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of :	Working Party on Health Questions
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Subject :	Proposal for a Directive of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States regarding the manufacture, presentation and sale of tobacco products ("recast")

At its meeting on 12 and 13 January 2000, the Working Party on Health Questions conducted a preliminary examination of Articles 1 to 8 of the above proposal [1].

Several delegations indicated that their positions were not yet final as the internal consultation and coordination procedures were still in progress.

The text of Articles 1 to 8 is annexed hereto, with the comments of the delegations and the Commission representative in the footnotes.

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[1] The French version of the official text of the proposal was submitted to the Council on 7 January 2000 while the other language versions were made available on 11 January 2000.

N.B. In the text of the proposal, the underlined passages correspond to new provisions. With regard to those passages which are not underlined, which are taken from Directive 89/622/EEC, as amended by Directive 92/41/EEC (labelling), and from Directive 90/239/EEC (tar yield), a table of equivalence is set out in Annex IV to the proposal.

ANNEX

Article 1 [1]

Objective

The objective of this Directive is the approximation of the laws, regulations and administrative provisions of the Member States concerning the tar yields of cigarettes [2] and the warnings regarding health to appear on packets of tobacco products, together with the approximation of the laws, regulations and administrative provisions of the Member States concerning carbon monoxide and nicotine yields [2] and the ingredients of tobacco products [3], taking as a base a high level of health protection [4].

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1 The F delegation, supported by FIN and I, reserved its position on the scope of this Article, wishing the Directive to extend also to the protection of young people and requirements concerning the packaging and presentation of tobacco products.

2 The NL delegation requested that the various yields should also apply to other tobacco products, and in particular to loose tobacco for cigarette-rolling, in order to ensure that different tobacco products were treated in the same way.
In that connection, the Commission representative pointed out that, at present, an internationally recognised measurement method existed only in respect of industrially manufactured cigarettes, and that quantities and compositions could vary widely, particularly in the case of hand-rolled cigarettes.

3 Several delegations, having drawn attention to the fact that the current wording seemed to suggest that the carbon monoxide and nicotine yields applied to all tobacco products, called for the text to be restructured by linking the phrase concerning carbon monoxide and nicotine yields directly to the phrase concerning tar yield.
In that connection, the Commission representative explained that the two elements in question had been split up in order to contrast those parts taken from existing directives with the proposed extension, and said he was willing to revise the text to make it clearer.

4 The NL delegation, supported by UK, expressed doubts as to the legal justification for reproducing a provision of the Treaty (Article 95 (3)). Together with FIN, those delegations considered that such a reference would be better incorporated in the form of a recital.
Five delegations (E, F, GR, I and IRL) declared themselves in favour of maintaining the phrase in question, which they regarded as politically important, while the F delegation considered that such a direct quotation did not in itself make the text legally contestable.
The Commission representative, who had an open mind on the issue, pointed out that the phrase in question already appeared in Article 1 of the existing directives, and that recital 4 of the proposal also contained an explicit reference to Article 95 (3).

Article 2

Definitions

For the purposes of this Directive:

1. *"Tobacco products"* are defined as products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco;

2. *"Tar"* means the raw anhydrous nicotine-free condensate of smoke [1];

3. *"Nicotine"* means nicotinic alkaloids;

4. *"Tobacco for oral use"* means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of these forms - particularly those presented in sachet portions or porous sachets - or in a form resembling a food product [2];

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[1] The IRL delegation wanted a more exhaustive definition of tar, including its chemical profile, in order to identify carcinogenic substances.

[2] The FIN, I and S delegations considered that the definition of tobacco for oral use was incomplete and unclear, in particular as regards its connection with the ban referred to in Article 9; the S delegation said it intended to submit suggestions for amendments.
In that connection, the Commission representative recalled that the text of the definition in question had been taken from Article 1 (c) of Directive 92/41/EEC, and that the same definition had been incorporated in Article 151 of the Act of Accession of Sweden.
He warned against reopening discussions on a definition established following lengthy negotiations and relating to a negligible share of the market for tobacco products. He also pointed out that the definition had not caused any problems since the 1992 Directive was implemented, and that any amendment would necessitate an amendment of the Act of Accession.

5. *"Ingredient"* means any substance except for natural tobacco leaf or its plant parts used as an additive in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form [3].

[4]

[3] The D delegation considered that the term "additive" was too limited to cover any substance other than tobacco.
The IRL delegation considered that this definition should cover in particular the use of reconstituted tobacco, ash, the ingredients of papers and filters and any residues, and should also enable the presence of genetically modified tobacco to be identified.
The Commission representative said he was willing to delete the words "as an additive", thereby allowing a wider meaning to be ascribed to the concept of "ingredients" without prejudice to the question of the use of genetically modified tobacco.

[4] The E delegation questioned the absence of a definition of the term "cigarette" in this Article.
The Commission representative replied that, for the purposes of the Directive, it was difficult to lay down a specific definition distinct from that used in the context of taxation.

Article 3

Cigarettes: tar, nicotine and carbon monoxide levels [1]

1. The tar yield of cigarettes released for free circulation, marketed or manufactured [2] in the Member States shall not be greater than 10 mg [3] per cigarette as from 31 December 2003.

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[1] The NL delegation reiterated its request that the yields should be applied to other tobacco products, in particular tobacco for cigarette-rolling, by means of a reference to a specific quantity, e.g. 100 g (cf. footnote 2 on p. 2).

[2] The E and A delegations questioned the legal justification for applying a Directive intended to ensure the smooth functioning of the internal market to products manufactured within the Community and intended for export to third countries.
The Commission representative pointed out that the standards proposed for the internal market also had an external dimension, as exemption for products intended for export to third countries could give rise to problems in terms of the equal treatment of third-country manufacturers.
Moreover, the manufacture of cigarettes which did not comply with the prescribed standards would present problems in terms of inspection, and could disturb the smooth functioning of the internal market. A double standard for consumer health protection inside and outside the Community would also give rise to ethical and political problems, in particular with a view to future negotiations on the WHO Framework Convention for Tobacco Control.

[3] The F delegation, supported by IRL and I, accepted the proposed yields as scientifically justified but considered that they should represent the first phase of a strategy of gradual reduction, and asked for the Directive to make provision for a mechanism for reviewing those yields.
More specifically, the IRL delegation suggested by way of illustration a subsequent reduction to 7 mg for tar and 5 mg for carbon monoxide by 2006.
In that connection, the DK delegation, while accepting the proposed nicotine yield, voiced doubts concerning the advisability of reducing that yield at a later stage, as that could encourage smokers to smoke more and thereby ingest a larger quantity of noxious substances.
The Commission representative explained that the proposed tar yield was in fact in line with a concept of gradual reduction. As far as nicotine and carbon monoxide were concerned, the proposed yields represented a first step; a subsequent reduction could be considered in the light of scientific studies.
The subsequent reduction of the tar yield, together with any necessary review of the nicotine and carbon monoxide yields, would be examined in connection with the reports referred to in Article 10 of the proposal.

2. The nicotine yield of cigarettes released for free circulation, marketed or manufactured [2] in the Member States shall not be greater than 1 mg [3] per cigarette as of 31 December 2003.

3. The carbon monoxide yields of cigarettes released for free circulation, marketed or manufactured [2] in the Member States shall not be greater than 10 mg [3] per cigarette as of 31 December 2003.

[4]

[5]

[2, 3] Cf. page 5.

[4] The S delegation wanted to add a provision to the text fixing the ratio of the tar yield to the nicotine yield at not more than 10:1; this was because a reduction in the nicotine yield alone without a corresponding reduction in the tar yield would lead to an increase in cigarette consumption and hence an increased intake of tar.
Several delegations (in particular D, DK, F, IRL and I) questioned the scientific justification for such a ratio between tar and nicotine yields; the DK and F delegations considered that a lower tar/nicotine ratio would be conceivable.
In that connection, the Commission representative said that there was currently no scientific basis to justify the fixing of such a ratio, and consequently a conventional approach had been chosen (i.e. the fixing of maximum yields based on scientific recommendations).
The D delegation also raised the question of a carbon monoxide/tar yield ratio.

[5] The E delegation thought that the dates referred to in the proposal might have to be reviewed depending on the progress of the decision-making process, and that it might then be preferable to use a formula of the type "x (= date of adoption) + n (= deadline to be fixed)".
The Commission representative, who had an open mind on the issue, said that, in any event, the dates indicated were purely indicative and the use of an abstract formula could lead to confusion.

Article 4 [1]

Derogation

1. For Greece, as a temporary derogation, the limit value of tar yield shall be 10 mg of tar and the date of implementation shall be 31 December 2006.

2. This derogation may not be used to justify controls at the Community's internal frontiers.

[1] The E and I delegations questioned the absence of a phased reduction of the tar content within this derogation. E also questioned the absence of a mechanism for monitoring products covered by the derogation.
The D delegation said it preferred not to make provision for such a derogation as there was a risk that it would encourage other delegations to submit requests for derogations.
The GR delegation stressed that the derogation was based on socio-economic grounds which remained valid, i.e. the single-crop farming of tobacco in the northern regions, which were among the poorest in the country. Although restructuring was in progress, it would take some time. The delegation also pointed out that the proposed derogation already incorporated a reduction in tar yield from 12 to 10 mg in relation to the current provisions.
The Commission representative thought that any arrangements for a phased reduction of the derogation were the preserve of the Member State concerned. He also noted that the eastern varieties of tobacco grown in Greece naturally contained a high tar yield.

Article 5

Measurement methods

1. The tar, nicotine and carbon monoxide yields referred to in Article 3 (1), (2) and (3), which must be indicated on cigarette packets, shall be measured on the basis of ISO methods ISO 4387 for tar, ISO 10315 for nicotine and ISO 8454 for carbon monoxide [1].

   The accuracy of the indications on the packets shall be verified in accordance with ISO standard 8243 [2].

2. Member States may require [3] that the tests referred to in paragraph 1 be carried out by a testing laboratory approved for the purpose by the relevant Member State authorities.

3. Member States may also require tobacco manufacturers or importers to carry out any other such tests as may be laid down by the appropriate national authorities in order to assess the yields of other substances produced by their tobacco products on a brand name by brand name basis. They may also require that such tests be carried out in approved testing laboratories as laid down in paragraph 2 [4].

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[1] Several delegations (B, F, I, IRL, S and UK) considered that the current ISO standards were unsatisfactory, but could accept them on a provisional basis in the absence of any alternative. The same delegations wanted the development of more reliable measurement methods to be actively encouraged, while B, F and IRL called for the text of the Directive to reflect their concerns.

[2] The D delegation noted that ISO standard 8243 did not apply to tar yield.

[3] The IRL delegation, supported by B, D and FIN, considered that the optional nature of this provision ran counter to the objective of harmonisation.

[4] The B and IRL delegations wanted a provision to the effect that all testing laboratories should be independent and approved on the basis of criteria defined at Community level.

4. The results of all such tests carried out under the provisions of paragraph 3 shall be disclosed to the relevant national authorities annually [5].

5. The Member States shall take such steps as are necessary to protect the trade secrecy of all data and information submitted pursuant to the requirements of this Article [6].

6. The Member States shall supply all data and information submitted pursuant to this Article to the Commission not later than 31 May of each year [6].

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[5] The IRL, NL and FIN delegations suggested that there should be a certain degree of flexibility as to the frequency of the disclosure of test results.

[6] Several delegations (BD, E, F, IRL, I, NL, FIN and UK) questioned the scope of the general trade secrecy provision contained in this Article (with regard to the trade secrecy of ingredients, cf. footnote 5 on page 16).
The E delegation, questioning the absence in the text of a requirement for the Commission to respect trade secrecy, suggested that the wording of paragraphs 5 and 6 be revised accordingly. In that connection, the Council Legal Service pointed out that such a requirement was covered by Article 287 of the Treaty.

Article 6

Labelling [1]

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered.

   This percentage shall be raised to 12% for countries with two official languages and 15% for countries with three official languages.

2. Each unit packet of tobacco products, except for smokeless and oral tobacco products, shall carry one of the following general warnings [2]:

   - "Smoking kills"

   - "Smoking can kill"

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[1] The IRL delegation considered that the requirements laid down in this Article should also apply to products intended for export, and that in particular the warnings should be drawn up in the language or languages of the country of destination.

[2] The E, F, IRL and I delegations were in favour of a single compulsory warning; the F and I delegations preferred the warning "Smoking kills".
In that connection, the F delegation, supported by I, said that relevant studies had shown that such warnings became less effective over time, and suggested that an adjustment procedure ("review committee") be introduced.
The IRL delegation wanted the following compulsory warning: "Tobacco is addictive".
The D, NL and A delegations questioned the effectiveness of the proposed warnings. The D delegation wondered whether they had any scientific basis, and questioned why there was no mention of the authority issuing the warning.
The A delegation speculated that the proposed warnings might have a counterproductive effect, in particular with regard to young people.
The GR delegation expressed reservations concerning the nature and presentation of the warnings and, more generally, the complexity of the proposed provisions.
In that connection, the Commission representative said that the warnings were based on scientific studies and recommendations.

Each unit packet of tobacco products, except for oral and smokeless tobacco products, shall carry an additional warning taken exclusively from Annex I. [3] [4]

Oral tobacco products, where they are permitted to be placed on the market pursuant to the provisions of Article 9, and smokeless tobacco products shall carry the warning in Annex II. This warning shall be placed on the most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on this surface in order to accommodate language requirements.

3. The general warning referred to in the first subparagraph of paragraph 2 shall be printed on the most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on this surface in order to accommodate language requirements.

The warning referred to in the second subparagraph of paragraph 2 shall be printed on the other most visible surface of the unit packet, and on any outside packaging used in the retail sale of the product. Member States shall have the right to determine the positioning of the warning on these surfaces in order to accommodate language requirements.

4. The text of warnings and yield indications required under this Article shall be:

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[3] Several delegations thought that the wording of this subparagraph was not sufficiently explicit as regards its application in relation to Annex I.
The Commission representative said he was prepared to accept a redrafting of that subparagraph.

[4] The F delegation, supported by I, thought that Member States should be allowed to make provision for additional warnings which took account of national specificities (e.g. a telephone number for information on stopping smoking). The I delegation also called for a compulsory warning indicating a ban on the sale of tobacco products to minors.
The Commission representative, while declaring himself sympathetic to those concerns in principle, warned against increasing the number of possible permutations, which could disturb the smooth functioning of the market.

- printed in black Helvetica bold type on a white background [5]. In order to accommodate language requirements, the Member States shall have the right to determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;

- in lower case type except for the first letter of the message;

- centred in the area in which the text is required to be printed, parallel to the top edge of the packet;

- surrounded by a black border not less than 3 mm in width and not more than 4 mm in width which does not interfere in any way with the text of the warning or information given [6];

- in the official language or languages of the Member State where the product is placed on the market.

5. The printing of texts as required by this Article on the underside or on the tax stamps of unit packets shall be prohibited. The texts required pursuant to this Article shall be irremovably fixed, indelible and shall not in any way be hidden, obscured or interrupted by other written or pictorial matter, nor by the opening of the packet.

6. The general warning required pursuant to the first subparagraph of paragraph 2 of this Article and the warning for smokeless and oral tobacco products referred to in the third subparagraph of paragraph 2 of this Article shall cover not less than 25% of the external area of the

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[5] The B delegation expressed a concern that warnings printed in black and white might have a different degree of visibility and hence a different impact depending on the colour of the packaging.

[6] In response to a question from the B delegation, the Commission representative said that the areas specified in paragraph 6 included the black borders.

corresponding surface of the unit packet of tobacco on which it is printed. This percentage shall be increased to 27% for countries with two official languages and 30% for countries with three official languages [7].

7. The additional warning referred to in the second subparagraph of paragraph 2 shall cover not less than 25% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. This percentage shall be increased to 27% for countries with two official languages and 30% for countries with three official languages.

The additional warnings referred to in the second subparagraph of paragraph 2 shall be rotated in such a way as to guarantee the successive appearance of each warning on an equal quantity of unit packets. A tolerance of 5% shall be permitted.

[7] The D, NL and A delegations thought that the dimensions laid down in this paragraph should be reconsidered with regard to cigars, for which the unit packets were generally larger than for cigarettes (e.g. by specifying a minimum area).

Article 7

Further product information [1]

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* French text of the title aligned with the English text, which is the original.

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[1] The D delegation, which had expressed doubts concerning the justification for and operational nature of this Article, reserved its final position on this Article.
Most delegations (B, E, F, IRL, I, FIN, S, UK) expressed varying degrees of reservations concerning the nature and scope of the proposed provisions, which were restricted to technical information without practical consequences for the consumer.
The B and F delegations, in particular, noted that the provisions would represent a backward step in relation to the legislation currently in force in their countries (positive list).
F pointed out that the proposed provisions did not correspond to any of the specific options which could be envisaged in that context, notably:

- direct consumer information
- negative list (banned substances)
- positive list (authorised substances)

In any case, B and F were in favour of banning all substances containing nicotine.
Several other delegations (IRL, S, FIN and UK) underlined the importance of consumer information, with UK considering that the dissemination of the information referred to in paragraph 1 could constitute a first positive step in that direction.
The IRL, I and FIN delegations thought that the place of origin of the products should be specified.

The Commission representative considered that, given the wide disparity between national laws concerning additives, and in the absence of full information on that subject, harmonisation could not realistically be attempted at this stage, and the proposed approach represented a preliminary step towards eventual Community legislation. The dissemination of "raw" data to consumers without an explanation of the effects of the substances in question would not be an appropriate solution.
As far as the preservation of existing national rules was concerned, he was prepared to accept a solution being sought within the scope of Article 11 (right of Member States to maintain or adopt more stringent national provisions).

1. Not later than 31 December 2003 [2], Member States shall require all manufacturers and importers of tobacco products to submit to them a list of all ingredients, including quantities thereof, used in the manufacture of their tobacco products by brand name. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients and constituents in their tobacco products.

Member States shall also require manufacturers and importers to provide all toxicological data on these non-tobacco ingredients in burnt and unburned form, and to demonstrate that the said ingredients are safe [3] for the health of the consumer when used as intended in their tobacco products [4]. This information, together with that referred to in the first subparagraph of this Article shall be submitted on an annual basis with effect from the date referred to in paragraph 1 of this Article.

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[2] The IRL and UK delegations considered that deadline too distant as manufacturers and importers should already be aware of the ingredients used, and the date should therefore coincide with the date on which the Directive enters into force.
The Commission representative said he was willing to reconsider that deadline, but pointed out that, at present, manufacturers and importers were not always aware of all the ingredients used as in certain cases they were supplied by other manufacturers.

[3] The B delegation thought that the term "safe for the health" did not have any legal force.

[4] The E and D delegations pointed out that it was difficult to provide scientific proof of the non-toxicity of a substance.

2. The Member States shall take such steps as are necessary to protect the trade secrecy of all such data and information submitted pursuant to the requirements of paragraph 1 of this Article [5].

3. The Member States shall supply all toxicological data and information submitted pursuant to this Article to the Commission not later than 31 May of each year [6].

[5] Several delegations stressed the importance of ensuring that the principle of the protection of trade secrecy could not apply in cases where there was a risk to health.
The D, E and NL delegations were in favour of making a distinction in that connection, considering that certain information (in particular, information relating to the manufacturing process) was in fact covered by trade secrecy.
While prepared to reconsider certain aspects of this provision, the Commission representative thought it necessary to ensure a certain level of protection with regard to the detailed lists of ingredients.

[6] The E delegation suggested reversing the order of paragraphs 2 and 3 (cf. footnote 6 on p. 9).

Article 8

Product description

1. The use of the terms "low tar", "light", "ultra light", "mild" [1] or any other similar terms which have the aim or the direct or indirect effect of conveying the impression that a particular tobacco product is less harmful than others shall be prohibited, unless such terms have been expressly authorised by the Member States where the products in question have been marketed or manufactured. [2]

2. The Member States which authorise the use of such terms shall notify the Commission thereof, together with the conditions applied to such authorisation. The Commission shall present this information in its report referred to in Article 10.

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[1] The NL delegation expressed doubts concerning the relevance of the reference to the term "mild" in this context, at least in respect of certain tobacco products - and in particular cigars - for which the term refers mainly to olfactory characteristics.

[2] In general, the B, E, F, IRL, I, FIN and UK delegations, while supporting the principle of the proposed provision to prohibit terms which might mislead the consumer (E: or, if necessary, to lay down relevant standards), expressed reservations concerning the exception provided for (the express right of the Member States to authorise such terms), which reduced the scope of the ban considerably and jeopardised the dual objective of harmonisation and health protection.
The GR delegation, on the other hand, expressed doubts concerning such a ban on the terms in question insofar as they did in fact refer to lower nicotine yields.

[1, 2] The Commission representative noted that the right accorded to Member States allowed account to be taken of special considerations such as that referred to in footnote 1 above, and that the provision in question represented a first step towards minimum harmonisation, the establishment of which would form the subject of a Commission report as referred to in Article 10. He stressed that a provision introducing a total ban should be based on scientifically proven and incontestable data.