# COMMISSION OF THE EUROPEAN COMMUNITIES

COM (88) 845 final/2 - SYN 116

Brussels, 2 February 1989

# CORRIGENDUM

THIS DOCUMENT CANCELS AND REPLACES DOCUMENT COM (88)845 final-SYN116 (CONCERNS ONLY THE ENGLISH VERSION)

Amended Proposal for a COUNCIL DIRECTIVE

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products

(presented by the Commission in accordance with Article 149(3) of the EEC Treaty)

Com 845 9.

AMENDED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS OF THE MEMBER STATES CONCERNING THE LABELLING OF TOBACCO PRODUCTS

35-51-5

#### COM(88)845 final

#### EXPLANATORY MEMORANDUM

On 4 February 1988, the Commission transmitted to the Council its proposal for a Directive concerning the labelling of tobacco products (1).

The Economic and Social Committee delivered its opinion on this proposal on 7 July 1988 (2).

The European Parliament, which was consulted by way of the cooperation procedure, gave a very favourable opinion on the original Commission proposal with a number of amendments.

This modified proposal takes account of these opinions. Furthermore, a number of drafting and technical amendments have been made following discussions which have taken place since the original proposal was presented.

#### EXAMINATION OF RECITALS

In accordance with amendment n° 1 adopted by the Parliament, a new recital has been introduced on the need for health education programmes for young people and public information and awareness campaigns.

### Comments on the individual articles

#### Article 1

A slight amendment has been made to the wording.

## Article 2

Unchanged.

# Article 3

To take account of amendment n° 3 by the European Parliament, a reference to ISO Standard 8243 on the verification of tar and nicotine yields indicated on cigarette packets has been included in paragraph 2 and paragraph 3 has been amended to cover those countries with more than one official language. A new paragraph 4 has been introduced to ensure that the tar and nicotine yields of cigarettes marketed in each Member State are known and published. This paragraph lays down that the Commission shall publish the information provided by the Member States in the Official Journal of the European Communities.

<sup>(1)</sup> OJ C48, 20.02.1988, p. 8

<sup>(2)</sup> OJ C237, 12.09.1988, p. 43

#### Article 4

Slight amendments have been made to the wording of the first paragraph. In paragraph 2, in addition to drafting amendments, a new provision introduces a 5 % tolerance for the frequency of appearance of specific warnings to be printed on cigarette packets in accordance with amendment n° 5 by the European Parliament. As in article 3, paragraph 3, a distinction is made in paragraph 3 of article 4 to cover countries with more than one official language, in accordance with amendment n° 6 by the European Parliament. In paragraph 4, legibility requirements have been introduced for tobacco products other than cigarettes.

#### Article 5

The aim of the modification made is to limit the mandate of the Committee on adaptation to technical progress to questions relating to methods of measurement, in accordance with amendment  $n^{\circ}$  7 by the European Parliament.

#### Article 6

Unchanged.

#### Article 7

Unchanged.

#### Article 8

To take account of amendment n° 11 by the European Parliament, a slight amendment has been made to the wording of the first paragraph and a new paragraph 2 seeks to indicate the conditions under which a Member State may adopt special rules on the sale and consumption of tobacco products, provided that this does not imply any changes to labelling as laid down in the Directive.

#### Article 9

Article 9 introduces a distinction between the final date for the adoption of national provisions to comply with this Directive and those for the implementation of such national provisions. In addition, the new paragraph 3 lays down that in the event of an amendment to the lists of warnings drawn up in accordance with the provisions of Article 4, paragraph 2, Member States must notify that amendment 18 months in advance to the Commission, which in turn must publish it in the Official Journal of the European Communities.

#### Article 10

Unchanged

#### Annex

There are no changes regarding the compulsory warnings.

However, as regards the optional warnings, drafting amendments have been made and new warnings added.

# PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS OF THE MEMBER STATES CONCERNING THE LABELLING OF TOBACCO PRODUCTS

# COM(87)719 final/modified

Original Text

Modified proposal

THE COUNCIL OF THE EUROPEAN COMMUNITIES

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

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

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

Whereas those obstacles should accordingly be eliminated and whereas to that end the marketing and free movement of tobacco products must be made subject to uniform rules concerning labelling;

Whereas such common rules must take due account of public health protection;

Whereas the European Council held in Milan on 28 and 29 June 1985 stressed the importance of launching a European Action programme against cancer; Unchanged

Unchanged

Unchanged

Unchanged

Unchanged

<sup>(1)</sup> OJ No C48, 20.02.1988, p. 8.

<sup>(3)</sup> OJ No C237, 12.009.1988, p. 43.

Whereas the Council and the Representatives of the Governments of the Hember States, meeting within the Council, in their resolution of 7 July 186 (1), set for this programme the objective of contributing to an approvement of the health and quality of life of citizens within the Community by reducing the number of cancers; whereas they have for this purpose identified the fight against the use of tobacco products as their prime objective;

Unchanged

Whereas the printing of health warnings on the packaging of all tobacco products concerning the risks of use of tobacco products are a vital factor in the protection of public health;

Unchanged

Whereas, for the purpose of improving health protection, the indication of the tar and nicotine yield on cigarette packets is essential for the health information and education of the general public;

Unchanged

Whereas this Directive calls for minimum provisions which will be reviewed on the basis of experience gained and the development of medical knowledge in this area, the objective being to achieve greater protection of individuals,

Unchanged

Whereas, finally, the initiatives set out in this Directive can only have a beneficial effect on public health if they are coupled with health education programmes beginning during the years of compulsory education and with periodic information and public awareness campaigns;

# HAS ADOPTED THIS DIRECTIVE :

#### Article 1

The objective of this Directive is the harmonization of the laws, requlations and administrative provisions of the Member States concerning the medical warnings on the unit packet of tobacco products and the indication of the tar and nicotine yield on cigarette packets, taking as a base a high level of health protection.

#### Article 1

The objective of this Directive is the harmonization of the laws, regulations and administrative provisions of the Member States concerning the warnings regarding health on the unit of packaging of tobacco products and the indication of tar and nicotine yield on cigarette packets, taking as a base a high level of health protection.

<sup>(1)</sup> OJ No C184, 27.7.1986, p. 19.

# Article 2

#### Article 2

For the purposes of this Directive :

Unchanged

- "tobacco products" means products for the purpose of smoking, sniffing, sucking or chewing, in as much as they are, even partly, made of tobacco;
- "tar" means the raw anhydrous nicotine-free condensate of smoke;
- "nicotine" means nicotinic alkaloids.

## Article 3

- The tar and nicotine yields to be indicated on cigarette packets shall be measured on the basis of the ISO 4387 and ISO 3400 methods respectively, or any other method which yields equivalent results.
- 2. Indications on packets shall be considered acceptable where they do not differ by more than 1 mg from the results of tests carried out by the bodies designated for that purpose by the Member States.
- 3. The indications concerned shall be 3. printed in the official language or languages of the consumer's country on the side of the packet or on a mobile part of the packet in clearly visible print on a contrasting background.

#### Article 3

- The tar and nicotine yields to be indicated on cigarette packets shall be measured on the basis of the <u>ISO 4387 and ISO 3400 methods</u> respectively.
- The accuracy of indications on packets shall be verified in accordance with ISO standard 8243.
- 3. The indications concerned shall be printed in the official language or languages of the country of final marketing in clearly visible print on a contrasting background so that at least 4 % of the corresponding surface is covered. This percentage shall be raised to at least 6 % for countries with two official languages and to at least 8 % for countries with three official languages.
- 4. In January each year the Member States shall forward to the Commission lists of the tar and nicotine yields of the cigarettes sold on their markets. The Commission shall publish this information in the Official Journal of the European Communities.

#### Article 4

All units of packaging of tobacco products shall carry the following warning in the official language or languages of the consumer's country, on one of the two largest surfaces: "Tobacco seriously damages health".

# Article 4

1. All unit of packaging of tobacco products shall carry the following warning in the official language or languages of the country of final marketing on the most visible surface: "Tobacco seriously damages health".

With regard to cigarettes packets, 2. With regard to cigarette packets, the other large surface shall carry in the official language or languages of the consumer's country a specific warning.

For this purpose, each Member State shall draw up a list of warnings taken from those listed in the That list must include Annex. however the following warnings :

- a) "smoking causes cancer";
- b) "smoking causes heart disease".

Those warnings shall appear on the unit of packaging according to a formula adopted by each Member State in such a way as to guarantee an equal frequency of display for each warning.

The warnings provided for in para- 3. graphs 1 and 2 shall be printed in letters of a minimum size of 3 mm and in such a way as to cover at least 2 % of the total surface of the corresponding side of the unit of packaging.

- the other large surface shall carry in the official language or languages of the country of final marketing specific warnings alternating in accordance with the following rule :
  - each Member State shall draw up a list of warnings taken from those listed in the Annex to this Directive;
  - the specific warnings selected shall be printed on the unit of packaging so as to ensure the appearance of each warning on an equal quantity of unit of packaging with a tolerance of around 5 %.
- On cigarette packets the warnings provided for in paragraphs 1 and 2 shall cover at least 4 % of the total surface of the unit of packaging. This percentage shall be increased to at least 6 % for countries with two official languages and to at least 8 % for countries with three official languages. The required warnings languages. The required warnings on the two largest surfaces of each cigarette packet :
  - a) shall be clear and legible;
  - b) shall be printed in bold <u>letters;</u>
  - c) shall not be printed in a place where they may be damaged when the package is opened;
  - d) shall not be printed on the transparent wrapper or any other external wrapping.
- In the case of tobacco products other than cigarettes, the general warning laid down in paragraph 1 shall be printed or irremmovably affixed in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. It shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.
- 4. The required warnings on the two sides of each unit of packaging :
  - a) shall be clear and legible;
  - b) shall be printed in bold letters;
  - c) shall be printed on a contrasting background;
  - d) shall not be printed in a place where they may be damaged when the packet is opened;

e) shall not be printed on the transparent wrapper or any other external wrapping.

#### Article 5

Adaptation to technical progress in accordance with the procedure provided for in Article 6 shall be limited to the obligatory indications given on cigarette packets as provided for in Article 3 as well as to the health warnings laid down in Article 4.

#### Article 5

Adaptation to technical progress in accordance with the procedure provided for in Article 6 shall be limited to the methods of measurement of the obligatory indications of tar and nicotine yields on cigarette packets as provided for in Article 3.

## Article 6

With a view to the adaptation to technical progress referred to in Article 5, the Commission shall be assisted by a Committee of an advisory nature composed of representatives of the Member States and chaired by the representative of the Commission.

#### Article 6

Unchanged

#### Article 7

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

#### Article 7

Unchanged

#### Article 8

Member States may not prohibit or restrict the sale of products which conform to this Directive.

#### Article 8

- 1. Member States may not, for reasons of labelling, prohibit or restrict the sale of products which conform to this Directive.
  - 2. The provisions of this Directive
    do not otherwise affect the right
    of the Member States to adopt, in
    accordance with the Treaty, rules
    concerning the sale and consumption
    of tobacco products which they deem
    necessary in order to protect public health, provided such rules do
    not imply any changes to labelling
    as laid down in this Directive.

#### Article 9

- 1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive before 31 December 1990. They shall forthwith inform the Commission thereof. However, products existing at that date which do not comply with this Directive may still be put on sale until 31 December 1992.
- 2. Member States shall communicate to 2. Member States shall bring into the Commission the provisions of national law which they adopt in the field governed by this Directive.

Article 9

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1990.

They shall forthwith inform the Commission thereof and communicate to it the provisions of national law which they adopt in the field governed by this Directive.

The Commission shall publish in the Official Journal of the European Communities the national lists drawn up in accordance with Article 4, paragraph 2.

force the above laws, regulations and administrative provisions before 31 December 1991.

However, products existing at that date which do not comply with this Directive may still be put on sale until 31 December 1992.

3. Member States which after 31
December 1991 amend their lists
drawn up in accordance with Article
4, paragraph 2 shall notify the
Commission of that amendment eighteen months before its implementation. The Commission shall publish it in the Official Journal of the European Communities.

#### Article 10

This Directive is addressed to the Member States.

#### Article 10

Unchanged

# List of health warnings

# Which must be included in the

by Member States:

I.

- list of warnings to be drawn up
  - a) Smoking causes cancer;b) Smoking causes heart disease.
- II. Which may be included in the list II. Unchanged of warnings to be drawn up by the Member States:

a) Smoking causes fatal disease.b) Smoking can kill you.c) Smoking when pregnant can injure your baby.

d) Stopping smoking reduces the risk of serious disease

- e) Smoking causes lung cancer, bronchitis and other chest diseases.
- f) More than (...) people die each year in (name of the country) from lung cancer.g) Smokers die younger.

# List of warnings

- I. Unchanged
  - a) Unchangedb) Unchanged

  - - a) Unchanged
    - b) Smoking kills.
    - c) Pregnant women : smoking harms your baby.
    - d) Unchanged
    - e) Smoking causes lung cancer, <a href="https://chronic.com/chroni chest diseases.
    - f) Unchanged
    - g) Smokers die prematurely.
    - h) Smoking damages the health of
    - those around you.

      i) Protect children from tobacco smoke - you yourself have the
    - j) Every year, ... (nationality)
      are killed in road accidents.
      ... times more die from their
      addiction to smoking.
    - Don't smoke if you want to stay healthy.
    - 1) Save money : stop smoking.