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Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs

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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 (1),

Having regard to the opinion of the Economic and Social Committee (2),

Having consulted the Scientific Committee for Food,

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

(1) 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 (4) provides for the adoption by the Council of the appropriate provisions concerning flavouring substances;

(2) Whereas the appropriate provisions apply without prejudice to the general framework established by Directive 88/388/EEC,

(3) Whereas differences between national laws relating to flavourings hinder the free movement of foodstuffs; whereas they may create conditions of unequal competition, thereby directly affecting the functioning of the internal market;

(4) Whereas national laws relating to flavourings for use in or on foodstuffs should take account primarily of human health requirements but also, as far as health protection allows, of economic and technical needs;

(5) Whereas, in order to achieve the free movement of foodstuffs, approximation of those laws is necessary;

(6) Whereas the Community measures envisaged by this Regulation are not only necessary but also essential to realize the stated objectives; whereas these objectives cannot be achieved by Member States individually;

(7) Whereas it is necessary to establish general criteria for the use of flavouring substances;

(8) Whereas, on the basis of the most recent scientific advice, it is necessary to lay down a list of flavouring substances which may be used in or on foodstuffs;

(9) Whereas that list must be open-ended and capable of being amended in the light of scientific and technical developments;

(10) Whereas already authorized flavouring substances which are produced using processes or from source materials which were not the subject of the evaluation carried out by the Scientific Committee for Food will be resubmitted for a comprehensive evaluation by that body;

(11) Whereas it may be necessary for health reasons to adopt conditions of use for certain flavouring substances;

(12) Whereas flavouring substances which are actually used in the Member States and the use of which cannot be challenged by any of the latter pursuant to the general rules of the Treaty should initially be listed in a register; whereas such registration does not come under Article 7 of Directive 88/388/EEC and does not, therefore, call for the intervention of the Scientific Committee for Food at this stage;

(13) Whereas, however, a safeguard clause must enable a Member State to take the necessary measures where a flavouring substance is likely to constitute a danger to public health;

(14) Whereas, in keeping with Article 214 of the Treaty, it is necessary to protect intellectual property linked to the development and production of 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 Directive 88/388/EEC. This Regulation shall apply without prejudice to the other provisions of Directive 88/388/EEC.

2. This Regulation shall apply to flavouring substances, as defined in Article 1 (2) (b) of Directive 88/388/EEC, used or intended for use in or on foodstuffs to impart odour and/or taste.

3. This Regulation shall apply without prejudice to specific Directives permitting flavouring substances covered by this Regulation to be used for purposes other than those referred to in Article 1 (2).

Article 2

1. The flavouring substances shall comply with the general use criteria referred to in the Annex.

2. A list of flavouring substances the use of which is authorized to the exclusion of all others shall be drawn up in accordance with Articles 3, 4 and 5.

Article 3

1. Within one year of the entry into force of this Regulation, the Member States shall notify to the Commission a list of the flavouring substances which may, in accordance with Directive 88/388/EEC, be used in or on foodstuffs marketed on their territory. Such notification shall contain any useful information regarding:

(a) the nature of such flavouring substances, such as the chemical formula, the CAS number, the EINECS number, the IUPAC nomenclature, their origin and, if necessary, the conditions for their use;

(b) the foodstuffs in or on which such flavouring substances are chiefly used;

(c) compliance at the level of each Member State with the criteria provided for in Article 4 of Directive 88/388/EEC, and the reasons for those criteria.

2. On the basis of the notification provided for in paragraph 1, and following Commission scrutiny of the notification, in the light of subparagraph (c), flavouring substances the legal use of which in one Member State must be recognized by the other Member States shall be entered in a register which shall be adopted in accordance with the procedure laid down in Article 7 within a year of the end of the notification period provided for in paragraph 1. If necessary, this register may comprise conditions of use.

These substances shall be designated in such a way as to protect the intellectual property rights of their manufacturer.

3. If, on the basis of a detailed notification and in the light of fresh data or a re-evaluation of existing data since the establishment of the register referred to in paragraph 2, a Member State notes that a flavouring substance may constitute a danger to public health, it may suspend or

restrict the use of that substance on its territory. It shall immediately inform the Commission and the other Member States thereof, stating the reasons for its decision.

The Commission shall examine as soon as possible the reasons invoked by the Member State concerned and shall consult the Standing Committee on Foodstuffs set up by Decision 69/414/EC (5). The Commission shall then deliver its opinion.

If the Commission considers that amendments to the register of flavouring substances are necessary to ensure protection of human health, it shall initiate the procedure provided for in Article 7 with a view to adopting such amendments. The State which adopted the safeguard measures may maintain them until the entry into force of such amendments.

Article 4

1. In order to check whether the flavouring substances contained in the register referred to in Article 3 comply with the general use criteria given in the Annex, a programme for the evaluation of these flavouring substances shall be adopted in accordance with the procedure laid down in Article 7 within ten months of the register being adopted.

That programme shall define in particular:

- the order of priorities according to which the flavouring substances are to be examined, taking into account their uses,
- the time limits,
- the flavouring substances which are to be the subject of scientific cooperation.

2. The persons responsible for placing the flavouring substances on the market shall forward the data necessary for the evaluation to the Commission, if necessary at the latter's request.

3. If it is apparent, following the evaluation, that a flavouring substance does not comply with the general use criteria given in the Annex, that substance shall be deleted from the register in accordance with the procedure laid down in Article 7.

Article 5

1. After completion of the evaluation programme provided for in Article 4, the list of flavouring substances referred to in Article 2 (2) shall be adopted in accordance with the procedure laid down in Article 8 within five years of adoption of that programme.

2. The use of a new flavouring substance not included in the register provided for in Article 3 (2) may be authorized in accordance with the procedure laid down in Article 7. To that end, it shall first be included in the evaluation programme referred to in Article 4 (1) in accordance with the procedure laid down in Article 7. It shall be evaluated on the basis of the place allocated to it in that programme.

Article 6

1. This Regulation shall apply without prejudice to the Community provisions authorizing the use, in or on 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 the general use criteria set out in the Annex.

Article 7

1. The Commission shall be assisted by the Standing Committee on Foodstuffs, hereinafter referred to as 'the Committee'.

2. Matters shall be referred to the Committee by its Chairman either on his own initiative or at the request of the representative of a Member State.

3. 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. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If the Council has not acted within three months of referral to it, the proposed measures shall be adopted by the Commission.

Article 8

In the case referred to in Article 5 (1), the procedure referred to in Article 7 shall apply, it being understood that if the Council has not acted within three months of referral to it, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

Article 9

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

Article 10

The provisions intended to align existing Community acts on this Regulation shall be adopted in accordance with the procedure laid down in Article 7.

Article 11

This Regulation shall enter into force on the day of its publication in the Official Journal of the European Communities.

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

Done at Luxembourg, 28 October 1996.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President

I. YATES

(1) OJ No C 1, 4. 1. 1994, p. 22 and OJ No C 171, 24. 6. 1994, p. 6.

(2) OJ No C 195, 18. 7. 1994, p. 4.

(3) Opinion of the European Parliament of 5 May 1994 (OJ No C 205, 25. 7. 1994, p. 398), Council common position of 22 December 1995 (OJ No C 59, 28. 2. 1996, p. 37) and Decision of the European Parliament of 22 May 1996 (OJ No C 166, 10. 6. 1996, p. 61). Council Decision of 25 June 1996.

(4) OJ No L 184, 15. 7. 1988, p. 61. Directive as amended by Directive 91/171/EEC (OJ No L 42, 15. 2. 1991, p. 25).

(5) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX

GENERAL CRITERIA FOR THE USE OF FLAVOURING SUBSTANCES REFERRED TO IN ARTICLE 2 (1)

1. The use of flavouring substances may be authorized provided that:

- they present no risk to the health of the consumer, in accordance with the scientific assessment provided for in Article 7 of Directive 88/388/EEC,
- their use does not mislead the consumer.

2. To be able to assess the possible harmful effects of a flavouring substance, the latter 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 of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), Articles 11 to 18 will not be applicable. However, the evaluation of the safety of this flavouring substance must take into account environmental safety as provided for in the said Directive.

3. All flavouring substances must be kept constantly monitored and must be re-evaluated whenever necessary.

(1) OJ No L 117, 8. 5. 1991, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).