

European Communities

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Working Documents

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DOCUMENT 1-643/81

Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (doc. 1-271/80) for a Directive on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

Rapporteur: Mr A. GHERGO

By letter of 12 June 1980 the Council of the European Communities consulted the European Parliament, pursuant to Article 43 of the EEC Treaty, on a proposal from the Commission of the European Communities for a directive on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production.

On 26 June 1980 the President of the European Parliament referred the proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs for its opinion.

At its meeting of 24 June 1980, the Committee on the Environment, Public Health and Consumer Protection appointed Mr Ghergo rapporteur.

At its meetings of 1 October 1980 and 26 June 1981 and 20 October 1981, the committee considered the proposal and at the last meeting it adopted the motion for a resolution with 12 votes in favour and 2 abstentions.

Present: Mr ALBER, Vice-Chairman and acting chairman;
Mr GHERGO, rapporteur; Mr CERAVOLO (deputizing for Mr SEGRE);
Miss HOOPER; Mrs LENTZ-CORNETTE; Mrs MAIJ-WEGGEN; Mr MERTENS; Mr PROVAN
(deputizing for Sir Peter VANNECK); Mrs SCHLEICHER; Mrs SCRIVENER;
Mrs SEIBEL-EMMERLING; Mr SHERLOCK; Mrs SPAAK and Mrs SQUARCIALUPI

The opinion of the Committee on Economic and Monetary Affairs is annexed to this report.

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On the basis of the attached explanatory statement, the Committee on the Environment, Public Health and Consumer Protection hereby submits the following amendments and motion for a resolution to the European Parliament:

AMENDMENT No. 1

tabled by the Committee on the Environment, Public Health and Consumer Protection

Article 1

Paragraphs 1 and 2(a) unchanged, paragraph 2(b) to read as follows:

'flavouring substance' means a defined chemical substance or defined mixture of substances with flavouring properties and is:

- 'natural' when isolated from natural flavouring materials, natural flavouring preparations or foodstuffs exclusively by appropriate physical processes (including distillation, solvent extraction)

... rest unchanged.

AMENDMENT No. 2

tabled by the Committee on the Environment, Public Health and Consumer Protection

Amend Article 5 to read as follows:

1. The Council shall, under the procedure provided for in Article 100 of the Treaty, adopt by means of specific directives special provisions applicable to groups of flavourings (e.g. special conditions governing their use which may be necessary and methods used in their production). These specific directives shall include lists of substances or materials the use of which is authorized to the exclusion of all others of:
 - (a) artificial flavouring substances;
 - (b) source materials for the production of artificial flavouring preparations;
2. Further specific directives shall include lists of substances or materials the use of which is prohibited to the exclusion of all others of:
 - (a) nature-identical flavouring substances;
 - (b) source materials for the production of natural flavouring preparations and natural flavouring substances;
3. Original paragraph 2 and points 2(a) and 2(b). The following to be added:
 - (c) specify the physical processes for the production of the natural flavouring preparations and natural flavouring substances referred to in paragraph 2(b);
4. The Commission shall submit the proposals for specific directives referred to in paragraph 1 and the other provisions referred to in paragraph 2 to the Council no later than 2 years after approval of this directive. Within the same period, the Commission shall inform Parliament of the progress made in the implementation of this part of the directive.

AMENDMENT No. 3

tabled by the Committee on the Environment, Public Health and
Consumer Protection

First line of Article 6 to read as follows:

The procedure laid down in Article 11 shall be used to determine
no later than 2 years after approval of this directive:

AMENDMENT No. 4

tabled by the Committee on the Environment, Public Health and
Consumer Protection

Article 8

After the first paragraph a new paragraph to be added as follows:

Where such amendments consist of the inclusion of new substances in
the lists, the Council shall adopt the appropriate decisions on a
proposal from the Commission, after consulting Parliament.

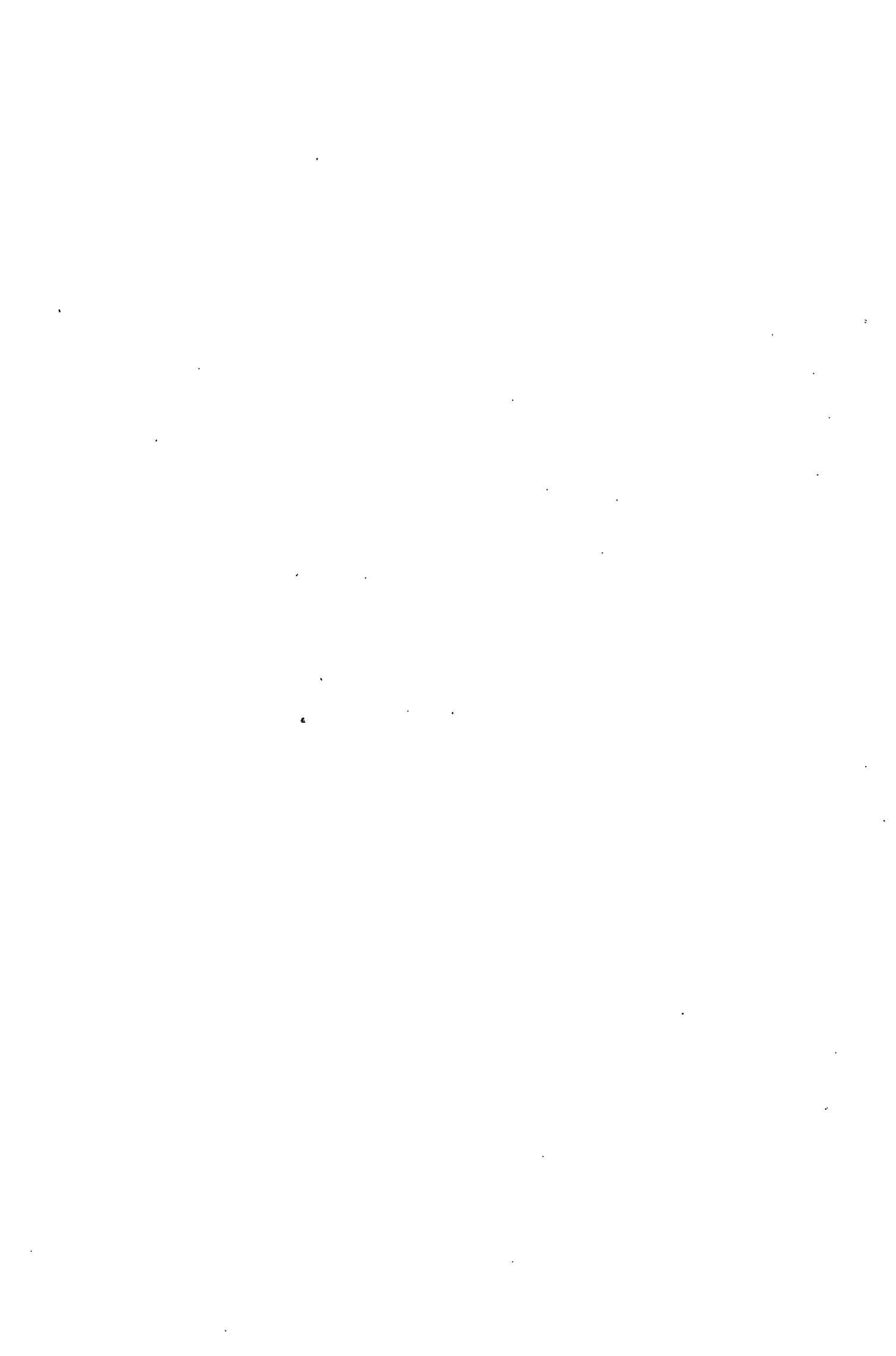
AMENDMENT No. 5

tabled by the Committee on the Environment, Public Health and Consumer Protection

Article 10

Unchanged up to paragraph 6 inclusive. The following paragraph to be added:

7. No later than 2 years after approval of this directive, the Commission shall submit provisions analogous to those referred to in the preceding paragraphs, on the labelling of products containing flavourings and intended for human consumption,



MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament
on the proposal from the Commission of the European Communities to the Council
for a directive on the approximation of the laws of the Member States relating
to flavourings for use in foodstuffs and to source materials for their
production

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council for a directive on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (COM (80) 286 final),¹
 - having been consulted by the Council (Doc. 1-271/80),
 - having regard to the opinion of the Economic and Social Committee (Doc. CES 15/81),
 - 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 (Doc. 1-643/81),
1. Agrees with and supports as a matter of principle any measures to protect public health and is therefore in favour of the adoption of Community legislation on the matter;
 2. Observes that in recent years, with the ever-increasing distribution of industrial foodstuffs, the problem of the correct use of flavourings has assumed importance in terms of the protection of public health and because of its economic and social repercussions;
 3. Points out therefore, that given the increasing trade in these products measures must be taken to harmonize national legislations with a view to improving public health protection, while at the same time safeguarding legitimate industrial and commercial interests, in accordance with the aims of the Treaty of Rome as regards both the protection of public health and the removal of any direct or indirect obstacles to the free movement of industrial products;

¹ OJ

4. Notes that this proposal for a directive is a viable instrument for the identification of certain general principles and concepts and for the determination of specific sectors for more urgent intervention;
5. Points out that no later than two years after the adoption of this directive, the general guidelines defined in it must be followed by specific directives as provided in Article 5 of this directive;
6. Hopes that the Commission will encourage and/or support any study or research measures designed to achieve the highest possible safety level for the consumer, from the dual standpoint of the non-toxicity of flavouring additives for use in foodstuffs and of accurate consumer information, in order to guarantee that the consumer has sufficient knowledge of the elements present in the product to make a really free choice;
7. Calls upon the Commission to ensure that experiments on live animals to establish the non-toxicity of flavourings are kept to the absolute minimum;
8. Is in favour of the adoption by the Council of this directive, subject to the attached amendments.

EXPLANATORY STATEMENTI. Introduction

The question of flavourings used in foodstuffs has come to the attention of the governments of various countries and of international organizations on various occasions. The EEC has also looked into it in the past, set up a committee of experts on the subject and submitted to the Commission of the European Communities draft proposals for directives on flavourings for use in foodstuffs which have been referred to the Advisory Committee on Foodstuffs.

Various countries have adopted laws and administrative provisions on the matter, and the ever-increasing volume of trade now makes it urgently necessary to take steps to harmonize national legislations with a view to improving health protection and the protection of legitimate industrial and commercial interests.

It must be pointed out here that in view of the complexity of the matter and the multiplicity of interests involved, it would not appear possible to find a full and definitive legislative solution at short notice, in particular since constant changes occur in this area as a result of technical and scientific advances which lead to the discovery of further new flavouring substances and at the same time make it possible to adopt more sophisticated methods to identify any harmful effects they might have.

For two reasons then, firstly the urgent need to deal with this matter and secondly the impossibility of finding any complete and definitive solution in the short term, the Commission's decision to present a proposal for an outline directive to establish certain general principles and concepts and to determine specific sectors for urgent action can be regarded as useful.

2. Objectives of the directive

The main objectives of the Commission's proposal for an outline directive are as follows:

- to adopt, within the Community, uniform definitions and terms to indicate the various presentations, characteristics, and methods of production and use of flavourings;
- to define the general purity requirements which such substances must satisfy if their use is not to constitute a health hazard, and the methods of analysis and sampling to ascertain that these requirements have been met;
- to establish the criteria on the basis of which the subsequent specific directives regulating at Community level the use of flavouring substances must be formulated;

- to define the guidelines for the harmonization of national legislations on the matter and the rules which the Member States must apply in order to obtain authorization within their territory for the use of particular flavouring substances;
- to define the procedures to be followed for amending the lists of flavourings in this and subsequent directives;
- to give a first list of flavouring substances in respect of which it is most urgent to define restrictions on their use.

The question of the definitions and terms to be used in this context and in the identification of flavouring substances, and their equivalents in all the Community languages, is not a purely technical problem, as emerged during the wide-ranging preliminary discussions on this matter.

As regards the classification of flavourings according to their origin and production method, the Commission's proposal to divide them into three groups (natural, nature-identical and artificial substances) may be regarded as acceptable in that it satisfies consumer protection requirements most fully.

The definition of natural flavouring substances (i.e. those isolated from natural flavouring materials, natural flavouring preparations or foodstuffs by appropriate physical processes) can be regarded as acceptable despite some reservations about the modifications that may occur as a result of certain extracting methods (e.g. the type of solvent used), provided no definitions have been proposed that satisfy the requirements more fully.

However, in order to make the concept of natural flavouring substances more precise, it would be useful to add the word 'exclusively' before the phrase 'by appropriate physical processes', leaving the definition of those physical processes which satisfy the requirements to a subsequent specific directive.

The committee has no other observations to make on the definitions and terms adopted, except for the expression 'materie aromatizzanti naturali' in the Italian text (second line of Article 2); this term does not correspond to that used in the other Community languages and the Commission is therefore asked to make the necessary corrections to the Italian text.

The inclusion of the group of 'nature-identical substances' in addition to the two traditional categories of natural and artificial substances gave rise to some discussion.

While sharing some of the reservations expressed (to the extent that chemical synthesizing processes may lead to considerable modifications in the

toxicological characteristics of the natural substances in question), the committee finds the solution adopted by the Commission in the proposal for a directive acceptable, given that it will subsequently present specific directives containing the lists of substances falling within the three groups mentioned, the use of which is authorized.

3. Purity criteria

The proposal for a directive rightly sets purity criteria to guarantee the quality of natural or artificial flavouring substances for use in food-stuffs, by analogy with the criteria laid down in earlier Community provisions on colourings, preservatives, emulsifiers and other substances.

Flavourings may not contain a toxicologically dangerous quantity of any element or substance and the directive defines the maximum permitted quantity of several chemical substances which need more specific controls because they are frequently found in various compounds and may be harmful (cf. Annex 1 to the proposal for a directive).

The analytic determination of the purity criteria for specific flavouring substances is left to subsequent provisions which the Commission is to adopt; however, in view of the importance of this question to consumer protection, it would be advisable to fix a two year deadline for the approval of these criteria.

4. Positive lists

Without doubt, the most important aspect of the proposal for a directive is the choice of a criterion to indicate which specific flavourings may be used in products intended for human consumption.

As is well known, the various countries at present apply two different criteria in different ways. The first is that of the so-called 'positive lists' which indicate all permitted substances, whether natural, nature-identical or artificial; no substance not included in the list may be used in foodstuffs.

This criterion certainly gives the best guarantee of the protection of public health and consumer interests.

The second criterion is based on the concept of 'negative lists' of flavourings, the use of which is not permitted, which means that any substance other than those on the list may be used freely. Clearly this system involves serious risks for consumers and public health since a substance is excluded only after it has been shown to have harmful effects.

Nor is it acceptable that the positive list should be limited only to artificial substances, since it is well known that harmful substances also exist in nature, especially if they occur in larger quantities, and that the nature-identical substances obtained by chemical synthesis may, as we have said, present different toxicological characteristics from those found in the natural substances to which they relate.

For these reasons, the committee cannot fully accept the approach taken by the Commission in its proposal for a directive as regards positive lists.

It should be pointed out that the Community adopted the same approach in the past as the basis for its legislation on materials and articles intended to come into contact with foodstuffs, specifying the need to 'take account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technological needs'.¹

There is no doubt that if the Community had taken a different approach on that occasion, there would have been an immediate reaction from public opinion which, as we know, is very sensitive to the issue of the health hazards of industrial products intended for human consumption.

For these reasons it seems clear that the outline directive proposed by the Commission of the European Communities satisfies the need to establish a number of general principles which the Member States must respect in their own rules on the matter but will have no practical legislative implications unless it is followed within a short space of time by specific directives which include lists of substances or products the use of which is authorized to the exclusion of all others.

The text submitted to the European Parliament for consideration specifies the procedures under which the Council shall adopt the specific directives (Article 5) but gives no indication of the period within which the Commission must submit the relevant proposals to the Council and makes no provision for informing Parliament on further developments in the matter.

In pointing out this requirement, the committee proposes setting an appropriate time limit (2 years after approval of this directive) by which the Commission must submit the specific directives to the Council and by which the European Parliament must be informed on the progress made in implementing the directive.

5. Provisions on labelling

The provisions contained in the proposal for a directive on the labelling

¹ Cf. Directive EEC 76/893 of 23.11.1976 (OJ No. L 340, 9.12.1976, p. 19)

of flavourings sold as such (Article 10) can be regarded as acceptable in that they offer a sufficient guarantee that the quality of the product contained in the packaging will correspond to the information on the labelling; in particular, the committee fully approves the restrictions on the use of the term 'natural' (which may be used only for flavourings which contain exclusively natural substances) and the provision that the word 'reproduced' must be inserted if the flavouring contains nature-identical substances obtained by synthetic chemical processes.

In the provisions of this part of the directive, the Commission rightly took account of the basic need of consumer protection. However it made no stipulations on the labelling of foodstuffs containing flavourings and put on sale to the public.

In the Explanatory Note attached to the directive (p. 6, paragraph 2.10), the Commission specifies that 'separate Community provisions will be drawn up for the ingredient declaration' but there is no reference to such provisions in the text of the directive.

In view of the importance of this question as regards the protection of consumer interests (given that the provisions contained in the proposed text offer direct guarantees to the foodstuffs industries but only indirect guarantees to consumers), the committee proposes that the Commission should adopt the appropriate provisions no later than two years after approval of the directive.

In its opinion on the proposal for a directive, the Committee on Economic and Monetary Affairs noted that following the judgment of the Court of Justice in case 120/78 of 23.2.78, national provisions on labelling may no longer constitute a 'legal' barrier to trade and that the labelling provisions contained in this proposal are therefore superfluous as means of eliminating technical barriers to trade.

In this context it must be noted, however, that these provisions remain valid as regards public health and consumer protection; it would therefore not be advisable to delete them.

It should also be pointed out that in its opinion on this directive the Economic and Social Committee hoped that the terms 'reproduced' and 'artificial' should always be included on the labelling of flavourings intended for the end consumer, to take account of consumer information requirements.

6. Amendment of lists

According to the directive proposed by the Commission (Article 8), amendments to the technical annexes of the specific directives referred to

in Article 5(1) and to the lists in the annexes to this directive shall be adopted in accordance with the procedure provided for in Article 11 of this directive; this procedure also applies to amendments to the lists of substances or materials (such as additives, solvents or processing aids) necessary for the production of flavouring substances (Article 5(2) and to determining the methods of analysis needed to verify compliance with the quality and purity criteria (Article 6).

It may be observed here that in the case of the latter, strictly technical aspects it seems justified to resort to the procedure referred to in Article 11, but the same cannot be said of the amendments to the positive lists which involve political decisions.

Under the procedure referred to in Article 11, the Commission shall adopt the relevant decisions if the Standing Committee on Foodstuffs gives a favourable opinion. If it gives an unfavourable opinion, the Commission shall submit the proposal to the Council which must act within three months. If the Council has not acted within that period, the Commission shall adopt the measures in question independently.

It is worth asking whether this procedure, which is clearly designed for dealing with particularly urgent problems, can be used to amend lists which the Council has already approved and on which the European Parliament has already been asked for its opinion.

In fact, amending the positive lists may consist in deleting flavouring substances which, on the basis of new technical and scientific information, have been proved to be harmful, or including flavouring substances which were not included in the original lists because they were unknown at the time or wrongly considered dangerous to health.

In the first case (substances including the lists and subsequently found to be harmful), there may be some justification for resorting to an emergency procedure such as that provided for in Article 11; in the second case (inclusion of new substances not on the lists), it would, on the contrary, be advisable for the decision to be adopted under the same procedure applied for approval of the lists, i.e. following a Council decision and after consulting Parliament.

7. List of flavouring substances subject to quantitative limits

Annex II of the proposal for a directive gives a list of substances present in food as consumed as a result of the use of natural flavouring materials and/or natural flavouring preparations in respect of which the Commission, after consulting the Advisory Committee for Foodstuffs, considered it useful to fix maximum tolerance levels because of their potential harmfulness.

Rightly, the Commission did not accept the principle that since these substances are normally present in foodstuffs (e.g. hydrocyanic acid in bitter almonds), their use should not be subject to any restrictions; moreover; in its Explanatory Note to the proposal for a directive, the Commission itself states that this is a 'first list' and Article 4(2) of the directive specifies that this list shall be completed 'as soon as possible'.

8. Opinions of the Economic and Social Committee and the Committee on Economic and Monetary Affairs

In its opinion on this directive, the Economic and Social Committee acknowledged the usefulness of Community provisions in this sector to reduce or avoid obstacles to trade, to take account of the highest level of health protection requirements and to satisfy the information needs of the user and the consumer.

The committee also stated that it did not propose to question the principle of positive lists again, as it had confirmed when it considered the directives on additives.

Lastly, it is worth noting that the Committee on Economic and Monetary Affairs called for an EEC directive on flavourings to prevent any future obstacles to trade caused by discrepancies between national provisions; the committee was in favour of positive lists in the case of 'artificial flavouring preparations' and, although recognizing that it was not competent to examine in detail the provisions contained in the proposal for a directive, expressed its agreement with the proposal from flavouring producers concerning the introduction of a system based on negative lists for 'nature-identical flavouring substances' and 'source materials for the production of natural flavouring preparations and natural flavouring substances'.

In the Explanatory Note, the Commission specifies that after discussions with non-government and government associations on the scheme for legislation most appropriate for the needs of the Community, it decided that while the mixed system proposed by the flavouring producing industry might have superficial advantages in the short term, the interests of the Community as a whole can best be served by the development of lists of authorized flavourings (whether natural or chemically derived). It also notes that the majority of the food industry, consumers, agriculture and commerce represented on the Advisory Committee for Foodstuffs endorses this approach.

9. Conclusions

On the basis of the above considerations, and subject to the amendments made, our committee can propose to Parliament that it deliver a favourable opinion on the proposal for a directive on flavourings presented by the Commission of the European Communities.

OPINION OF THE COMMITTEE ON ECONOMIC AND MONETARY AFFAIRS

Letter from the chairman of the committee to Mr COLLINS, chairman of the Committee on the Environment, Public Health and Consumer Protection

At its meeting of 19 March 1981 the Committee on Economic and Monetary Affairs, following thorough-going discussions in the Working Party on Technical Barriers to Trade, considered the proposal from the Commission for a Council directive on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (Doc. 1-271/80).

The committee wishes to emphasize that the flavouring content of foodstuffs has not as yet created serious problems in connection with the free movement of goods within the Community. On the other hand, there are many signs that several Member States intend to introduce provisions in this area which may eventually create barriers to trade; given that such provisions are aimed at protecting the health of consumers, they hardly conflict with Article 30 of the EEC Treaty. The Committee on Economic and Monetary Affairs therefore agrees that an EEC directive should be issued to cover this area, with a view to preventing barriers to trade from arising in future because of differences in national legislation.

The Committee on Economic and Monetary Affairs has not considered it its task to enter into a detailed discussion of all the provisions contained in the proposal for a directive, but has concentrated its attention on those provisions which relate directly to the free movement of goods and on the consequences of the implementation of the Commission's proposal in terms of expenditure.

20 March 1981

It seems doubtful whether it is necessary for the so-called 'positive list' (whereby only specifically authorized substances may be used) to be applied to all flavourings and all source materials for their production. In this context, it should be pointed out that in its comments on Article 5, the Commission itself acknowledges that a 'positive list system' will be costly to enforce and make controls difficult to apply.

The producers of flavourings have proposed an alternative solution, whereby negative lists would be used for substances which occur naturally in the diet and positive lists for substances not yet found to occur in the human diet.

A solution of this type would not preclude the retention of the maximum limits for the amounts of certain natural flavouring materials to be used in foodstuffs which are set out in Annex II of the Commission's proposal.

The Commission has not demonstrated convincingly to the committee that the less costly solution proposed by the producers of flavourings entails any risks for consumers.

The Committee on Economic and Monetary Affairs has therefore reached the conclusion that Article 5(1) should provide for:

- positive lists in respect of the 'artificial flavouring substances' and 'source materials for the production of artificial flavouring preparations' referred to under (a) and (d);
- negative lists in respect of the 'nature-identical flavouring substances' and 'source materials for the production of natural flavouring substances' referred to under (b) and (c).

However, the Committee notes that this requires the development of a suitable method of analysis for detecting nature-identical flavouring substances in foodstuffs.

The Committee also wishes to draw attention to the fact that national provisions on labelling can no longer constitute a 'legal' barrier to trade (see the communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 23 February 1978 in Case 120/78 ('Cassis de Dijon') (OJ No. C 256, 3.10.1980)). From the point of view of removing technical barriers to trade, Article 10 of the Commission's proposal is therefore superfluous.

I would ask you to regard this letter, the text of which was adopted unanimously¹, as the opinion of the Committee on Economic and Monetary Affairs on the proposal for a directive in question.

Yours sincerely,

Jacques DELORS

¹Present: Mr Deleau, vice-chairman and acting chairman; Mr Carossino (deputizing for Mr Fernandez), Mr Collomb, Mr Delorozoy, Mr Herman, Mr Nyborg, Mr Petronio, Mr Schinzel, Mr Turner, Mr Wagner, Mr Walter and Mr von Wogau.