:

##### Smokeless Tobacco Products

Member States shall require that only smokeless tobacco products that comply with the constituent limits and reporting requirements in Annex IV be permitted to be placed on the market.

#### Article 9

##### Adaptations

The Commission shall, in accordance with the procedure laid down in Article 10(2), adapt to scientific and technical progress:

(a) the measurement methods laid down in Article 4 and the definitions relating thereto;

(b) the health warnings to be shown on unit packets of tobacco products as set out in Annex I and the frequency of rotation of the health warning;

(c) the marking for identification and tracing purposes of tobacco products

#### Article 10

##### Regulatory procedure

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Article 5 and 7 of Decision

1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

#### *Article 11*

##### **Report**

No 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.

With a view to drafting the report referred to in the first paragraph, the Commission shall be assisted by scientific technical experts in order to have all the necessary information available.

On submission of the first report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:

- subsequent reduction of the maximum yields laid down in Article 3(1).
- Possible links between these yields,
- Improvements in health warnings, in terms of size, position and wording,
- New scientific and technical information regarding labelling and the printing on cigarette packets of photographs or other illustrations to depict and explain the health consequences of smoking,
- Methodologies for more realistically assessing and regulating toxic exposure and harm,
- Evaluation of the addictive effects of those ingredients which encourage addiction,
- Evaluation of tobacco products which may have the potential to reduce harm,
- Development of standardised testing methods to measure the yields of constituents in cigarette smoke and other than tar, nicotine and carbon monoxide,
- Toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use,

The report shall also examine the links between the labelling requirements laid down in Article 5 and consumer behaviour. That report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary 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 to take into account any new development based on scientific facts and developments on internationally agreed product standards.

#### *Article 12*

##### **Common list of ingredients**

In the framework of the first report referred to in Article 11, at the latest by 31 December 2004, and with a view to the proper functioning of the internal market, the Commission is invited to submit, on the basis of the information provided under Article 6, a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, *inter alia*, their addictiveness.

[For smokeless tobacco products, only ingredients permitted for food must be used. Guidance for use is proposed in Annex V.](#)

#### *Article 13*

##### **Import, sale and consumption of tobacco products**

1. Member States may not, for considerations relating to the limitation of the tar, nicotine or carbon monoxide yields of cigarettes, to health warnings and other indications or to other requirements of this Directive, prohibit or restrict the import, sale or consumption of tobacco products which comply with this Directive, with the exception of measures taken for the purposes of verifying the data provided under Article 4.

2. This Directive shall not affect the right of Member States to keep or introduce, in accordance with the Treaty, more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order to protect public health, in-so-far as such rules do no prejudice the rules laid down in this Directive.

3. In particular, Member States may provide for the prohibition, pending the establishment of the common list of ingredients referred to in Article 12, of the use of ingredients which have the effect of increasing the addictive properties of tobacco products.

#### *Article 14*

##### **Implementation**

1. Without prejudice to the first paragraph of Article 15, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 2002 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 shall be accompanied by such reference on the occasion of their official publication. The methods of

making such reference shall be laid down by Member States.

2. Products which do not comply with the provisions of this Directive may continue to be marketed for one year after the date referred to in paragraph 1.

3. By way of derogation from paragraph 2, products other than cigarettes which do not comply with the provision of this Directive may continue to be marketed for two years after this date referred to in paragraph 1.

4. Member States shall communicate to the Commission the text of provisions of domestic law which they adopt in the field of governed by this Directive.

#### *Article 15*

##### **Repeal**

Directives 89/662/EEC and 90/239/EEC are hereby repealed, without prejudice to the obligations of Member States concerning the time limits for transposition and application of the Directives listed in Annex II.

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

#### *Article 16*

##### **Entry into force**

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

#### *Article 17*

##### **Addressees**

This Directive is addressed to the Member States.

Done at Luxembourg, 5 June 2001.

*For the European Parliament For the Council*

*The President*

*The President*

N. FONTAINE

L.ENGQVIST

## ANNEX 1

**List of additional health warnings**

(referred to in Article 5(2)(b))

1. Smokers die younger.
2. Smoking clogs the arteries and causes heart attacks and strokes.
3. Smoking causes fatal lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: don't make them breathe your smoke.
6. Your doctor or your pharmacist can help you stop smoking.
7. Smoking is highly addictive, don't start.
8. Stopping smoking reduces the risk of fatal heart and lung diseases.
9. Smoking can cause a slow and painful death.
10. Get help to stop smoking: (telephone/postal address/internet address/consult your doctor/pharmacist).
11. Smoking may reduce the blood flow and causes impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage the sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

## ANNEX II

**Time-limits for transposition and implementation of repealed Directives**

(referred to in Article 15)

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 (1) 31 December 1992 (2) 31 December 1998 (2) 31 December 2000(2) 31 December 2006(2)
92/41/EEC (OJ L 158, 11.6.1992, p. 30)		1 July 1992 1 January 1994 31 December 1994

(1) For all Member States except Greece  
(2) Derogation applying to Greece only.

## ANNEX III

**CORRELATION TABLE**

This directive	Directive 89/622/EEC as amended by Directive 92/41/EEC	Directive 90/239/EEC
Article 1	Article 1	Article 1
Article 2(1), (2) and (3)	Article 2(1), (2) and (3)	Article 2(1)
Article 2(4)	Article 2(4)	
Article 2(5)		Article 2(2)
Article 3(1)		Article 2(3)
Article 3(3)	Article 3(1)	Article 3 and 4
Article 4(1), first subparagraph		
Article 4(1), second subparagraph	Article 3(2)	
Article 4(2) to (5)		
Article 5(1)	Article 3(3)	
Article 5(2), first subparagraph	Article 4(1)	
Article 5(2), first subparagraph	Annex I	
Article 5(2), second subparagraph	Article 4(2a)(a)	
Article 5(4)		
Article 5(5), first subparagraph		
Article 5(5), second subparagraph		
Article 5(6)		
Article 5(7)		
Article 5(8)	Article 4(4)	
Article 5(9)	Article 4(4)	
Article 6		
Article 7		
Article 8		
Article 9	Article 4(5)	
Article 10		
Article 11		
Article 12		
Article 13(1)		
Article 13(2)	Article 8(a)	
Article 14(1)		
Article 14(2)		
Article 14(3)		
Article 15	Article 8(1)	
Article 16	Article 8(2)	Article 7(1)
Article 17	Article 9(1)	Article 7(2)
Annex I	Article 9(2)	Article 8(1)
Annex II	Article 9(1)	Article 8(2)
Annex III		Article 8(3)
	Article 10	
	Annex I	Article 9

## ANNEX IV

**Constituent limits for smokeless tobacco products**

(referred to in Article 8)

Actual levels of the following constituents should be reported to Member States annually. Products, whose level(s) of constituent(s) exceed the set limits, are not allowed for sale (after an agreed period for compliance).

Constituent	Limit (dry weight)
Tobacco Specific Nitrosamines (TSNA)	10 mg/kg
Nitrosodimethylamine (NDMA)	10 microg/kg
Benzo(a)pyrene	20 microg/kg
Lead	2 mg/kg
Cadmium	2mg/kg
	Limit (fresh weight)
Aflatoxin B <sub>1</sub> ,B <sub>2</sub> ,G <sub>1</sub> ,G <sub>2</sub> (sum of)	0.005mg/kg

Levels of the following constituents should also be reported annually:

Constituent
Arsenic
Nickel
Chromium
Nitrate

## ANNEX V

**Ingredients for use in smokeless tobacco products**

(referred to in Article 12)

Food regulation should be a guiding principle for regulating ingredients added to smokeless tobacco products. Using the terminology for food ingredients, the ingredients used in smokeless tobacco products can be separated into:

- i) food items, e.g. fruit juices
- ii) chemically defined flavouring substances, e.g. benzaldehyde
- iii) oils and extracts of botanical origin, e.g. geranium oil
- iv) additives (substances added intentionally to foodstuffs to perform certain technological functions, for example to colour, sweeten or preserve) e.g. glycerol.

The reporting requirements of the EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products should be retained (see below). Taking into account the types of ingredients used on smokeless tobacco products, it is proposed that :

- Food items are permitted for use.
- The EU-wide positive list of chemically defined flavouring substances permitted for use on foods should also be applied to smokeless tobacco products.
- Oils and extracts of botanical origin should be permitted, unless they are prohibited for use in the German Tobacco Ordinance or in food regulation (see Table below). Proven hazardous ingredients such as areca nuts present in certain types of smokeless tobacco products should also be banned.
- Only EU authorised food additives should be accepted for use in smokeless tobacco products.

Ingredients prohibited for use in tobacco products according to the German Tobacco Ordinance.

Agaric acid	Bitter almond oil with free or bound cyanides
Birch tar oil	Juniper tar oil
Sassafras oil	Coumarin
Camphor oil	Thujone
Safrole	Camphor wood
Stipules of bittersweet	Mint of Penny-royal
Polypody root	Quillaia bark
Qassia	Rue
Tansy	Sassafras leaves
Sassafras wood	Melilot
Sassafras bark	Deertongue leaves
Tonka beans	Woodruff

**Non-tobacco materials**

Non-tobacco materials for smokeless tobacco products comprise e.g. inert sachet (sometimes called pouch) fabrics. These materials should be of food grade standard and reporting requirements are proposed.

**Packaging materials**

Only packaging permitted for food materials must be used for smokeless tobacco products.