

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

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

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 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 the first step should be to lay down in a framework Directive provisions on general purity criteria, definitions, labelling, and the principles on the basis of which legal differences may subsequently be eliminated;

Whereas, on the basis of the inventory of source materials and substances used in the preparation of flavourings established by the Commission on the basis of Decision 88/389/EEC (1), the Council will at a later stage adopt, under the procedure laid down in Article 100a of the Treaty, appropriate provisions concerning individual categories of flavourings and source materials and any necessary measures concerning their use and methods of production;

Whereas on the most recent scientific and technical advice certain components on vegetable or animal raw materials used in the preparation of flavourings ought to be limited in foodstuffs;

Whereas specific purity criteria for given flavourings, microbiological criteria for flavourings, methods of analysis and sampling of flavourings and the substances listed in the Annexes in and on foodstuffs should be established;

Whereas, should the use in a flavouring of a substance or material authorized on the basis of this Directive or provisions adopted at a later stage or the presence of one of the substances listed in Annex II appear to constitute a health risk, Member States should be authorized to suspend or limit such use, or to reduce the maximum limits provided, pending a decision at Community level;

Whereas the drawing up of the list of substances or materials authorized as additives necessary for the storage and use of flavourings as solvents and diluents of flavouring, and as processing aids, and the establishment of specific criteria of purity for flavourings, the procedure for taking samples and the methods of analysis of flavourings in or on foodstuffs and the verification of the maximum limits laid down in the Annexes constitute technical implementing measures; whereas in order to simplify and expedite the procedure, the adoption of such measures should be entrusted to the Commission;

Whereas, it is desirable that in all cases where the Council empowers the Commission to implement rules relating to flavourings for use in foodstuffs, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs set up by Decision 69/414/EEC (1);

Whereas, without prejudice to the application of national rules which, in the absence of specific Directives on flavouring, apply to certain groups of flavourings, the requirements laid down in

the following provisions shall be applied in such a way as to authorize, two years after adoption of this Directive, trade in and use of flavourings complying with the provisions of this Directive and to prohibit, three years after the adoption thereof, trade in and use of flavourings which do not comply therewith,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to 'flavourings' used or intended for use in or on foodstuffs to impart odour and/or taste, and to source materials used for the production of flavourings.

2. For the purposes of this Directive:

(a) 'flavouring' means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof;

(b) 'flavouring substance' means a defined chemical substance with flavouring properties which is obtained:

(i) by appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation),

(ii) by chemical synthesis or isolated by chemical processes and which is chemically identical to a substance naturally present in material of vegetable or animal origin as described in (i),

(iii) by chemical synthesis but which is not chemically identical to a substance naturally present in material of vegetable or animal origin as described in (i);

(c) 'flavouring preparation' means a product, other than the substances defined in (b) (i), whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

(d) 'process flavouring' means a product which is obtained according to good manufacturing practices by heating to a temperature not exceeding 180°C for a period not exceeding 15 minutes a mixture of ingredients, not necessarily themselves having flavouring properties, of which at least one contains nitrogen (amino) and another is a reducing sugar;

(e) 'smoke flavouring' means a smoke extract used in traditional foodstuffs smoking processes.

3. Flavourings may contain foodstuffs as well as other substances as described in Article 6 (1).

Article 2

This Directive shall not apply to:

- edible substances and products intended to be consumed as such, with or without reconstitution,
- substances which have exclusively a sweet, sour or salt taste,
- material of vegetable or animal origin, having inherent flavouring properties, where they are not used as flavouring sources.

Article 3

Member States shall take the necessary measures to ensure that flavourings may not be marketed or used if they do not comply with the rules laid down in this Directive.

Article 4

Member States shall take all measures necessary to ensure that:

(a) - flavourings do not contain any element or substance in a toxicologically dangerous quantity;

- subject to any exceptions provided for in the specific criteria of purity referred to in Article 6

(2), third indent, they do not contain more than 3 mg/kg of arsenic, 10 mg/kg of lead, 1 mg/kg of cadmium and 1 mg/kg of mercury;

(b) the use of flavourings does not result in the presence in foodstuffs as consumed of undesirable substances listed in Annex I in quantities greater than those specified therein;

(c) the use of flavourings and of other food ingredients with flavouring properties does not result

in the presence of substances listed in Annex II in quantities greater than those specified therein.

Article 5

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;

2. Any special provisions which may be necessary, for the protection of public health or trade, concerning:

- the use and methods of production of flavourings, including physical processes or enzymatic or microbiological processes for the production of flavouring preparations and flavouring substances as referred to in Article 1 (2) (b) (i) and (c),
- the conditions for the use of the substances and materials referred to in Article 6 (1);

3. Amendments concerning the maximum limits laid down in the Annexes.

Article 6

The following shall be adopted in accordance with the procedure set out in Article 10:

1. the list of substances or materials authorized in the Community as:

- additives necessary for the storage and use of flavourings,
- products used for dissolving and diluting flavourings,
- additives necessary for the production of flavourings (processing aids) where such additives are not covered by other Community provisions;

2. where necessary:

- the methods of analysis needed to verify compliance with the levels referred to in Article 4,
- the procedure for taking samples and the methods for qualitative and, where appropriate, quantitative analysis of flavourings in or on foodstuffs,
- the specific criteria of purity for given flavourings;

3. - the microbiological criteria applicable to flavourings,

- the designation criteria given to the more specific names referred to in Article 9 (1) (b);

4. the appropriate steps, to be taken by 1 July 1990 to supplement this Directive with labelling rules for flavourings intended for sale to the final consumer.

Article 7

Provisions that may have effects on public health shall be adopted only after consulting the Scientific Committee for Food.

Article 8

1. Where, as a result of new information or of a re-assessment of existing information made since this Directive or one of the Directives provided for in Article 5 was adopted, a Member State has detailed evidence:

- that the presence of one of the substances listed in the Annexes to this Directive or the maximum levels stipulated, while complying with the provisions of this Directive, or
 - that the use of a flavouring, while complying with the relevant Directive or with this Directive, or
 - that the presence of a substance similar to those referred to in the Annexes constitutes a danger to human health, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.
2. The Commission shall examine as soon as possible the evidence given by the Member State and consult the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures, which may replace the measures referred to in paragraph 1.
3. If the Commission considers that amendments to this Directive or to one of the Directives referred to in Article 5 are necessary in order to alleviate the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 10, with a view to adopting these amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.

Article 9

1. Flavourings not intended for sale to the final consumer may not be marketed unless their packagings or containers bear the following information, which should be easily visible, clearly legible and indelible:

(a) the name or business name and address of the manufacturer or packer, or of a seller established within the Community;

(b) the sales description: either the word 'flavouring' or a more specific name or description of the flavouring.

Member States may maintain for a period of three years following the adoption of this Directive, more specific names to designate flavourings composed of mixtures of flavouring preparations and flavouring substances.

Before this period expires, it shall be decided according to the procedure provided for in Article 10 whether or not these names shall be included in this Directive;

(c) either the statement 'for foodstuffs' or a more specific reference to the foodstuff for which the flavouring is intended;

(d) a list in descending order of weight of the categories of flavouring substances and flavouring preparations present classified as follows:

- natural flavouring substances in the case of flavouring substances defined in Article 1 (2) (b) (i),

- flavouring substances identical to natural substances in the case of flavouring substances defined in Article 1 (2) (b) (ii),

- artificial flavouring substances in the case of flavouring substances defined in Article 1 (2) (b) (iii),

- flavouring preparations in the case of preparations defined in Article 1 (2) (c),

- process flavourings in the case of flavourings defined in Article 1 (2) (d),

- smoke flavourings in the case of flavourings defined in Article 1 (2) (e);

(e) in the case of a mixture of flavourings with other substances or materials referred to in the first and second indents of Article 6 (1), a list in descending order of weight in the mixture of:

- the categories of flavourings classified as in (d) of this paragraph,

- the names of each of the other substances or materials or, where appropriate, their 'EEC' numbers;

(f) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in a foodstuff or appropriate information enabling the purchaser to comply with the Community provisions or, where there are none, national provisions applying to that foodstuff;

- (g) an indication identifying the consignment;
- (h) the nominal quantity expressed in units of mass or volume.

2. Without prejudice to paragraph 1 (d), the word 'natural', or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring preparations as defined in Article 1 (2) (c).

If the sales description of the flavouring contains a reference to a foodstuff or a flavouring source, the word 'natural', or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

3. By way of derogation from paragraph 1, the information required in paragraph 1 (d), (e) and (f) may appear merely on the trade documents relating to the consignment which are to be supplied with or prior to the delivery, provided the indication 'intended for the manufacture of foodstuffs and not for retail' appears in a conspicuous part of the packaging or container of the products in question.

4. Member States shall refrain from laying down requirements more detailed than those contained in this Article concerning the manner in which the particulars provided for are to be shown.

The particulars provided for in this Article shall be given in terms easily understood by purchasers unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs either on his own initiative or at the request of the representative of a Member State. 2. The Commission representative shall submit to the Committee a draft of 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 qualified majority laid down in Article 148(2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.

(b) Where the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures.

Article 11

1. This Directive shall also apply to flavouring intended for use in foodstuffs, and to foodstuffs, imported into the Community.

2. This Directive shall apply neither to flavourings, nor to foodstuffs, intended for export outside the Community.

Article 12

1. The Member States may not invoke reasons of composition or labelling of flavourings or their behaviour in foodstuffs to prohibit, restrict, or hamper the marketing or use of flavourings which comply with this Directive and with the Directives referred to in Article 5.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of the Directives as referred to in Article 5.

Article 13

1. Member States shall take the measures necessary to comply with this Directive within 18 months of its adoption. They shall forthwith inform the Commission thereof. The measures taken shall:

- authorize, two years after adoption of this Directive, the marketing and use of flavourings complying with this Directive,

- prohibit, three years after adoption of this Directive, the marketing and use of flavourings which do not comply with this Directive.

2. Paragraph 1 shall not affect those national provisions which, in the absence of the Directives referred to in Article 5, apply to certain groups of flavourings or specify the foodstuffs in or on which flavourings complying with the Directive may be used.

Article 14

The Directive is addressed to the Member States.

Done at Luxembourg, 22 June 1988.

For the Council

The President

M. BANGEMANN

ANNEX I

Maximum limits for certain undesirable substances present in foodstuffs as consumed as a result of the use of flavourings

1.2.3 Substance Foodstuffs Beverages 3,4 benzopyrene 0,03 mg/kg 0,03 mg/kg

ANNEX II

Maximum limits for certain substances obtained from flavourings and other food ingredients with flavouring properties present in foodstuffs as consumed in which flavourings have been used

1.2.3.4 Substances Foodstuffs mg/kg Beverages mg/kg Exceptions and/or special restrictions

Agaric acid (1) 20 20 100 mg/kg in alcoholic beverages and foodstuffs containing mushrooms

Aloin (1) 0,1 0,1 50 mg/kg in alcoholic beverages Beta asarone (1) 0,1 0,1 1 mg/kg in alcoholic

beverages and seasonings used in snack foods Berberine (1) 0,1 0,1 10 mg/kg in alcoholic

beverages Coumarin (1) 2 2 10 mg/kg in certain types of caramel confectionery 50 mg/kg in

chewing gum 10 mg/kg in alcoholic beverages Hydrocyanic acid (1) 1 1 50 mg/kg in nougat,

marzipan or its substitutes or similar products 1 mg/ % volume of alcohol in alcoholic beverages

5 mg/kg in canned stone fruit Hypericine (1) 0,1 0,1 10 mg/kg in alcoholic beverages 1 mg/kg in

confectionery Pulegone (1) 25 100 250 mg/kg in mint or peppermint-flavoured beverages 350

mg/kg in mint confectionery Quassine (1) 5 5 10 mg/kg in confectionery in pastille form 50

mg/kg in alcoholic beverages Safrole and isosafrole (1) 1 1 2 mg/kg in alcoholic beverages with

not more than 25 % volume of alcohol 5 mg/kg in alcoholic beverages with more than 25 %

volume of alcohol 15 mg/kg in foodstuffs containing mace and nutmeg Santonin (1) 0,1 0,1 1

mg/kg in alcoholic beverages with more than 25 % volume of alcohol Thuyone (alpha and beta)

(1) 0,5 0,5 5 mg/kg in alcoholic beverages with not more than 25 % volume of alcohol 10 mg/kg

in alcoholic beverages with more than 25 % volume of alcohol 25 mg/kg in foodstuffs containing

preparations based on sage 35 mg/kg in bitters

(1) May not be added as such to foodstuffs or to flavourings. May be present in a foodstuff either naturally or following the addition of flavourings prepared from natural raw materials.