COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 16 January 1991

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

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(presented by the Commission)

EXPLANATORY MEMORANDUM

Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products[1], adopted on 13 November 1989, harmonized the regulations on the labelling of tobacco products, taking as a base a high level of health protection.

The present proposal introduces amendments to the existing Directive with a view to further harmonizing national provisions on the labelling of tobacco products.

Like Directive 89/622/EEC, this proposal for a directive has as its context the completion of the Internal Market in 1992.

1. SUMMARY OF THE SITUATION

Directive 89/622/EEC provides that all packets of tobacco products shall carry a general warning: "Tobacco seriously damages health".

In addition to the general warning, a second, specific warning is required for cigarette packets. To this end, Member States are required to draw up national lists of warnings to be printed on an alternating basis on cigarette packets, based on the warnings contained in the Annex to the Directive. The Annex contains two parts : part A, containing two warnings which must be included on the national lists ("Smoking causes cancer", "Smoking causes heart disease"), and part B, containing 14 warnings from amongst which Member States may choose when drawing up their list.

Directive 89/622/EEC also provides that the tar and nicotine yields must be indicated on cigarette packets and specifies the ISO standards to be used for measurement and verification of these yields.

In other words, the harmonization provided for by the Directive is based on full labelling of cigarette packets, cigarettes representing more than 90% of the total market in tobacco products in the Community. As in most Member States, the labelling laid down in the Directive for tobacco products other than cigarettes is limited to the general warning. Moreover, in the absence of a recognized measurement method, the tar and nicotine yields are still not shown for any other tobacco products.

The situation as regards national provisions on the labelling of tobacco products has been radically altered by Directive 89/622/EEC, due to come into force on 31 December 1991.

Member States are on the point of adopting provisions to transpose this Directive into national law. To date, this transposition shows a certain delay in relation to the deadlines set out in Article 9, paragraph 1, of the text requesting Member States to notify the European Commission of measures taken to comply with this Directive (only three notifications have been officially received). However, no Member State has called into question the deadline for implementation specified in Article 9(2), (31 December 1991).

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(1) OJ No L 359, 8.12.1989.

Pending implementation, the situation is as follows :

In most Member States which have regulations in this field, tobacco products other than cigarettes are covered, at least partially, by a single warning or various different warnings.

A general warning on the harmfulness of the product to health is obligatory on all tobacco products in France ("Abuse is dangerous"), Portugal ("Tobacco damages health and, in particular, causes cancer"), Belgium ("Tobacco damages health") and, more recently, Greece ("Tobacco seriously damages health"). In Spain, optional warnings are applicable to all tobacco products ("Smoking seriously damages health", "Smoking causes cancer", "Smoking causes heart disease", "Smoking when pregnant harms your baby"). In Germany a general warning ("Tobacco damages your health") covers all smoking tobacco products. In the Netherlands a general warning covers cigarettes and rolling tobacco ("Smoking damages health. It can cause lung cancer and heart disease"). In the United Kingdom, alternating warnings are applied to cigarettes and rolling tobacco ("Smoking can cause fatal diseases", "Smoking can cause heart disease", "Smoking when pregnant can injure your baby and cause premature birth", "Stopping smoking reduces the risk of serious diseases", "Smoking can cause lung cancer, bronchitis and other chest diseases", "More than 30 000 people die each year in the United Kingdom from lung cancer"). In Ireland the regulations provide for a general warning ("Smoking is a health hazard") as well as alternating warnings for cigarettes and rolling tobacco ("Smoking causes cancer", "Smokers die younger", "Smoking kills", "Smoking causes heart disease"), and before the banning of chewing tobaccos, a warning ("This product can cause oral cancer") was applied to these products. In Denmark there is a general warning for use on cigarette packets only ("Tobacco damages health"). In Italy and Luxembourg no regulations have yet been adopted.

2. BASIS FOR THE COMMUNITY ACTION

During discussion and adoption of Directive 89/622/EEC the Member States had asked the Commission to present a new proposal as soon as technically possible containing additional provisions for the labelling of tobacco products other than cigarettes with appropriate warnings. The Commission, after receiving the opinion of the Committee of Cancer Experts of the Europe Against Cancer Programme, has thus decided to introduce the amendments necessary to provide for specific warnings for tobacco products other than cigarettes.

Additionally, in line with the agreement established with the Council for the regular updating of the list of optional warnings in the Annex to the Directive, which have so far applied to cigarettes only, the Commission is taking the opportunity to supplement this list.

Finally, the proposal seeks to harmonize Member States' national provisions concerning oral moist snuff tobaccos. Given that the Member States most affected by these new products have banned them, the measure provided for in this present proposal is also based on a total ban.

The legal basis employed for the present proposal is Article 100a of the EEC Treaty, as it was for the earlier Directive. In keeping with paragraph 3 of this Article, it takes as a basis a high level of protection.

3. THE PROPOSED AMENDMENTS

These come under three distinct headings:

a. Specific warnings for tobacco products other than cigarettes.

As stated earlier, the Commission had given an undertaking to the Council to propose an instrument establishing specific warnings for tobacco products other than cigarettes.

This proposal is based on the opinion of the scientific experts, and in particular on the opinion of the Committee of Cancer Experts of the Europe Against Cancer Programme, as well as on the opinion of the International Agency for Research on Cancer (IARC).

From the technical and scientific point of view, and for the purposes of their specific labelling, tobacco products other than cigarettes need to be divided into three distinct groups.

The technical requirements concerning the presentation of the specific warnings on the packagings of these three types of products correspond to the flexible approach established in Article 4(5) of Directive 89/622/EEC for tobacco products other than cigarettes.

These groups are:

- Rolling tobaccos. Consumption of these products is similar in nature to that of cigarettes and carries the same health risks. Consequently, the unit packets of these products should carry the same warnings as those listed for cigarettes in the Annex to Directive 89/622/EEC.

- Other smoking tobaccos (pipe tobacco, cigars, cigarillos, etc.). The consumption of these products has certain special characteristics. Lacking of enough scientific data available it does not seem necessary, as regards the labelling of these products, to apply warnings linking their use to heart disease. However, all the other warnings established for cigarettes and rolling tobacco are applicable.

- Smokeless tobacco products (e.g. chewing tobacco and snuff). These products have only a very small market in Europe. Their consumption, by mouth or nose, has quite different characteristics from that of smoking tobacco. Chewing tobacco and snuff are products with a long tradition of manufacture and use in Europe. Since the 1920's, however, their use has been in steady decline, to the point where they now have virtually no market outside certain socio-professional groups (seafarers, miners and sectors of the army) and regions. Moreover, on the basis of available epidemiologic studies, it has been proved that these products can provoke cancer. Consequently, the approach adopted consists of a specific warning on the potential carcinogenicity of the product.

In this context, a distinction needs to be made between smokeless tobaccos such as chewing tobacco and snuff, and certain new products - oral moist snuff tobaccos. Section c below is devoted to these new products.

b. Warning concerning the addiction caused by the use of tobacco products

The Commission considers that this proposal for an amendment offers an appropriate opportunity to introduce a warning concerning the addiction caused by the use of tobacco products.
Addiction is a characteristic inherent in any tobacco product, due to the presence of nicotine. Nicotine, as has recently been established by, inter alia, the Surgeon General of the United States in his 1988 report "The Health Consequences of Smoking - Tobacco Addiction", has all the properties associated with the definition of a drug: neurophysiological stimulation, tolerance, physical and psychological addiction, permanent risk of recidivism after giving up, etc.
The inclusion of this message in the list of warnings liable to be carried on all tobacco products is important in that it gives the consumer objective information concerning the characteristics of the product. Moreover, the message should have a powerful dissuasive effect on persons who have not yet started using tobacco regularly, and young persons in particular.

c. Moist snuff tobaccos for oral use

This proposal for a directive also aims to harmonize Member States' national provisions on oral moist snuff tobaccos.

The first action plan of the "Europe against cancer" programme (1987-1989) already attracted attention to certain new tobacco products which have recently been put on the market. The principal producers of this new product on the world market are the American group USTC-United States Tobacco Company and the Swedish company Svenska Tobaks A.B.
In 1985, the American group opened a factory near Glasgow, in the United Kingdom, which employed 19 people.

Following the adoption by the British Authorities in December 1989 of a measure banning the production and marketing of this product, which came into effect on 13 March 1990, the factory closed on the same date.

As concerns the marketing of this product in the other Member States, the situation is as follows :

. Ireland banned this product in 1988;

. In Denmark, the Netherlands and Germany, this product has not been marketed although it is starting to be known among young people of these countries;

. Belgium has informed us of a forthcoming law banning this product;

. In other Member States, this product is not known.

On several occasions, the Health Authorities of the Member States and the services of the European Commission have been warned by numerous organizations and scientists of international reknown, who have drawn attention to the dangers of this new type of smokeless tobacco product for oral use.

Studies published by the International Agency for Research on Cancer in Lyon in 1985 ("Monographs on the evaluation of the risks of carcinogenic substances to humans" - Volume 37) and the report of the Surgeon General of the United States in 1986 show that significant amounts of carcinogenic substances are present in oral moist snuff tobaccos, such as Polonium-210 (known for its carcinogenic effects by irradiation), and two categories of highly carcinogenic agents : polycyclic aromatic hydrocarbons and nitrosamines. The nitrosamines present in moist snuff tobacco products are more highly concentrated than in chewing tobacco.

Moist snuff tobacco contains from 1,6 to 135 mg per kg of NNN and from 0,1 to 14 mg per kg of NNK, two substances of the carcinogenic nitrosamine category presenting the highest concentration. As a comparison, in the United States, food and drink must not contain more than 0,01 mg per kg of nitrosamines. Therefore, the principal carcinogenic substances in moist snuff tobacco are 10.000 times higher than those allowed in food products and 100 times higher than in cigarettes.

As concerns nicotine, substance leading to addiction, the studies referred to show that in moist snuff tobacco, the concentration ranges from 4,6 to 15 mg per gram. Recent studies tend to show that exposure to nicotine is more important for these products than for cigarettes with a higher impact on heart rythm and blood pressure. The concentration of nicotine in the blood is maintained longer in consumers of moist snuff tobacco, due to the fact that the nicotine is introduced directly into the blood stream through the oral cavity.

In accordance with the conclusions referred to, these new products provoke cancers of the mouth, and increased risks of cancer of the nasal cavity, the pharynx, the larynx and even other organs such as the pancreas and the urinary tract. For pregnant women, moist snuff tobacco due to its passage through the placenta, is harmful to the foetus.

In 1988 the first European Conference on Tobacco or Health (Madrid, 7-11 November), organized jointly by WHO and the European Community, produced a ten-point strategy for a "Europe without tobacco", point 8 of which recommends banning all new tobacco products containing nicotine.

Finally, in 1989 and 1990, the European Committee of Cancer Experts renewed its recommendations along these same lines on the basis of the epidemiological studies on the subject.

The situation described above as concerns the marketing of these products in the Member States shows that those most exposed have already taken measures to ban this product. The others, where it is still little known, even unknown, have not yet reacted.

This new product, which has started to be distributed on the market of certain Member States, is marketed in such a way as to attract young consumers.

Faced with existing scientific data, and at the request of the Committee of Cancer Experts, the European Commission has found itself confronted with the need to take preventive measures concerning these products. After examining the problem, it has taken note that the only effective preventive measure against the consumption of this product, is to ban it, before it is too widely spread in Community territory.

Reinforcing the labelling of moist snuff tobacco products, for example a special warning addressed to young people, does not seem to be a sufficient measure for their protection taking account of the attraction of this product as shown by several statistics.

The Community system for information and the adoption of measures banning dangerous substances in food products does not seem to be applicable for these new tobacco products. This system, based on the presence of substances in food products and not on the product itself, cannot constitute a valid basis for action in this case which concerns a new non-food product characterized by high presence of an important number of carcinogenic substances.

Moreover, the Federal Justice Authority of the United States declared in 1986 that the only measure capable of slowing down the expansion of the product in the United States would be a ban if consumption was not already so widespread in this country.

Furthermore, the establishment of common technical standards providing for maximum content of carcinogenic substances is not technically feasable. Although it is possible through chemical analysis to measure composants of the product, there are to date no measures in standards recognised at international level which would insure at the time of manufacture the drastic production of dangerous substances contained in this product. Besides, the main effect of this new product being to attract and then make young people addictive to nicotine, the establishment of such technical norms would not offer an efficient protection to them.

The European Commission has also examined the possibility of a ban of the sale of these products to young people under the age of 18 years. Nevertheless, this measure would not be sufficient to prevent consumption by younger people, once the product was in circulation. It would even risk having the inverse effect, inciting young people to consumption.

The European Commission has, as a result, come around to the position adopted by two Member States (very soon three) and proposes the ban of the introduction of this product on the Community market.

The European Commission considers that the preventive action for tobacco products already existing for many years, and firmly fixed in the habits of European consumers, aims to reduce significantly their consumption through a series of measures foreseen in the successive "Europe against cancer" action plans. This action is concentrated principally on smoking tobacco taking account of the fact that smokeless tobacco made traditionally, as pointed out in point a), is decreasing and is limited to certain socio-professional groups or to certain regions of the European Community.

On the contrary, as concerns new products scientifically recognised to be harmful and which are not widespread among European consumers, the most efficient cancer prevention measure is the ban of this product, before the economic and personal interests of the consumers are affected.

This conviction of the Commission has been reinforced by the fact that, according to all available statistical data, this product has a particular attraction for young people.

Thus, in the United States, at the beginng of the seventies, less than 1% of young people consumed smokeless tobacco in any form. In the United States the consumption of moist snuff tobacco has increased 15 times since 1970 among young boys from 17 to 19 years.

The quantity of moist snuff tobacco has increased by 30,7 million pounds in 1981 to 42,6 million pounds in 1989 and is calculated at 46 million for 1990.

In Sweden, the consumption of smokeless tobacco has dropped by approximately 75% between 1920 and 1986. But although the consumption of moist snuff tobacco was 10% in 1976, among young people from 18 to 24 years, it reached 37% in 1986 among young people from 16 to 24 years.

Finally, the justification made by the British Authorities in their notification (No 89/0192/UK) in the framework of the Directive 83/189/EEC of their project for the regulation banning the production and the marketing of moist snuff tobacco led the Commission, on 30 October 1989, to not oppose the British regulation. It has, in the same connection, dropped the complaint lodged against the United Kingdom by US-Tobacco International.

The existence of the ban of this product in the two Member States confronted with this problem has reinforced the conviction of the necessity of proposing the harmonization in this direction of national legislation applicable to this product of which the dangers for human health are evident.

The data which have served as a base for the preparation of this proposal figure in the studies and reports for which complete references are given in annex.

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13. World Health Organization. Smokeless Tobacco Control. Report of a WHO Study Group. Technical Report Series 773. Geneva: WHO. 1988.

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16. "Smokeless Tobacco Use in the United States". National Cancer Institute Monographs - 1989.

17. "Tobacco habits in Sweden: a short history, Stockholm, National Smoking and Health Association, 1986.

18. Youth use of smokeless tobacco: more than a pinch of trouble. National Program Inspection Jan. 86, Dept of Health and Human Services, U.S.A.

19. "Correlates of Use and expected use of smokeless tobacco among kindergarten children". M. Young and D. Williamson, Psychol. Rep. 56: 63-66, 1985.

20. "CONNOLLY, G.N. (1990) Back to the future with oral snuff, British Journal of Addiction - volume 85, p. 1102, 1104.

21. Representative Henry Waxman, US Haouse of Representatives to John Chambers, Hong Kong Secretary of Health, November, 1986.

COMMENTS ON THE ARTICLES

Article 1

1. An amended version of Article 2 of the Directive.

This Article defines tobacco products for the purposes of their labelling, but excludes oral moist snuff tobaccos, for which a specific definition is introduced. The aim of this amendment is to define clearly these new products whose marketing is prohibited by the new Article 8a.

2. An amended version of Article 4 of the Directive.

The amendment concerns the specific warnings introduced in respect of tobacco products other than cigarettes.
A distinction is made, in a new paragraph 2, between three groups of products with differing labellings:

- Rolling tobaccos. The specific warnings already established for cigarettes in the Annex to the Directive are applicable to these products.

- Cigars, cigarillos, pipe tobacco and smoking tobacco products other than cigarettes or rolling tobacco. The same warnings apply to these products as to cigarettes, with the exception of warning No 2 in part A of the Annex, which concerns heart disease.

- Smokeless tobacco products. This group refers in particular to snuff and chewing tobacco. One warning only is proposed : "Can cause cancer".

In addition, the rules on the establishment by Member States of national lists of warnings for cigarettes as well as the rules on the frequency of the appearance of the different messages are extended to all smoking tobaccos.

The purpose of amending Article 4(5) of the Directive is to extend to the new warnings the provisions concerning the technical characteristics to be followed in the printing or affixing of warnings on tobacco products other than cigarettes. Given the nature of these products and of their packaging a flexible approach is called for here, as was the case in the former paragraph 5 concerning the general warning on tobacco products other than cigarettes. This provision thus takes account of the great diversity in the packaging of products other than cigarettes and of the specific characteristics of their presentation on the market.

3. Technical amendment of Article 5

4. Introduction of a new Article 8a prohibiting the marketing of oral moist snuff tobaccos. The definition of the product covers all the existing forms in which this new product, mainly known in the countries concerned as "skoal bandit" or "moist snuff", is marketed. The definition excludes traditional products such as chewing tobacco and snuff.

5. This paragraph introduces amendments to the Annex to the Directive.

The amendments to Article 4 also entail amending the title of the Annex. Henceforth, the Annex will serve as the basis for warnings applicable to all smoking tobacco products.

A new optional warning, No 15, is added to part B of the Annex: "Smoking causes addiction".
This joins the list of warnings from amongst which Member States may choose when drawing up their lists of warnings for the various types of smoking tobacco products.

Articles 2, 3 and 4

These are standard legislative provisions.

Proposal for a
COUNCIL DIRECTIVE
amending Directive 89/662/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 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 a high level of 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 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;

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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;

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, 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 of approximate the laws of Member States in this subject taking as a base a high level of protection, the only appriopriate measure being a total ban,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. Article 2 is amended as follows:

(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;".

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".

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%.

(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."

3. Article 5 is 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 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.

Done at Brussels, For the Council

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."

TOBACCO PRODUCTS

IMPACT ON COMPETITIVENESS AND EMPLOYMENT

1. What is the principal reason for the measure ?

   The establishment of the internal market taking as a base a high level of health protection.

2. Characteristics of the concerned enterprises. In particular :

   a. Is there a large number of SME ? The number of SME producing cigarettes is rather small. On the other hand there is a larger number of SME producing other tobacco products, particularly in Germany. This is also the case in the area of distribution. Moist oral snuff is produced by large enterprises in third countries.

   b. Are there concentrations in these regions : No

      - eligible for regional aide for Member states ? No

      - eligible for EFRA ? No

3. What are the obligations imposed directly on enterprises ?

   This proposal aimes at developing the dispositions of directive 89/622/EEC to establish specific advertisements for tobaco products other than cigarettes in order to inform about the health risks connected with their consumption :
   the packages of these products will carry, besides a general warning already provided by directive 89/622/EEC, a specific warning. The selection rules for this warning are set up by the present proposal.
   It also provides for the banning of marketing of moist oral snuff.

4. What obligations might be imposed indirectly on enterprises by local authorities ?

   None.

5. Are there special measures for SME ?

   No

6. What is the probable impact :

   a. on the competitiveness of enterprises ?

      The proposal establishes a common set of rules for the marketing of all concerned products on community territory.
      It is very difficult to predict the impact of the directive on the demand for these products. The improvement of information and health education of smokers should, in general, not have much impact on the European SMEs. The objective of these improved labelling, however, is of course to reduce the consumption of tobacco products.

   b. on employment ? No direct significant impact.

7. Have the two sides of industry been consulted ? What is their opinion ?

   The proposition is the implementation of a commitment taken by the Commission with the Council on the occasion of the adoption of directive 89/622/EEC. It has been prepared after consultation of the cancer experts and the national health authorities.

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