COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption

(89/107/EEC)

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,

In cooperation with the European Parliament (1),

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

Whereas differences between national laws relating to food additives and the conditions for their use hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the common market;

Whereas the approximation of these laws is therefore necessary;

Whereas these requirements should be included in a comprehensive directive, where neccessary drawn up in stages;

Whereas the drawing-up of lists of categories of food additives to be covered by a directive is a matter to be decided by the Council acting under the procedure laid down in Article 100a of the Treaty;

Whereas the use of food additives belonging to such categories should be authorized only on the basis of agreed scientific and technological criteria laid down by the Council;

Whereas in drawing up lists of additives and the conditions for their use the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (3), should be consulted before the adoption of provisions likely to affect public health;

Whereas it must be possible to adopt the list of authorized additives to scientific and technical developments; whereas in that case, it may be appropriate also to have, in addition to the rules of procedure laid down by the Treaty, a system permitting the Member States to contribute, by the adoption of temporary national measures, to the search for a Community solution;

Whereas the determination of the criteria of purity for such food additives and the drawing-up of methods of analysis and sampling are technical matters to be entrusted to the Commission;

Whereas existing Community provisions on colouring matters, preservatives, anti-oxidants and emulsifiers, stabilizers, thickeners and gelling agents will require amendment on the basis of this Directive;

Whereas, in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs set up by Commission Decision 69/414/EEC (4),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to food additives the various categories of which are given in Annex I and which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff and are still present in the final product, even if in altered form, hereinafter called 'food additives'.

2. For the purposes of this Directive 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

(1) OJ No C 99, 13. 4. 1987, p. 65 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 328, 22. 12. 1986, p. 5.
(3) OJ No L 136, 20. 5. 1974, p. 1.
(4) OJ No L 291, 19. 11. 1969, p. 9.

3. This Directive shall not apply to:

(a) processing aids (1);

(b) substances used in the protection of plants and plant products in conformity with Community rules relating to plant health;

(c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC (2);

(d) substances added to foodstuffs as nutrients (for example minerals, trace elements or vitamins).

Article 2

1. In respect of any category of food additive listed in Annex I for which lists have been drawn up pursuant to Article 3 (3), only those food additives included in such lists may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

2. The inclusion of food additives in one of the categories in Annex I shall be on the basis of the principal function normally associated with the food additive in question. However, the allocation of the additive to a particular category does not exclude the possibility of the additive being authorized for several functions.

3. Food additives shall be included in a list on the basis of the general criteria described in Annex II.

Article 3

1. Particular provisions in respect of the additives in the categories given in Annex I shall be laid down in a comprehensive directive, including existing specific directives on particular categories of additives. That directive may, however, be drawn up in stages.

2. The Council shall, acting on a proposal from the Commission under the procedure laid down in Article 100a of the Treaty, adopt:

(a) a list of additives the use of which is authorized to the exclusion of all others;

(b) the list of foodstuffs to which these additives may be added, the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use;

(c) the rules on additives used as carrier substances and solvents, including where necessary their purity criteria.

3. The following shall be adopted under the procedure laid down in Article 11:

(a) the criteria of purity for the additives in question;

(b) where necessary, the methods of analysis needed to verify that the criteria of purity referred to in (a) are satisfied;

(c) where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs;

(d) other rules necessary to ensure compliance with the provisions of Article 2.

Article 4

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive, or the comprehensive directive referred to in Article 3, was adopted, has detailed grounds for considering that the use of additives in food, although it complies with this Directive or any list drawn up under Article 3, endangers human health, that Member State may temporarily suspend or restrict application of the provisions in question in 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 the grounds given by the Member State referred to in paragraph 1 as soon as possible within the Standing Committee on Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to this Directive or to the comprehensive directive referred to in Article 3 are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 11, with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 5

1. In order to take account of scientific or technical developments which have occurred since the adoption of a list in accordance with Article 3, a Member State may

(1) For the purpose of this Directive, 'processing aid' means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

(2) OJ No L 184, 15. 7. 1988, p. 61.

provisionally authorize the marketing and use within its territory of an additive from one of the categories listed in Annex I and not included in the relevant list provided that the following conditions are satisfied:

(a) the authorization shall be limited to a maximum period of two years;

(b) the Member State shall ensure that foodstuffs containing an additive which it has authorized are officially monitored;

(c) in the authorization the Member State may require that foodstuffs manufacted with the additive in question shall bear a special indication.

2. The Member State shall communicate to the other Member States and to the Commission the text of any authorization decision adopted pursuant to paragraph 1, within two months of the date on which the decision takes effect.

3. Before the two-year period stipulated in paragraph 1 (a) has expired the Member State may request the Commission to include in the list adopted in accordance with Article 3 the additive which had been the subject of national authorization pursuant to paragraph 1 of this Article. At the same time, the Member State shall provide the evidence which, in its view, supports such inclusion and shall indicate how the additive is to be used. If the Commission considers this request to be justified, it shall operate the procedure laid down in Article 100a of the Treaty in order to amend the list adopted in accordance with Article 3. The Council shall act on a proposal from the Commission, within 18 months from the date on which the matter was referred to it.

4. If, within the two-year period stipulated in paragraph 1, the Commission does not submit a proposal in accordance with paragraph 3, or if the Council does not act within the 18-month period stipulated in paragraph 3, the national authorization must be cancelled. At the same time, any authorization granted by another Member State for the same additive must be cancelled.

5. No new authorization for the same additive may be granted unless the scientific or technical development made since the cancellation provided for in paragraph 4 so justifies.

Article 6

Provisions that may have effect upon public health shall be adopted after consultation with the Scientific Committee for Food.

Article 7

1. Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) — for food additives sold singly or mixed with each other, for each additive, the name laid down by any Community provisions applying and its EEC number or, in the absence of such provisions, a description of the additive that is sufficiently precise to enable it to be distinguished from additives with which it could be confused, in descending order of the proportion by weight in the total,

— when other substances or materials or food ingredients to facilitate storage, sale, standardization, dilution or dissolution of a food additive or food additives are incorporated in the additives, the name of the additive in accordance with the first indent and an indication of each component in descending order of the proportion by weight in the total;

(b) — either the statement 'for use in food',

— or the statement 'restricted use in food',

— or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and use;

(d) directions for use, if the omission thereof would preclude appropriate use of the additive;

(e) a mark identifying the batch or lot;

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

(g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions, or in their absence national provisions, applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;

(h) the net quantity;

(i) any other information provided for in the comprehensive Directive referred to in Article 3.

2. By way of derogation from paragraph 1, the information required in point (a), second indent, and points (d) to (g), may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'intended for the manufacture of foodstuffs and not for retail sale' appears on a conspicuous part of the packaging or container of the product in question.

Article 8

Food additives intended for sale to the ultimate consumer may be marketed only if their packagings or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) the name under which the product is sold. This name shall be constituted by the name laid down by any Community provisions applying to the product in question plus its EEC number or, in the absence of such provisions, by a description of the product that is sufficiently precise to enable it to be distinguished from products with which it could be confused;

(b) the information required by Article 7 (1) (a) to (f), and (h);

(c) the date of minimum durability within the meaning of Article 9 of Council Directive 79/112/EEC [1];

(d) any other information provided for in the comprehensive directive referred to in Article 3.

Article 9

Articles 7 and 8 shall not affect more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures, or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or the transport of such substances.

Article 10

Member States shall refrain from laying down requirements more detailed than those contained in Articles 7 and 8 concerning the manner in which the particulars provided for therein are to be shown.

The particulars provided for in Articles 7 and 8 shall appear in a language easily understandable to 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 11

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on 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 12

1. Member States shall take all measures necessary to ensure that food additives belonging to the categories defined in Annex I may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto.

2. Member States may not prohibit, restrict or obstruct the marketing of food additives, food or food ingredients on grounds relating to food additives, if these comply with the provisions of this Directive, the existing specific directives and the comprehensive directive referred to in Article 3.

3. Paragraph 2 shall not affect national provisions applicable in the absence of corresponding provisions in the comprehensive directive referred to in Article 3.

Article 13

Measures to bring existing Community directives into line with this Directive shall be adopted according to the procedure laid down in Article 11.

Article 14

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

— authorize, two years after notification of this Directive, the marketing and use of food additives complying with this Directive;

[1] OJ No L 33, 8. 2. 1979, p. 1.

— prohibit, not later than three years after notification (1) of this Directive, the marketing and use of food additives which do not comply with this Directive.

2. Paragraph 1 shall not affect existing Community provisions or those national provisions which, in the absence of the comprehensive directives referred to in Article 3, apply to certain groups of food additives or specify the foodstuffs in or on which food additives complying with this Directive may be used.

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

(1) This Directive was notified to the Member States on 28 December 1988.

ANNEX I

Categories of food additives

Colour
Preservative
Anti-oxidant
Emulsifier
Emulsifying salt
Thickener
Gelling agent
Stabilizer (1)
Flavour enhancer
Acid
Acidity regulator (2)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (3)
Flour treatment agent
Firming agent
Humectant
Sequestrant (4)
Enzyme (4) (5)
Bulking agent
Propellent gas and packaging gas

(1) This category also comprises foam stabilizers.
(2) These can act as two-way acidity regulators.
(3) These substances include lubricants.
(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.
(5) Only those used as additives.

ANNEX II

General criteria for the use of food additives

1. Food additives can be approved only provided that:

— there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,

— they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,

— they do not mislead the consumer.

2. The use of food additives may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as 'need'. The use of food additives should serve one or more of the purposes set out from points (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

(d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3. To assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

4. All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

5. Food additives must at all times comply with the approved criteria of purity.

6. Approval for food additives must:

(a) specify the foodstuffs to which these additives may be added and the conditions under which they may be added;

(b) be limited to the lowest level of use necessary to achieve the desired effect;

(c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups.