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## R E P O R T

of the Committee on the Environment, Public Health and Consumer Protection

on the Commission 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 (COM(90) 0538 final - C3-0042/91 - SYN 314)

Rapporteur: Mr Jacques VERNIER

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Or. FR

A Series: Reports - B Series: Motions for Resolutions, Oral Questions - C Series: Documents received from other Institutions (e.g. Consultations)



= Consultation procedure requiring a single reading



= Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment



= Cooperation procedure (first reading)



= Parliamentary assent which requires the votes of a majority of the current Members of Parliament

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By letter of 30 January 1991 the Council consulted the European Parliament, pursuant to Article 100a of the EEC Treaty, on the Commission proposal for a Council directive amending Directive 89/622/EEC on the labelling of tobacco products.

At the sitting of 18 February 1991 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Agriculture, Fisheries and Rural Development and the Committee on Economic and Monetary Affairs and Industrial Policy for their opinions.

At its meeting of 8 February 1991 the Committee on the Environment, Public Health and Consumer Protection had appointed Mr Vernier rapporteur.

At its meetings of 20 March and 25 April 1991 it considered the Commission proposal and draft report.

At the latter meeting it adopted the draft legislative resolution by 25 votes to 3, with 1 abstention.

The following were present for the vote: Collins, chairman; Schleicher, vice-chairman; Vernier, rapporteur; Alber, Amendola, Banotti, Bertens, Bjornvig, Bombard, Bowe, Breyer (for Quistorp), de la Camara Martinez, Canavarro, Chanterie, Diez de Rivera Icaza, Di Rupo, Estgen (for Douste-Blazy), Guidolin, Hadjigeorgiou (for Florenz), Jensen, Kuhn, Llorca Vilaplana, Monnier-Besombes, Oomen-Ruijten, Partsch, Pimenta, Roth-Behrendt, Simmonds, Valverde Lopez, Veil, Vertemati, Vittinghoff and Vohrer.

The opinion of the Committee on Economic and Monetary Affairs and Industrial Policy is attached. The Committee on Agriculture, Fisheries and Rural Development decided on 18 April 1991 not to deliver an opinion.

The report was tabled on 29 April 1991.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

Commission 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

Commission text<sup>1</sup>

Amendments

(Amendment No. 1)

Title

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

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 prohibiting the production and placing on the market of certain tobacco products

(Amendment No. 2)

Fourteenth recital

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

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

(Amendment No. 3)

Fifteenth recital

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

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

<sup>1</sup> For full text see COM(90) 0538 final - OJ No. C 29, 5.2.1991, p. 5

Commission text

Amendments

(Amendment No. 4)

Article 1, after the opening clause, paragraph 0a (new)

0a. The title is amended as follows :  
Council Directive on the  
approximation of the laws,  
regulations and administrative  
provisions of the Member States  
concerning the labelling of tobacco  
products and prohibiting the  
production and placing on the market  
of certain tobacco products

(Amendment No. 5)

ARTICLE 1(1)

Article 2 (Directive 89/622/EEC)

(1) Article 2 is amended as follows:

(1) Deleted

(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 fine-cut, ground or particulate form or in any combination of these forms, which are for oral use other than smoking;"

Commission text

Amendments

(Amendment No. 6)  
Article 1(1a)(new)

1a.the following paragraph 5 is inserted in Article 3 :

'5.Not later than 31 December 1991, the Commission shall submit proposals for measuring standards for tar and nicotine in tobacco products other than packet cigarettes.

Parallel to the above, the Commission shall take account of those standards in order to propose appropriate revisions to this Directive and to Directive 90/239/EEC on maximum authorized tar and nicotine yields with a view to widening the scope of the latter to include tobacco products other than cigarettes.'

(Amendment No. 7)  
ARTICLE 1(2)(a)  
Article 4(2)(b) (Directive 89/622/EEC)

(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.

(b) The unit packets of 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.

Commission text

Amendments

(Amendment No. 8)

Article 1(2)(a), paragraph 2(c)a (new)

'(c)a the Commission shall provide financial support to enable scientific studies to be conducted with a view to demonstrating the existence of a link between the incidence of cardiovascular diseases and consumption of smoking tobacco products other than cigarettes.

On the basis of the findings of those studies, it shall propose, where appropriate and by 31 December 1993 at the latest, that the warning No. 2 provided for in part A of the Annex be extended to cover the above products;'

(Amendment No. 9)

ARTICLE 1(2)(b)

Article 2(5) (Directive 89/622/EEC)

(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."

(b) Paragraph 5 is replaced by the following:

"5. (a) Packets of rolling tobacco and unit packets of cigars, cigarillos, pipe tobacco or other smoking products with the exception of cigarettes shall carry a non-alternating supplementary warning to be selected by each Member State from the list of alternating warnings in the Annex.

(b) On tobacco products other than cigarettes, the general warning provided for in paragraph 1 and the non-alternating supplementary warning provided for in Article 4(5)(a) 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."

Commission text

Amendments

(Amendment No. 10)  
Article 1(4)

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.'

4. the following Article 8a is inserted :

'Article 8a

Member States shall prohibit the production and release on the market of snuff tobacco products for oral use.'

2. Other smokeless tobacco products may continue to be produced and placed on the market within the limits of the quantities produced and placed on the market in each Member State in 1990.'

(Amendment No. 11)  
Article 2(1)

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

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



DRAFT LEGISLATIVE RESOLUTION  
(Cooperation procedure : first reading)

embodying the opinion of the European Parliament on the Commission 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

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0538 final - SYN 314)<sup>2</sup>,
  - having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-0042/91),
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (A3-0106/91),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
  2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;
  3. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;
  4. Instructs its President to forward this opinion to the Council and Commission.

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<sup>2</sup> OJ No. C 29, 5.2.1991, p. 5

**EXPLANATORY STATEMENT****I. Summary of the Commission proposal****A. Labelling : more information**

The Commission proposal seeks to strengthen the provisions of Directive 89/622/EEC, on the labelling of tobacco products, with a view to improving the degree of protection afforded to public health.

The following amendments have thus been proposed to Directive 89/622/EEC :

**1. An additional specific warning**

A new specific warning, which Member States may choose from a list now comprising 15 options, has been introduced : 'Smoking causes addiction'.<sup>3</sup>

**2. Two warnings (instead of one) on all tobacco products**

Under Directive 89/622/EEC as it now stands, the specific warnings apply only to packet cigarettes. By contrast, other tobacco products have hitherto been required merely to carry a general warning : 'Tobacco seriously damages health'.

The Commission is now proposing that the requirement for a second specific warning, chosen from the list in the Annex to the directive, to appear on the label be extended to other tobacco products.

Smokeless tobacco products, however, shall remain subject to the requirement to carry just one specific warning : 'Can cause cancer'.

Furthermore, in the case of smoking tobacco products other than packet or hand-rolled cigarettes (cigarillos, cigars, and pipe tobacco), the warning about the risk of cardiovascular diseases is not included on the list.

**B. Ban on oral moist snuff tobaccos**

The Commission is also proposing to prohibit oral moist snuff tobaccos from being placed on the market, the ban taking effect not later than 1 July 1992.

<sup>3</sup> See for instance the report by Mr Albert HIRSCH and others to the French Minister for Health and Family Affairs : 'Lutter contre le tabagisme' pp. 17-18. La Documentation Française, official reports series, September 1987, Paris

## II. Importance of the proposal in public health terms

### A. Tobacco : a considerable death rate

A few figures will suffice. In France, in 1982, 54 000 deaths (over 10% of the total!) were attributable to tobacco : 32 000 from cancer (of the lung, of the airways or digestive tract, or of the bladder), 11 000 from cardiovascular diseases (coronary heart disease, cerebrovascular diseases, aortic aneurysm), 6 000 from chronic respiratory diseases (chronic bronchitis, emphysema), and 5 000 from various other causes. Tobacco, indeed, is thought to be the cause of 25% of all cancers. In France the lung cancer death rate in men increased from 1950 to 1984 by . . . 366% (i.e. 15 in every 100 000), a more modest increase being recorded among women<sup>4</sup>.

On the world scale, according to a New Zealand estimate<sup>5</sup>, the number of tobacco-related deaths is equal to the adult population of New Zealand (about 2.5 million people)!

The Commission's proposals to strengthen the warnings provided on labels consequently deserve our total support, especially as regards the specific warnings which are now also to appear on tobacco products other than packet cigarettes : these products (which generally have no filters and are very high in nicotine) can prove more dangerous than cigarettes.

### B. Oral snuff tobacco : a highly carcinogenic and very powerfully addictive product

The proposal to ban oral moist snuff tobaccos is to be welcomed. There is still time to ban these products (and three Member States, the United Kingdom, Ireland, and Belgium, have already done so), since the market for them in the Community is still relatively small. Swift action is needed at all costs, before they become irreversibly established on the market (as, sadly, is already the case in Sweden and the United States - see charts in the Annex).

The product really is dangerous : its carcinogenic properties are acknowledged (reports by the US Surgeon General in 1986<sup>6</sup> and the WHO in 1988<sup>7</sup>), the resulting cancers occurring most commonly in the buccal cavity, owing to the presence of at least three families of carcinogenic substances, polonium 210, nitrosamines, and polycyclic aromatic hydrocarbons. The concentrations of some of these carcinogens found in oral snuff tobacco are 10 000 times higher than the permitted maximum limits for foodstuffs and 100 times higher than the levels in cigarettes! Furthermore, because of the higher nicotine concentrations, the addictive effect appears to be far more potent than that produced by smoking tobacco products.

<sup>4</sup> 'Lutter contre le tabagisme', op. cit., p. 12

<sup>5</sup> 'Health or Tobacco - An end to tobacco advertising and promotion'  
Toxic Substances Board, Wellington, NZ, May 1989, p. 8

<sup>6</sup> 'The Health consequences of using smokeless tobacco. A report of the  
Advisory Committee of the US Surgeon General'  
US Dept. of Health and Human Services  
NIH Publication 86.2874 April 1986

<sup>7</sup> 'Smokeless tobacco control' WHO Technical Report Series 773, WHO,  
Geneva, 1988

The Commission's brave proposal can consequently only be endorsed.

### III. Amendments proposed to the directive

#### 1. Amendment of the title of the directive

It might seem somewhat illogical for a directive on the labelling of tobacco products to include a provision prohibiting certain tobacco products from being placed on the market. Such a ban is justified in view of the urgency of the situation (see above) but will require amendment of the titles of both the directive concerned here (Amendment No. 1) and Directive 89/622/EEC (Amendment No. 4).

#### 2. Need for more thorough research into the risk of cardiovascular diseases

With regard to the specific warning about the risks of cardiovascular diseases, the situation is not yet very clear.

Although cigar and cigarillo smokers in particular are known to suffer from cardiovascular diseases, it is also true, as the Commission avers, that the scientific correlation between use of these tobacco products and the onset of cardiovascular disorders has not yet been brought to light.

However, there are still too few studies being conducted on the effects in terms of cardiovascular diseases stemming from tobacco products other than cigarettes. Amendment No. 8 aims to fill the gap in order to enable an early decision to be taken - should this prove necessary - to extend the compulsory specific warning No. 2 to cover other smoking tobacco products.

#### 3. Information about tar and nicotine yields must also appear on products other than packet cigarettes

Similarly, given the rapid pace of current technical advances, it ought to be possible for standards for measuring tar and nicotine in tobacco products other than packet cigarettes to be worked out fairly quickly. Germany, for example, has recently perfected a measuring method for rolling tobacco (Amendment No. 7).

#### 4. A ban on all oral snuff tobaccos (moist or cured) and a freeze on production of other tobaccos for oral use to maintain the current levels

With regard to tobacco products for oral use, the most appropriate way to proceed would no doubt be as follows :

- any ban should not be confined to placing on the market but also extend to production (Amendments Nos. 1, 4 and 9);
- measures should not be restricted to oral moist snuff tobacco alone. It is also essential to be in a position to prevent the emergence of new products falling to some extent outside this unduly narrow definition. The tobacco industry has already shown itself to be extraordinarily adept at circumventing the most stringent laws (witness the regrettable case in France involving 'Chevignon' cigarettes).

In practice, the only products that should continue to be allowed are traditional products such as chewing tobacco (quids) or snuff for sniffing, which are already very firmly established among certain population groups but account for only a minute proportion of total consumption of tobacco products.

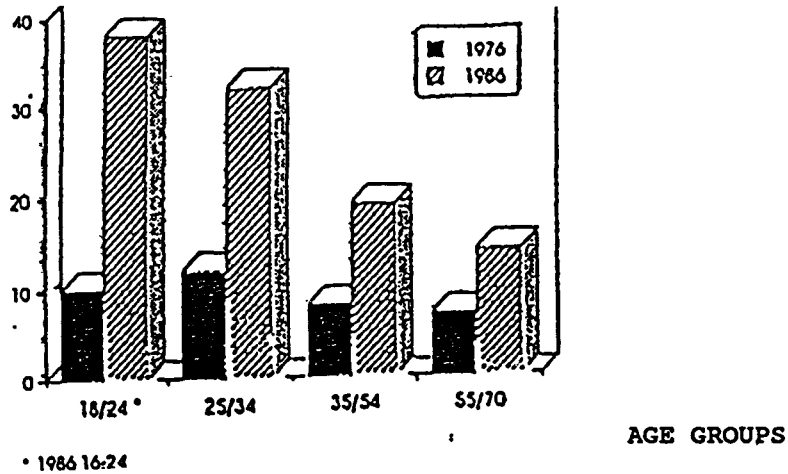
The articles of the proposal relating only to oral moist snuff tobaccos must accordingly be extended to cover all oral snuff tobaccos, following the UK practice (Amendments Nos. 2, 3, 5, 6, 9 and 10);

- as regards the traditional products that will still be allowed, a provision should also be introduced (on the grounds that two precautions are better than one) to the effect that the quantities produced and marketed in the future may not exceed the levels recorded in each Member State in 1990 (Amendment No. 9).

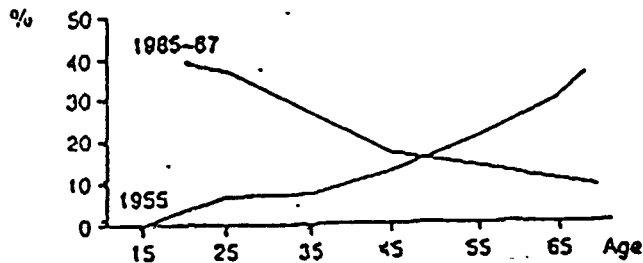
ANNEX

I - The rapid rise in oral moist snuff tobacco consumption among young people in Sweden and the United States

SWEDISH MALE CONSUMERS OF ORAL MOIST SNUFF TOBACCO AS PERCENTAGE OF THEIR RESPECTIVE AGE GROUPS 1976 and 1986

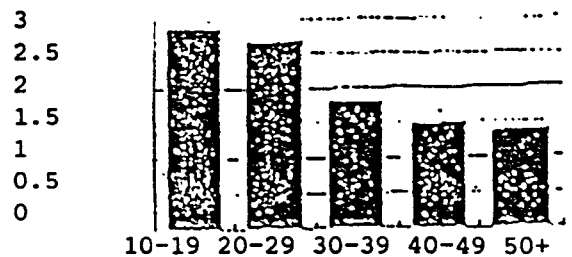
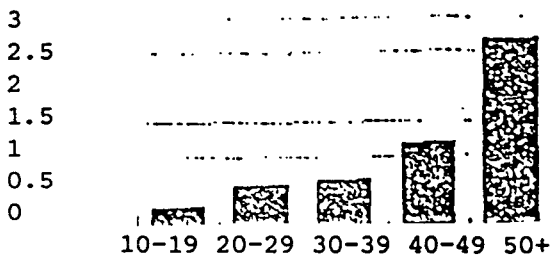


USE OF ORAL MOIST SNUFF TOBACCO AMONG SWEDISH MEN 1955 AND 1985-87



ORAL MOIST SNUFF TOBACCO CONSUMPTION AMONG US MEN (1970 AND 1985)

% of population



Source : 'Une nouvelle forme de tabacs sans combustion : le tabac humidifié à sucer' BASP, December 1990

O P I N I O N

(Rule 120 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy for  
the Committee on the Environment, Public Health and Consumer Protection

Draftsman: Mr M. PAPAYANNAKIS

At its meeting of 28 February 1990 the Committee on Economic and Monetary Affairs in Industrial Policy appointed Mr PAPAYANNAKIS draftsman.

At its meeting of 24 April 1991 it considered the draft opinion.

At that meeting it adopted the amendments by 17 votes to 6.

The following were present for the vote: Beumer, chairman; Papayannakis, draftsman, Barton, P. Beazley, Bernard-Reymond, Cassidy, Cooney (for Merz), de Donnea, De Piccolli, Ernst de la Graete, Herman, Hoff, Hoppenstedt, Lulling, Maher (for Punset i Casals), Martinez (for Megret), Medina Ortega (for Colom i Naval), Metten, Mielsen (for Visetini), Patterson, Pinxten, Porto (for Cox), Riskær Pedersen, Rothley (for Ford), Saridakis (for Gallenzi), Siso Cruellas, Tongue, van Hemeldonck (for Mihr), Wettig and von Wogau.

## Introduction

This proposal for a directive seeks to amend Directive 89/622/EEC<sup>1</sup>. Its primary aim is to complement the basic directive by making its compulsory to label tobacco products other than cigarettes with appropriate consumer health warnings.

There are three separate aspects to the proposed amendments:

- a) specific warnings for rolling or pipe tobacco, cigars, cigarillos, etc.
- b) a warning concerning nicotine addiction;
- c) a ban on moist snuff tobacco for oral use.

This covers only 10% of total trade in tobacco products.

## The substance of Directive 89/622/EEC

The basic directive, 89/622/EEC, covers cigarettes only and concerns the harmonization of the laws, regulations and administrative provisions of the Member States concerning the medical warnings that should appear on the packaging of tobacco products. Cigarette packets must also indicate tar and nicotine content.

Apart from the general warning provided for in Article 4: 'Tobacco seriously damages health', two further compulsory warnings are proposed in the Annex to Directive 89/622/EEC:

1. smoking causes cancer;
2. smoking causes heart disease.

Member States may also chose various warnings from among 14 listed in the Annex and the options selected must be printed on cigarette packets.

Article 9 of Directive 89/622/EEC requires the Member States to implement the necessary laws, regulations and administrative provisions by 31 December 1991, but this is not proceeding according to schedule and so far only three countries have incorporated the relevant legal provisions into national law.

With this proposal, the Commission is seeking to complement the basic directive and extend the use of appropriate warnings to other tobacco products thus enabling the other Member States to amend their legislation once only.

## Proposed amendments

The proposal for a directive covers 4 groups of tobaccos:

- a) rolling tobacco
- b) pipe tobacco, cigars, cigarillos, etc.
- c) chewing tobacco and snuff;
- d) oral moist snuff tobacco.

As regards rolling tobacco, consumption of such products involves virtually identical health risks, provided we compare equal amounts of tobacco

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<sup>1</sup> OJ No. L 359, 8.12.1989.



irrespective of their final form or packaging. Amending Article 4 of the basic directive to extend the specific warnings on cigarette packets to rolling tobacco is therefore a commendable step.

As regards cigars, cigarillos and pipe tobacco, the Commission proposes specific warnings on packaging. Of the two compulsory warnings in Section A of the Annex, the Commission proposes the compulsory marking of packaging with the warning 'Smoking causes cancer' but not with 'Smoking causes heart disease'.

It is estimated that cigars and cigarillos account for only 1% of total consumption of tobacco products. Their consumption is also declining and has fallen by 50% in the last 10 years. Moreover, it is considered that additional warnings - apart from the general warning laid down by Article 4 'Tobacco seriously damages health' - will alter the design and increase the cost of their packaging, and invalidate the copyright. Small industries in the Community will be forced to close in the face of competition from outside the Community. Furthermore, cigars and cigarillos are not in direct competition with cigarettes and are smoked mainly by elderly consumers over the age of 60. Cigars and cigarillos should therefore probably not be regarded as equally dangerous for young smokers or as causing the same degree of dependency.

As regards smokeless tobacco products such as chewing tobacco or snuff, the Commission proposes two warnings on the packaging: 'Seriously damages health' and 'Can cause cancer'. Consumption of these tobacco products is also extremely limited in Europe. However, the Commission insists that 'on the basis of available epidemiological studies, it has been proved that these products can provoke cancer' (p. 4)'.

Oral moist snuff tobacco has serious implications for the health of young consumers. There are two main producers in the world: the American group the United States Tobacco Company and the Swedish company 'Svenska Tobaks A.B.'. Referring to the report by the U.S. Surgeon-General of 1986 the Commission states 'that significant amounts of carcinogenic substances are present in oral moist snuff tobaccos, such as Polonium-210 (known for its carcinogenic effects by radiation), 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' (p. 6).

The Commission therefore rightly recommends that moist snuff tobacco be banned from 1 July 1992.

There are discrepancies, however, between the new proposal and the basic directive which could affect competition, consistency and coherence. Article 3 of Directive 89/622/EEC, for example, requires cigarette manufacturers to indicate the tar and nicotine yields on cigarette packets. It also stipulates that these must be measured using the ISO 4387 and 3400 methods and that the accuracy must be verified in accordance with ISO standard 8243.

There is no such provision in the new proposal and this, therefore, creates a degree of inconsistency. Without this provision, some tobacco products will indicate their tar and nicotine yields while their direct competitors will carry no warning.

Amendment No. 1 seeks to re-establish equal terms of competition and maintain consistency between the two directives.

The Commission has raised an important subject in amending the Annex to the original directive, introducing a 15th optional warning which reads '15. Smoking causes addiction.' A warning of this kind puts smokers in the same category as drug-users. This is an exaggeration, given that the number of smokers - some 35-40% of the population - is steadily falling, whereas drug-users are on the increase and a distinction should be made between the two groups.

Amendment No. 2 proposes a different warning, i.e. '15. Smoking is habit-forming'.

#### Amendments

In the light of the foregoing, the following two amendments are proposed:

#### Commission text

(Amendment No. 1)  
Article 1 (1a) (new)

#### Amendments

In Article 3 add a new paragraph 5

5. The Commission shall submit a proposal by 31 December 1992 on suitable methods for measuring, where appropriate by category, the tar and nicotine content of the tobacco products referred to in Article 2(1) with the exception of cigarettes.

(Amendment No. 2)  
Annex, paragraph 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.'

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

'15. Smoking is habit-  
forming.'

