

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 336 final - SYN 314

Brussels, 18 September 1991

**AMENDED PROPOSAL FOR A COUNCIL DIRECTIVE AMENDING
DIRECTIVE 89/622/EEC 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**

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

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Explanatory memorandum

On 14 November 1990, the Commission adopted and forwarded to the Council a proposal for a Directive amending Directive 89/622/EEC.¹

The Economic and Social Committee gave its opinion on this proposal on 29 May 1991.

Consulted under the procedure for cooperation, the European Parliament gave its opinion on 8 July 1991. Its resolution is broadly in favour of the proposal.

The Commission has broadly taken these opinions into account. This applies in particular to the redefinition of the tobaccos for oral use that are to be banned. In line with Parliament's opinion, the ban now appears in the title of this amended proposal and in the title of the Directive itself.

In response to the deliberations in the Council, the Commission has also made considerably more flexible the rules for specific warnings for smoking tobaccos other than cigarettes and rolling tobaccos, limiting to four the warnings that may be used. This greater flexibility also accords with the European Parliament's opinion. These warnings will be the same for all the Member States, thus constituting a common European list.

In addition, the Commission is maintaining its commitment to extend the indication of tar and nicotine content to products other than cigarettes as soon as recognized international standards for such measurements are defined. This undertaking was given in a declaration accompanying the minutes of the adoption of Directive 89/622/EEC.

The amended proposal accepts the postponement to 31 December 1994 of the final date for the sale of stocks not complying with the provisions for products other than cigarettes. As regards cigarettes and their specific and general labelling, Directive 89/622/EEC already included an extension to the deadline for the sale of stocks, so any modification of the deadline fixed by this Directive is not justified.

In addition, linguistic changes and modifications of a technical, legal nature have been made and the terms of reference of the Consultative Committee slightly extended to take into account the discussions in the Council since the initial proposal was submitted.

¹ OJ C29, 5.2.1991

Commentary on the text

(A) Recitals:

The tenth, eleventh, thirteenth and seventeenth recitals have been modified to bring them into line with the amendments to the Articles. The new tenth recital thus takes into account the provision for specific warnings for smoking tobaccos other than cigarettes and rolling tobaccos. The eleventh recital places stronger emphasis on the risk of cancer posed by smokeless tobaccos, while the thirteenth recital has been modified to take better account of the amendments to the definition of tobaccos for oral use that are subject to a marketing ban. The seventeenth recital has, in turn, been expanded to expressly exclude traditional tobacco products for oral use from the ban. A new eighteenth recital has been added, reproducing the text of the final recital in Directive 89/622/EEC and providing for information and public awareness campaigns and health education campaigns in schools.

In addition, the references in the recitals to banned products have been brought into line with the new definitions adopted.

(B) Articles:

Article 1:

Paragraph 1:

This paragraph is intended to modify the title of Directive 89/622/EEC to include the ban on the marketing of certain types of tobacco for oral use.

Paragraph 2:

This paragraph concerns the definitions in Article 2 of Directive 89/622/EEC. In contrast with the initial proposal, it is now considered preferable not to amend the general definition of tobacco products in Directive 89/622/EEC (point (1)).

The new point (4), however, contains a new definition of the tobaccos for oral use banned by Article 8a. The main feature of this new definition is the deletion of the adjective "moist" and the inclusion of examples of the main forms in which such products have hitherto been presented: sachet portions, porous sachets or forms resembling food products.

Paragraph 3:

This paragraph amends Article 4(2) of Directive 89/622/EEC by adding a new paragraph 2a providing for specific warnings for tobacco products other than cigarettes. It likewise amends Article 4(5) by specifying how the warnings on these products should look.

- Paragraphs 2 and 2a concern the Annexes to the Directive. Two are proposed:

* Annex I, which covers cigarettes and rolling tobaccos and includes the warnings listed in Directive 89/622/EEC plus a new warning concerning the addiction caused by consuming these products.

* Annex II, which contains four warnings concerning smoking tobacco products other than cigarettes.

* Finally, a single warning, with no alternatives, is required for smokeless tobacco products. Compared with the initial proposal, it now reads: "causes cancer".

In addition, this paragraph extends to rolling tobaccos the rule for cigarettes in Directive 89/622/EEC calling for the warnings to appear in rotation on an equal quantity of unit packets with a tolerance of 5%. On the other hand, it provides greater flexibility for other smoking tobacco products, requiring them to be "effectively rotated".

- Finally, Article 4(5) of Directive 89/622/EEC is replaced with a provision requiring the general and specific warnings on tobacco products other than cigarettes to cover at least 1% of the total surface of the packet.

Paragraph 4:

This paragraph amends Article 5 of Directive 89/622/EEC to allow the Consultative Committee to make changes to the definitions in Article 2, should this prove necessary as a result of advances in the methods for measuring the tar and nicotine content of the products in question.

Paragraph 5:

This paragraph introduces a new Article 8a, rephrasing the ban on the marketing of tobaccos for oral use as defined in Article 2(4).

Paragraph 6:

This paragraph adds Annexes I and II to this proposal for a directive. They replace the former single annex to Directive 89/622/EEC.

Article 2:

This Article contains the final and transitional provisions. Compared with the initial proposal, the final date for the sale of products other than cigarettes that exist on the date of entry into force of the Directive (31 December 1992) but do not comply with the requirements of the Directive has been put back to 31 December 1994.

Article 3:

This Article has merely been reworded to bring it into line with the preceding amendments.

Article 4:

This is a standard formula and remains unchanged.

Annex:

The annex to Directive 89/622/EEC becomes Annex I, covering cigarettes and rolling tobaccos.

Part B of Annex I now includes a new warning, No 15, on the addiction caused by consuming these products.

A new Annex II has been introduced containing a single list of four warnings applicable to smoking tobacco products other than cigarettes and rolling tobaccos.

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Unchanged

Having regard to the proposal from the Commission,¹

Unchanged

In cooperation with the European Parliament,²

Unchanged

Having regard to the opinion of the Economic and Social Committee,³

Unchanged

Whereas there are differences between the laws, regulations and administrative provisions of the Member States on the labelling of tobacco products; whereas these differences are likely to constitute barriers to trade and to impede the establishment and operation of the internal market;

Unchanged

Whereas these possible barriers should be eliminated and whereas, to that end, the marketing and free movement of tobacco products should be made subject to common rules concerning labelling;

Unchanged

Whereas such common rules must take due account of public health protection, and of the protection of young persons in particular, taking as a base a high level of protection, according to Article 100a(3) of the Treaty;

Unchanged

Unchanged

1
2
3

Whereas the Council and the representatives of the Governments of the Member States, meeting within the Council, in their resolution of 7 July 1986 on a programme of action of the European Communities against cancer,⁴ set for this programme the objective of contributing to an improvement of the health and quality of life of citizens within the Community by reducing the number of cancers and whereas they have for this purpose identified a fight against the use of tobacco products as their prime objective;

Unchanged

Whereas, for the purposes of providing objective information on the risks entailed in tobacco consumption, Council Directive 89/622/EEC⁵ established a general warning to be carried on the unit packaging of all tobacco products, together with additional warnings exclusively for cigarettes;

Unchanged

Whereas the Commission, at the request of the Council, undertook to propose an amendment to Directive 89/622/EEC so as to establish additional warnings to be carried on the unit packaging of tobacco products other than cigarettes;

Unchanged

Whereas scientific experts are of the opinion that all tobacco products carry health risks;

Unchanged

4 OJ No C 184, 23.7.1986, p. 19

5 OJ No L 359, 8.12.1989, p. 1

Whereas, in relation to their effects on health and for the purposes of their labelling, a distinction needs to be made between smoking tobacco products and smokeless tobacco products;

Whereas rolling tobaccos carry the same health risks as cigarettes and it is therefore appropriate that the specific warnings selected for cigarettes should also apply to rolling tobaccos;

Whereas other smoking tobacco products carry similar health risks to those carried by cigarettes, but there are still reservations concerning their contribution to heart disease; whereas these products should therefore be required to carry the specific warnings selected for cigarettes and rolling tobacco, with the exception of the warning concerning heart disease;

Whereas it has been proved that smokeless tobacco products can provoke cancer and that, consequently, they must be subject to a specific warning on tobacco products;

Whereas scientific experts are of the opinion that the addiction caused by tobacco consumption constitutes a danger meriting a specific warning on every tobacco product;

Unchanged

Unchanged

Whereas other smoking tobacco products carry similar health risks to those carried by cigarettes; whereas, however, the range of such products is more varied; whereas such products should therefore be required to carry specific warnings in an appropriate manner;

Unchanged

Whereas it has been proved that smokeless tobacco products are a major risk factor as regards cancer; whereas they should therefore carry a specific warning of that risk;

Unchanged

Unchanged

Whereas, moreover, new smokeless tobacco products - moist snuff - designed for oral use, which have appeared recently on the market in certain Member States, exercise a particular attraction for young persons, and whereas the Member States most exposed to this problem have already placed total bans on these new tobacco products or are about to do it;

Whereas there are differences between the laws, regulations and administrative provisions of the Member States in respect of oral moist snuff tobaccos, and whereas these products therefore need to be made subject to common rules;

Whereas there is a real risk that oral moist snuff tobaccos could be used, particularly by young persons, as substitutes for smoking tobacco products, causing nicotine addiction, if restrictive measures are not taken in time;

Whereas, in accordance with the conclusions of the studies conducted by the International Agency for Research on Cancer, oral moist snuff tobaccos contain particularly large quantities of carcinogenic substances, and whereas these new products cause cancer of the mouth in particular;

Whereas, moreover, new tobacco products for oral use which have appeared on the market in certain Member States are particularly attractive to young people; whereas the Member States most exposed to this problem have already placed total bans on these new tobacco products or are about to do so;

Whereas, regarding such products, there are differences between the laws, regulations and administrative provisions of the Member States; whereas these products therefore need to be made subject to common rules;

Whereas there is a real risk that those new products for oral use will be used, particularly by young people, and will thus lead to nicotine addiction, if restrictive measures are not taken in time;

Whereas, in accordance with the conclusions of the studies conducted by the International Agency for Research on Cancer, tobacco for oral use contains particularly large quantities of carcinogenic substances; whereas these new products cause cancer of the mouth in particular;

Whereas, the sales bans for moist oral snuff already adopted by two Member States have a direct impact on the establishment and operation of the internal market, hence the necessity to approximate the laws of Member States in this subject taking as a base a high level of protection, the only appropriate measure being a total ban,

Whereas, the sales bans on such tobacco already adopted by three Member States have a direct impact on the establishment and operation of the internal market; whereas it is therefore necessary to approximate Member States' laws in this area, taking as a base a high level of health protection; whereas the only appropriate measure is a total ban; whereas however, such a ban should not affect traditional tobacco products for oral use, which will remain subject to the provisions of Directive 89/622/EEC, as amended by this directive, applicable to smokeless tobacco products;

Whereas, finally, the initiatives set in this Directive will have an even more beneficial effect on public health if they are coupled with health education programmes during the years of compulsory education and with information and public awareness campaigns;

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Amended proposal for a Council Directive amending
Directive 89/622/EEC 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

Text of Com 90/538 final

Amended text

Article 1

Article 1

Directive 89/622/EEC is hereby
amended as follows:

Directive 89/622/EEC is hereby
amended as follows:

1. The following shall be added to
the title and to Article 1:

"and the prohibition of the
marketing of certain types of
tobacco for oral use."

1. Article 2 is amended as
follows:

2. The following point (4) shall be
added to Article 2:

(a) Point 1 is replaced by the
following:

"(1) "tobacco products" means
products for the purpose of
smoking, sniffing, sucking
or chewing, with the
exception of oral moist
snuff tobaccos, inasmuch as
they are, even partly, made
of tobacco;"

(b) The following point (4) is
added:

"(4) "oral moist snuff tobaccos"
means all products made
wholly or partly of
moistened tobaccos, in
finecut, ground or
particulate form or in any
combination of these forms,
which are for oral use
other than smoking;"

"(4) Tobacco for oral use, for the
purposes of Article 8a, means
all products for oral use,
except those intended to be
smoked or chewed, made wholly
or partly of tobacco, in
powder or 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."

2. Article 4 is amended as follows:

(a) Paragraph 2 is replaced by the following:

"2. Apart from the general warning referred to in paragraph 1, tobacco product packaging shall carry specific warnings as follows:

(a) With regard to cigarette packets and rolling tobacco, the other large surface of the packet shall carry specific warnings. To this end, each Member State shall draw up a list of warnings taken exclusively from those listed in the Annex;

(b) the unit packets of cigars, cigarillos, pipe tobacco or other smoking tobacco products with the exception of cigarettes and rolling tobacco shall carry, in addition to the general warning provided for in paragraph 1, a specific warning. To this end, each Member State shall draw up a list of warnings taken exclusively from those listed in the Annex, with the exception of warning No 2 in Part A of the Annex.

(c) unit packets of smokeless tobacco products shall carry, in addition to the warning provided for in paragraph 1, the following specific warning:
"Can cause cancer".

3. Article 4 shall be amended as follows:

A) In paragraph 2 the word "Annex" shall be replaced by "Annex I".

B) A paragraph 2a shall be inserted as follows:

"2a. In addition to the general warning referred to in paragraph 1, unit packets of tobacco products other than cigarettes shall carry specific warnings as follows:

(a) on rolling tobacco packets, the specific warnings, of which each Member State shall draw up a list taken exclusively from the warnings listed in Annex I, shall be rotated in such a way as to guarantee the successive appearance of each warning on an equal quantity of unit packets, with a tolerance of approximately 5%;

(b) unit packets of cigars, cigarillos, pipe tobacco or other smoking tobacco products with the exception of cigarettes and rolling tobacco shall carry a special warning from among those in Annex I, in such a way as to ensure that they are effectively rotated;

(c) unit packets of smokeless tobacco products shall carry the following specific warning:
"Causes cancer"

The specific warnings provided for in this paragraph shall be printed or irremovably affixed on the unit packets in the official language or languages of the country of final marketing, in such a way as to guarantee, in the cases referred to in points a) and b), the appearance in rotation of each warning on an equal quantity of unit packets with a tolerance of 5%."

The specific warnings shall be printed on, or irremovably affixed to, the unit packets in the official language or languages of the country of final marketing.

C. Paragraph 3 shall be replaced by the following:

"3. Member States may stipulate that the warnings referred to in paragraphs 1, 2 and 2a be combined with the indication of the authority that is their author."

(b) Paragraph 5 is replaced by the following:

"(5). Without prejudice to paragraph 4, the general warning provided for in paragraph 1 and the specific warning provided for in paragraph 2 shall be printed in, or irremovably affixed to, a conspicuous place on a contrasting background and in such a way as to be easily visible, clearly legible and indelible. The warnings shall not in any way be hidden, obscured or interrupted by other written or pictorial matter".

D. Paragraph 5 shall be replaced by the following:

"5. On tobacco products other than cigarettes, the general warning provided for in paragraph 1 and the specific warning provided for in paragraph 2a shall be printed or irremovably affixed. Each warning must, in each language used, cover at least 1% of the total surface of the unit packet. It must, in any event, be easily visible, clearly legible and indelible. The warnings must appear in a conspicuous place on a contrasting background and must not in any way be hidden, obscured or interrupted by other written or pictorial matter."

3. Article 5 is replaced by the following::

4. Article 5 shall be replaced by the following:

"Article 5

The Commission shall adopt the measurement and verification methods referred to in Article 3(1) and (2) in accordance with the procedure provided for in Articles 6 and 7."

4. The following Article 8a is inserted:

"Article 8a

Member States shall prohibit the release on the market of moist snuff tobacco products for oral use."

5. The Annex is amended as set out in the Annex to this Directive.

Article 2

1. The prohibition of moist snuff tobacco products shall enter into force before 1 July 1992.

2. For the other amendments made by this Directive to Directive 89/622/EEC, Member States shall take the necessary steps to comply before 1 July 1992. They shall immediately inform the Commission thereof and shall send to it the provisions they have adopted.

When Member States adopt these provisions they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference

"Article 5

The Commission shall adapt to technical progress, in accordance with Articles 6 and 7, the measurement and verification methods referred to in Article 3(1) and (2) and, if necessary, the definitions referred to in Article 2(2) and (3)."

5. The following Article 8a shall be inserted:

"Article 8a

Member States shall prohibit the placing on the market of tobacco for oral use as defined in Article 2(4).

6. The Annex shall be replaced by those attached to this Directive.

Article 2

1. The prohibition referred to in Article 8a of Directive 89/622/EEC shall enter into force before 1 July 1992.

2. Member States shall, before 1 July 1992, take the necessary steps to comply with the other amendments made to Directive 89/622/EEC by Article 1 of this Directive. They shall forthwith inform the Commission thereof and shall communicate to it the provisions of national law which they have adopted.

Unchanged

shall be adopted by Member States.

3. Member States shall bring into force the provisions referred to in paragraph 2 before 31 December 1992. Nevertheless, products existing at that date which do not comply with Article 1(2)(a) may still be marketed until 31 December 1993.

Article 3

1. The Commission shall publish the national lists of warnings provided for in Article 4(2) subparagraph 1, point a) for rolling tobaccos and point b) for other smoking tobaccos in the Official Journal of the European Communities.

2. Member States which, after 31 December 1992, modify their lists of warnings as provided for in Article 4(2)(a) and (b) shall notify this modification 18 months before its application to the Commission, which shall publish it in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

3. Member States shall bring into force the provisions referred to in the first subparagraph of paragraph 2 by 31 December 1992. However, products existing at that date which do not comply with the requirements of Article 4(2a), (3) and (5) of Directive 89/622/EEC may still be put on sale until 31 December 1994.

Article 3

1. The Commission shall publish in the Official Journal of the European Communities the national lists of warnings provided for in Article 4(2a)(a) of Directive 89/622/EEC for rolling tobacco.

2. Member States which, after 31 December 1992, amend their list of warnings as referred to in paragraph 1 shall notify such amendment eighteen months before its application to the Commission, which shall publish it in the Official Journal of the European Communities.

Article 4

Unchanged

Annex

1. The title of the Annex to the Directive shall be worded as follows:

"List of health warnings referred to points a) and b) of subparagraph 1 of Article 4 (2)"

2. In part B of the Annex, the following new warning, No 15, shall be added after warning No 14:

"15. Smoking causes addiction."

Annex

"ANNEX I

List of health warnings referred to in Article 4(2) and (2a)(a)

A. Warnings which must be included on the national lists

1. Smoking causes cancer
2. Smoking causes heart disease.

B. Warnings from amongst which Member States may choose

1. Smoking causes fatal diseases
2. Smoking kills.
3. Smoking can kill.
4. Smoking when pregnant harms your baby.
5. Protect children: don't make them breathe your smoke.
6. Smoking damages the health of those around you.
7. Stopping smoking reduces the risk of serious disease.
8. Smoking causes cancer, chronic bronchitis and other chest diseases.
9. More than (...) people die each year in ... (name of country) from lung cancer.
10. Every year, ... people are killed in road accidents in (name of country) - ... times more die from their addiction to smoking.
11. Every year, addiction to smoking claims more victims than road accidents.
12. Smokers die younger.
13. Don't smoke if you want to stay healthy.
14. Save money: stop smoking.
15. Smoking causes addiction.

ANNEX II

List of health warnings referred to in Article 4(2a)(b)

1. Smoking causes cancer
2. Smoking causes fatal diseases.
3. Smoking damages the health of those around you.
4. Smoking causes heart disease."

ISSN 0254-1475

COM(91) 336 final

DOCUMENTS

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Catalogue number : CB-CO-91-387-EN-C

ISBN 92-77-75643-8
