II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/41/EEC

of 15 May 1992

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

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 these differences are likely to constitute barriers to trade and to impede the establishment and operation of the internal market;

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 their labelling;

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 of high level of health protection, according to Article 100a (3) of the Treaty;

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;

Whereas, for the purposes of providing objective information on the risks entailed in tobacco consumption, Council Directive 89/622/EEC (5) established a general warning to be carried on the unit packaging of all tobacco products, together with additional warnings exclusively for cigarettes;

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

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

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 apply also to rolling tobaccos;

⁽¹) OJ No C 29, 5. 2. 1991, p. 5; OJ No C 260, 5. 10. 1991, p. 7. (²) OJ No C 240, 16. 9. 1991, p. 24; OJ No C 94, 13. 4. 1992. (³) OJ No C 191, 22. 7. 1991, p. 37.

^(*) OJ No C 184, 23. 7. 1986, p. 19. (*) OJ No L 359, 8. 12. 1989, p. 1.

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 warning which accord with appropriate rules;

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

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;

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

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

Whereas there is a real risk that the new products for oral use will be used above all by young people, thus leading to nicotine addiction, unless restrictive measures are 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 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, regulations and administrative provisions 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,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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.'

- 2. The following point shall be added to Article 2:
 - '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.'
- 3. Article 4 shall be amended as follows:
 - (a) in paragraph 2 the word 'Annex' shall be replaced by 'Annex I';
 - (b) the following paragraph shall be inserted:
 - '2a. In addition to the general warning referred to in paragraph 1, unit packets of tobacco products other than cigarettes shall carry specific warnings which accord with the following rules:
 - (a) on the other large surface of 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 specific warning from among those in Annex II, in such a way as to ensure that they are in actual fact rotated;
 - (c) unit packets of smokeless tobacco products shall carry the following specific warning: "Causes cancer".

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.'

- (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.'
- 4. Article 5 shall be replaced by the following:

'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 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. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive not later than 1 July 1992. They shall immediately inform the Commission thereof and shall communi-

cate to it the essential provisions of national law they have adopted in the field covered by this Directive.

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

2. The amendment to Directive 89/622/EEC referred to in Article 1 (5) become applicable not later than 1 July 1992. The amendments to Directive 89/622/EEC referred to in Article 1 (3), (4) and (6) shall become applicable not later than 1 January 1994. However, products existing at that date which do not comply with the requirements of Article 4 (2a), (3) and (5) of Directive 89/662/EEC may still be marketed 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 89/662/EEC for rolling tobacco.
- 2. Member States which, after 31 December 1993, 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

This Directive is addressed to the Member States.

Done at Brussels, 15 May 1992.

For the Council

The President

Arlindo DE CARVALHO

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) of 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.'