

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 609 final - COD 478

Brussels, 1 December 1993

Proposal for a  
**EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)**  
laying down a Community procedure for flavouring substances  
used in foodstuffs

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(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Article 5(1) of Directive 88/388/EEC<sup>(1)</sup> states that:

"The Council, acting in accordance with the procedure laid down in Article 100a of the Treaty, shall adopt

1. Appropriate provisions concerning:

- flavouring sources composed of foodstuffs, and of herbs and spices normally considered as foods,
- flavouring sources composed of vegetable or animal raw materials not normally considered as foods,
- flavouring substances obtained by appropriate physical processes or by enzymatic or microbiological processes from vegetable or animal raw materials,
- chemically synthesized or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in foodstuffs or in herbs and spices normally considered as foods,
- chemically synthesized or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in vegetable or animal raw materials not normally considered as foods,
- chemically synthesized or chemically isolated flavouring substances other than those referred to in the fourth and fifth indents,
- source materials used for the production of smoke flavourings or process flavourings, and the reaction conditions under which they are prepared."

This Regulation deals with flavouring substances. Where necessary, other provisions will be proposed for the other categories of flavourings.

2. The Scientific Committee for Food was consulted in December 1991 concerning the principles of the safety evaluation of flavouring substances. Its opinion was published (29th series). It recommended that flavouring substances should be subject to an appropriate safety evaluation. The Committee agreed to take into account the findings of Council of Europe's committee of experts on flavourings, the Food and Drug Administration (FDA) and the Flavours and Extracts Manufacturers Association (FEMA). The Committee has also defined criteria for the safety evaluation of flavouring substances. The flavouring substances will be evaluated in groups of substances having a similar chemical structure.

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(1) OJ No L 184, 15.7.1988, p. 61

3. This Regulation defines general criteria (Annex I) for the use of flavouring substances in foodstuffs. On the basis of these general criteria and the opinion of the Scientific Committee for Food, a Community positive list of flavouring substances will be drawn up by a committee procedure. The substances deemed acceptable by the Scientific Committee for Food will be included in the list; given that technical measures are involved, the committee procedure is the most appropriate. This list will be drawn up in stages.
4. After 31 December 1993, the food industry will have to use the flavouring substances which have been subject to the procedure laid down in this Regulation. Some members of the industry will therefore have to adapt their manufacturing processes.

This draft Regulation is unlikely to have any negative effect on employment.

5. Justification of the proposal with regard to the principle of subsidiarity

**What are the objectives of the proposed measure in terms of the obligations of the Community?**

The main aims of the proposed Regulation are

- to achieve a high level of protection for consumers
- to improve the free movement of goods in the internal market, and
- to create greater legal certainty for economic operators and, in particular, for the food industry

in relation to the use of flavouring substances in foodstuffs.

These objectives satisfy the requirements of Article 100a of the Treaty and fit in with Article 5 of Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production.

**Does the proposed measure involve any sharing of competence with the Member States?**

Yes, competence is shared.

**What is the scale of the problem?**

The legislative situation differs widely from one Member State to another. Some States have compiled positive lists of flavouring substances, others are content with the general principle of non-toxicity or a list of prohibited substances. These differences constitute barriers to trade in foodstuffs containing flavourings.

**What is the most effective solution, given the respective resources of the Community and of the Member States?**

In line with the recommendations of the Scientific Committee for Food (see 29th report - 1993) flavouring substances are required to undergo an appropriate toxicological evaluation. In view of the number of substances involved (between 2000 and 3000), these evaluations should be undertaken at Community level using resources that exist in the Member States under the auspices of scientific cooperation.

**What concrete added value does the envisaged Community measure have and what would be the cost of failing to act?**

The proposed regulation will facilitate the free movement of foodstuffs in the Community. Failure to act would perpetuate the compartmentalization of national markets.

**What means of action are available to the Community?**

The completion of the internal market necessitates the use of a binding legal instrument.

**Are uniform rules necessary or would a directive specifying general objectives and leaving it to the Member States to adopt appropriate measures to implement them suffice?**

Total harmonization is necessary because the ultimate aim is to have a Community list of substances that are toxicologically acceptable.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission,<sup>(1)</sup>

Having regard to the opinion of the Economic and Social Committee,<sup>(2)</sup>

Having consulted the Scientific Committee for Food,

Whereas Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production,<sup>(3)</sup> provides for the adoption by the Council of the appropriate provisions concerning flavouring substances,

Whereas differences between national laws relating to flavourings hinder the free movement of foodstuffs and may create conditions of unequal competition, thereby directly affecting the establishment or functioning of the common market,

Whereas the approximation of those laws is necessary if the free movement of foodstuffs is to be achieved,

Whereas, according to the scope and effects of the proposed action, the Community measures envisaged by this Regulation are not only necessary but indispensable for the attainment of the stated objectives, and whereas these objectives cannot be achieved by Member States individually,

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(1) OJ L 184, 15.07.1988, p. 61

(2)

(3) OJ No L 184, 15.07.1988, p. 61

Whereas laws relating to flavourings for use in foodstuffs should take account primarily of human health requirements but also, within the limit required for the protection of health, of economic and technical needs,

Whereas it is necessary to establish general criteria for the use of flavouring substances,

Whereas on the basis of the most recent scientific advice it is necessary to lay down a list of flavouring substances that may be used in food,

Whereas this list must be open and capable of being amended in the light of scientific and technical developments;

Whereas it may be necessary for health reasons to adopt conditions of use for certain flavouring substances,

HAVE ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down the procedure for the establishment of rules in respect of the flavouring substances referred to in the third, fourth, fifth and sixth indents of Article 5(1) of Council Directive 88/388/EEC.
2. This Regulation shall apply to flavouring substances used or intended for use in or on foodstuffs to impart odour and/or taste, as defined in Article 1(2)(b) of Directive 88/388/EEC.
3. This Regulation shall apply without prejudice to specific directives permitting substances covered by this Regulation to be used for purposes other than those mentioned in Article 1(2).

Article 2

1. Only flavouring substances conforming to the general criteria set out in Annex I of this Regulation may be used in foodstuffs.
2. A list of flavouring substances the use of which is authorized to the exclusion of all others will be laid down. This list may be drawn up in stages.  
This list shall be adopted in accordance with the procedure laid down in Article 4 and may include conditions under which flavouring substances may be added.
3. Flavouring substances will be included in the list mentioned in paragraph 1 on the basis of the general criteria described in Annex I.



### Article 3

1. This Regulation shall apply without prejudice to the Community provisions governing the use, in certain foodstuffs, of certain categories of flavouring substances as defined in Article 1 of Directive 88/388/EEC.
2. However, flavouring substances of these categories must conform with Annex I.

### Article 4

The Commission shall be assisted by the Standing Committee for Foodstuffs set up by Council Decision 69/414/EEC<sup>(5)</sup>. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes : in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

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(5) OJ No L 291, 19.11.1969, p. 9

Article 5

Member States may not prohibit, restrict or obstruct the marketing, or the use in foodstuffs, of flavouring substances if these comply with the provisions of this Regulation.

Article 6

Measures to bring existing Community provisions into line with this Regulation shall be adopted according to the procedure laid down in Article 4.

Article 7

This Regulation shall enter into force on 31 December 1993.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the Council  
The President

For the European Parliament  
The President

Annex I

General criteria for the use of flavouring substances:

1. Flavouring substances can be approved provided that:
  - they present no risk to the health of the consumer, so far as can be judged on the scientific evidence available
  - and their use does not mislead the consumer, for instance by disguising the effects of the use of faulty raw materials or of undesirable manufacturing practices.
2. To assess the possible harmful effects of a flavouring substance, it must be subjected to appropriate toxicological evaluation. When a flavouring substance contains or consists of a genetically modified organism within the meaning of Article 2(1) and (2) of Council Directive 90/220/EEC<sup>(6)</sup>, Articles 11 to 18 of Directive 90/220/EEC will not be applicable. However, the evaluation of the safety of this flavouring substance must take into account environmental safety as provided for in Directive 90/220/EEC.
3. All flavouring substances must be kept under constant supervision and must be reevaluated whenever necessary.

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(6) OJ L 117, 8.5.1990, p. 15

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# DOCUMENTS

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