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ภาคผนวก

ภาคผนวก ก

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,

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 (1)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (2)
Flour treatment agent
Firming agent
Humectant
Sequestrant (3)
Enzyme (3) (4)
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.

ภาคผนวก ข

Proposal for a Council Directive on food additives other than colours and sweeteners

(92/C 206/03)

COM(92) 255 final — SYN 424

(Submitted by the Commission on 18 June 1992)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Having regard to Council Directive 89/107/EEC 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 (1), and in particular Article 3 (2),

Whereas, differences between national laws relating to preservatives, antioxidants and other additives and their conditions of use hinder the free movement of foodstuffs; whereas these may create conditions of unfair competition;

Whereas, the prime consideration for any rules on these food additives and their conditions of use should be the need to protect the consumer;

Whereas a food additive may only be used when there is evidence that the use of this additive has an advantage for the consumer;

Whereas it is generally recognized that unprocessed foodstuffs and certain other foodstuffs should be free from food additives;

Whereas, having regard to the most recent scientific and toxicological information on these substances some of these are to be permitted only for certain foodstuffs and under certains conditions of use;

Whereas it is necessary to lay down strict rules for the use of food additives in infant formula, follow-on formula, and weaning foods, as mentioned in Directive 89/398/EEC (2), and in particular Article 4 (1) (c);

Whereas this directive does not intend to affect rules relating to sweeteners and colours;

Whereas, awaiting for specific provisions pursuant to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (3), and under Council Directive 90/642/EEC of 27 November 1990 on fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (4), certain substances belonging to this category are provisionally covered by this Directive;

Whereas the Commission shall adapt Community provisions to accord with the rules laid down in this Directive,

Whereas the Scientific Committee for Food has been consulted for those substances not yet being the subject of a Community provision;

Whereas it is necessary to include in this Directive specific provisions concerning additives mentioned in other Community provisions;

Whereas it is desirable that when a decision on whether a particular foodstuff belongs to a certain category of foods, the consultation of the Standing Committee for Food procedure is followed;

Whereas the modification of existing purity criteria on food additives other than colours and sweeteners and new specifications for those where no purity criteria exist, will be adopted in accordance with the procedure of Article 11 of Directive 89/107/EEC;

Whereas flour treatment agents are still lacking the opinion of the Scientific Committee for Food, they will be the subject of a separate directive;

Whereas this Directive replaces Directives 64/54/EEC (5), 70/357/EEC (6), 74/329/EEC (7) and 83/463/EEC (8) these are hereby repealed,

(1) OJ No L 40, 11. 2. 1989, p. 27.
(2) OJ No L 186, 30. 6. 1985, p. 27.
(3) OJ No L 230, 19. 8. 1991, p. 1.
(4) OJ No L 350, 14. 12. 1990, p. 71.
(5) OJ No L 12, 27. 1. 1964, p. 161/164.
(6) OJ No L 157, 18. 7. 1970, p. 31.
(7) OJ No L 189, 12. 7. 1974, p. 1.
(8) OJ No L 255, 15. 9. 1983, p. 1.

OPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive forming a part of the comprehensive Directive within the meaning of Article 3 of Directive 89/107/EEC applying to additives other than colours, sweeteners and flour treatment agents.

2. For the purpose of this Directive:

— *preservatives* are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms,

— *antioxidants* are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes,

— *carriers*, including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technological effect to themselves) in order to facilitate its handling, application or use,

— *acids* are substances which increase the acidity of a foodstuff and/or impart a sour taste to it,

— *acidity regulators* are substances which alter or control the acidity or alkalinity of a foodstuff,

— *anti-caking agents* are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another,

— *anti-foaming agents* are substances which prevent or reduce foaming,

— *bulking agents* are substances which contribute to the bulk of a foodstuff without contributing significantly to its available energy value,

— *colour stabilizers* are substances which stabilize, retain or intensify the colour of a foodstuff,

— *emulsifiers* are substances which make it possible to form or maintain a uniform mixture of two or more immiscible phases such as oil and water in a foodstuff,

— *emulsifying salts* are substances which rearrange cheese proteins in the manufacture of processed cheese, in order to prevent fat separation,

— *firming agents* are substances which make or keep tissues of fruit or vegetable firm or crisp, or interact with gelling agents to produce or strengthen a gel,

— *flavour enhancers* are substances which enhance existing taste and/or odour of a foodstuff,

— *foaming agents* are substances which make it possible to form a uniform dispersion of a gaseous phase in a liquid or solid foodstuff,

— *gelling agents* are substances which give a foodstuff texture through formation of a gel,

— *glazing agents* (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating; inedible and easily separable coatings are not considered to be glazing agents,

— *humectants* are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium,

— *modified starches* are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached,

— *packaging gases* are gases other than air, introduced into a container before, during or after the placing of foodstuff in that container,

— *propellants* are gases other than air which expel a foodstuff from a container,

— *raising agents* are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter,

— *sequestrants* are substances which form chemical complexes with metallic ions,

— *stabilizers* are substances which make it possible to maintain a uniform dispersion of two or more immiscible substances in a foodstuff. Stabilizers include foam stabilizers,

— *thickeners* are substances which increase the viscosity of a foodstuff.

3. Flour treatment agents other than emulsifiers are substances which are added to flour or dough to improve its baking quality.

4. In application of Article 1 of Directive 89/107/EEC the following are not considered as food additives:

(a) substances used for the treatment of drinking water;

(b) products containing pectin and derived from apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial

neutralization with sodium or potassium salts ('liquid pectin');

(c) chewing-gum bases;

(d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function.

Article 2

1. Only substances listed in Annexes I, III, IV and V may be used in foodstuffs for the purposes mentioned in Article 1 (2).

2. Food additives listed in Annex I are generally permitted in foodstuffs for the purposes mentioned in Article 1 (2).

3. Paragraph 2 does not apply to:

(a) unprocessed foodstuffs and honey, virgin oils, butter, pasteurized and sterilized (including UHT sterilization) milk and cream (including skimmed, plain and semi-skimmed), mineral waters as mentioned in Directive 80/777/EEC (1), coffee and tea and sugars as mentioned in Directive 73/437/EEC (2), except where specially provided for.

Within the meaning of this Directive, unprocessed foodstuffs are foodstuffs that have not undergone any treatment resulting in a substantial change of the original state of the foodstuffs. However, they may have been, for example, divided, parted, severed, boned, skinned, pared, peeled, ground, cut, cleaned, trimmed, chilled, frozen, deep-frozen, unpacked or packed in the presence or not of packaging gases;

(b) infant formula, follow-on formula and weaning foods, as mentioned in Directive 89/398/EEC. These foodstuffs are subject to the provisions of Annex VI;

(c) chocolate and cocoa as mentioned in Directive 73/241/EEC (3), fruit juices as mentioned in Directive 75/726/EEC (4), jams, jellies and marmalades as mentioned in Directive 79/693/EEC (5), partially or totally dehydrated milks as mentioned in Directive 76/118/EEC (6).

These foodstuffs may only contain additives mentioned in Annexes II, III and IV and under the conditions specified therein.

4. Additives listed in Annexes III and IV may only be used in the foodstuffs mentioned in these annexes and under the conditions specified therein.

5. Additives listed in Annex V may be used as carriers or carrier solvents under the conditions specified therein.

6. Maximum levels indicated in the Annexes refer to foodstuffs as marketed, unless otherwise stated.

Article 3

1. Without prejudice to other Community provisions, the presence of a food additive in a foodstuff is permissible:

— in a compound foodstuff to the extent that the food additive is permitted in the separate ingredients that make up the compound foodstuff,

or

— if the foodstuff is destined to be used solely in the preparation of another foodstuff and to such an extent that the compound foodstuff conforms to the provisions of this Directive.

2. Paragraph 1 does not apply to infant formula, follow-on formula and weaning foods, as mentioned in Directive 89/398/EEC, except where specially provided for.

Article 4

This Directive shall apply without prejudice to specific directives permitting additives listed in the annexes to be used as sweeteners or colours.

Article 5

Where necessary, it may be decided by the procedure laid down in Article 7 of this Directive:

— whether a particular foodstuff belongs to a category of foodstuffs mentioned in Article 2 or in one of the Annexes,

or

— whether a food additive listed in Annex I is used in accordance with the criteria mentioned in Annex I,

or

— whether a substance is a food additive in the sense of Article 1.

(1) OJ No L 229, 30. 8. 1980, p. 1.
(2) OJ No L 356, 27. 12. 1973, p. 71.
(3) OJ No L 228, 16. 8. 1973, p. 23.
(4) OJ No L 311, 1. 2. 1975, p. 40.
(5) OJ No L 205, 13. 8. 1979, p. 5.
(6) OJ No L 24, 30. 1. 1976, p. 49.

Article 6

Any provision necessary to adapt existing Community provisions to the rules laid down in this Directive shall be adopted within six months of its notification according to the procedure laid down in Article 7 of this Directive.

Article 7

The Commission is assisted by the Standing Committee for Foodstuffs as created by Council Decision 69/414/EEC (1).

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.

Article 8

In accordance with the General Criteria of point 4 of Annex II to Directive 89/107/EEC, within five years from the adoption of this Directive, the Commission shall review the conditions of use mentioned in this Directive, and propose modifications where necessary.

Article 9

1. Directives 64/54/EEC, 70/357/EEC, 74/329/EEC, 83/463/EEC and their subsequent modifications are hereby repealed.

2. References to these repealed Directives and to the purity criteria of certain food additives mentioned in them shall be henceforth understood to be references to this Directive.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1993 in order to:

— allow trade in and use of products conforming to this Directive not later than 1 January 1993,

— prohibit trade in and use of products not conforming to this Directive not later than 1 January 1994.

They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 11

This Directive is adressed to the Member States.

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

ANNEX I

GENERALLY PERMITTED FOOD ADDITIVES

Notes

1. Substances in this list may be added to all foodstuffs with the exception of those mentioned in Annex II following the *quantum satis* principle. *Quantum satis* means that no maximum level is specified. However, these food additives should be used according to good manufacturing practice at a level not higher than is necessary to achieve the intended purpose, and provided they do not mislead the consumer.

2. The substances listed under EEC number E 440 may be standardized with sugars, on condition that this is stated in addition to its number and designation.

EEC No	Name
E 170	Calcium carbonates (i) Calcium carbonate (ii) Calcium hydrogen carbonate
E 260	Acetic acid
E 261	(i) Potassium acetate
E 262	Sodium acetates (i) Sodium acetate (ii) Sodium hydrogen acetate (sodium diacetate)
E 263	Calcium acetate
E 270	Lactic acid
E 290	Carbon dioxide (1)
E 296	Malic acid
E 300	Ascorbic acid
E 301	Sodium ascorbate
E 302	Calcium ascorbate
E 304	Fatty acid esters of ascorbic acid (i) Ascorbyl palmitate (ii) Ascorbyl stearate
E 306	Tocopherol-rich extract
E 307	Alpha-tocopherol
E 308	Gamma-tocopherol
E 309	Delta-tocopherol
E 322	Lecithins
E 325	Sodium lactate
E 326	Potassium lactate
E 327	Calcium lactate
E 330	Citric acid
E 331	Sodium citrates (i) Monosodium citrate (ii) Disodium citrate (iii) Trisodium citrate
E 332	Potassium citrates (i) Monopotassium citrate (ii) Tripotassium citrate
E 333	Calcium citrates (i) Monocalcium citrate (ii) Dicalcium citrate (iii) Tricalcium citrate
E 334	Tartaric acid (L(+)–)
E 335	Sodium tartrates (i) Monosodium tartrate (ii) Disodium tartrate

(1) May be used as packaging gases in the foodstuffs mentioned in Article 2 (3), except E 942 — Nitrous oxide in infant formula, follow-on formula and weaning foods.

EEC No	Name
E 336	Potassium tartrates (i) Monopotassium tartrate (ii) Dipotassium tartrate
E 337	Sodium potassium tartrate
E 350	Sodium malates (i) Sodium malate (ii) Sodium hydrogen malate
E 351	(i) Potassium malate
E 352	Calcium malates (i) Calcium malate (ii) Calcium hydrogen malate
E 354	Calcium tartrate
E 380	Triammonium citrate
E 400	Alginic acid
E 401	Sodium alginate
E 402	Potassium alginate
E 403	Ammonium alginate
E 404	Calcium alginate
E 406	Agar
E 410	Locust bean gum
E 412	Guar gum
E 413	Tragacanth
E 414	Acacia gum (gum arabic)
E 415	Xanthan gum
E 417	Tara gum
E 418	Gellan gum
E 422	Glycerol
E 440	Pectins (i) pectin (ii) amidated pectin
E 460	Cellulose (i) Microcrystalline cellulose (ii) Powdered cellulose
E 470(a)	Sodium, potassium and calcium salts of fatty acids
E 470(b)	Magnesium salts of fatty acids
E 471	Mono- and diglycerides of fatty acids
E 472(a)	Acetic acid esters of mono- and diglycerides of fatty acids
E 472(b)	Lactic acid esters of mono- and diglycerides of fatty acids
E 472(c)	Citric acid esters of mono- and diglycerides of fatty acids
E 472(d)	Tartaric acid esters of mono- and diglycerides of fatty acids
E 472(e)	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids
E 472(f)	Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
E 500	Sodium carbonates (i) Sodium carbonate (ii) Sodium hydrogen carbonate (iii) Sodium sesquicarbonate
E 501	Potassium carbonates (i) Potassium carbonate (ii) Potassium hydrogen carbonate
E 503	Ammonium carbonates (i) Ammonium carbonate (ii) Ammonium hydrogen carbonate
E 504	Magnesium carbonates (i) Magnesium carbonate (ii) Magnesium hydroxide carbonate (syn.: Magnesium hydrogen carbonate)

EEC No	Name
E 507	Hydrochloric acid
E 508	Potassium chloride
E 509	Calcium chloride
E 511	Magnesium chloride
E 513	Sulphuric acid
E 514	Sodium sulphates (i) Sodium sulphate (ii) Sodium hydrogen sulphate
E 515	Potassium sulphates (i) Potassium sulphate (ii) Potassium hydrogen sulphate
E 516	Calcium sulphate
E 518	Magnesium sulphate
E 524	Sodium hydroxide
E 525	Potassium hydroxide
E 526	Calcium hydroxide
E 527	Ammonium hydroxide
E 528	Magnesium hydroxide
E 529	Calcium oxide
E 530	Magnesium oxide
E 570	Fatty acids
E 574	Gluconic acid
E 575	Glucono-delta-lactone
E 576	Sodium gluconate
E 577	Potassium gluconate
E 578	Calcium gluconate
E 620	Glutamic acid
E 621	Monosodium glutamate
E 622	Monopotassium glutamate
E 623	Calcium diglutamate
E 624	Monoammonium glutamate
E 625	Magnesium diglutamate
E 640	Glycine and its sodium salt
E 938	Argon (1)
E 939	Helium (1)
E 941	Nitrogen (1)
E 942	Nitrous oxide (1)
E 947	Hydrogen (1)
E 948	Oxygen (1)
E 1200	Polydextrose
E 1404	Oxidized starch
E 1410	Monostarch phosphate
E 1412	Distarch phosphate
E 1413	Phosphated distarch phosphate
E 1414	Acetylated distarch phosphate
E 1420	Acetylated starch
E 1422	Acetylated distarch adipate
E 1440	Hydroxy propyl starch
E 1442	Hydroxy propyl distarch phosphate
E 1450	Starch sodium octenyl succinate
E 1518	Glyceryl triacetate (Triacetin)

(1) May be used as packaging gases in the foodstuffs mentioned in Article 2 (3), except E 942 — Nitrous oxide in infant formula, follow-on formula and weaning foods.

ANNEX II

FOODSTUFFS IN WHICH A LIMITED NUMBER OF ADDITIVES OF ANNEX I MAY BE USED

Foodstuff	Additive		Maximum level
Cocoa and chocolate products as mentioned in Directive 73/241/EEC (1)	E 330	Citric acid	0,5 %
	E 322	Lecithine	*Quantum satis*
	E 334	Tartaric acid	0,5 %
	E 422	Glycerol	*Quantum satis*
	E 471	Mono and diglycerides of fatty acids	*Quantum satis*
	E 500	Sodium carbonates	5 % on dry material without fat
	E 501	Potassium carbonates	
	E 503	Ammonium carbonates	
	E 504	Magnesium carbonates	
	E 524	Sodium hydroxide	
	E 525	Potassium hydroxide	
	E 526	Calcium hydroxide	
	E 527	Ammonium hydroxide	
	E 528	Magnesium hydroxide	
	E 530	Magnesium oxide	
	E 1200	Polydextrose	*Quantum satis*
Fruit juices and nectars as mentioned in Directive 73/437/EEC (2)	E 290	Carbon dioxide	*Quantum satis*
	E 300	Ascorbic acid	*Quantum satis*
Pineapple juice as mentioned in Directive 73/437/EEC (2)	E 296	Malic acid	3 g/l
	E 330	Citric acid	3 g/l
Nectars mentioned in Directive 73/437/EEC (2)	E 330	Citric acid	5 g/l
	E 270	Lactic acid	5 g/l
Grape juice as defined in Directive 73/437/EEC (2)	E 170	Calcium carbonates	*Quantum satis*
	E 336	Potassium tartrates	*Quantum satis*
Jams, jellies, marmelades and chestnut puree as defined in Directive 79/693/EEC (3)	E 170	Calcium carbonate	200 mg Ca/kg
	E 270	Lactic acid	*Quantum satis*
	E 440	Pectins	*Quantum satis*
	E 296	Malic acid	*Quantum satis*
	E 352	Calcium malate	*Quantum satis*
	E 350	Sodium malate	*Quantum satis*
	E 509	Calcium chloride	200 mg/kg
	E 578	Calcium gluconate	200 mg/kg
	E 500	(i) Sodium carbonate	*Quantum satis*
	E 500	(ii) Sodium bicarbonate	*Quantum satis*
	E 300	Ascorbic acid	*Quantum satis*
	E 325	Sodium lactate	*Quantum satis*
	E 330	Citric acid	*Quantum satis*
	E 331	Sodium citrate	*Quantum satis*
	E 333	Calcium citrate	*Quantum satis*
	E 334	Tartaric acid	*Quantum satis*

(1) OJ No L 228, 16. 8. 1973, p. 23.
(2) OJ No L 356, 27. 12. 1973, p. 71.
(3) OJ No L 205, 13. 8. 1979, p. 5.

Foodstuff	Additive		Maximum level
	E 335	Sodium tartrate	*Quantum satis*
	E 327	Calcium lactate	*Quantum satis*
	E 400	Alginic acid	10 g/kg
	E 401	Sodium alginate	10 g/kg
	E 402	Potassium alginate	10 g/kg
	E 403	Ammonium alginate	10 g/kg
	E 404	Calcium alginate	10 g/kg
	E 410	Locust bean gum	10 g/kg
	E 471	Mono and diglycerides of fatty acids	*Quantum satis*
	E 524	Sodium hydroxide	*Quantum satis*
Partially dehydrated and dehytrated milk as mentioned in Directive 76/118/EEC (1)	E 300	Ascorbic acid	*Quantum satis*
	E 301	Sodium ascorbate	*Quantum satis*
	E 304	Fatty esters of ascorbic acid	*Quantum satis*
	E 307	Alpha-tocopherol	*Quantum satis*
	E 308	Gamma-tocopherol	*Quantum satis*
	E 309	Delta-tocopherol	*Quantum satis*
	E 322	Lecithin	*Quantum satis*
	E 331	Sodium citrate	*Quantum satis*
	E 332	Potassium citrate	*Quantum satis*
	E 500	(ii) Sodium bicarbonate	*Quantum satis*
	E 501	(ii) Potassium bicarbonate	*Quantum satis*
	E 509	Calcium chloride	*Quantum satis*
Sterilized and UHT cream	E 270	Lactic acid	*Quantum satis*
	E 322	Lecithine	*Quantum satis*
	E 330	Citric acid	*Quantum satis*
	E 400	Alginic acid	*Quantum satis*
	E 440	Pectins	*Quantum satis*
		Modified starches	*Quantum satis*

(1) OJ No L 24, 30. 1. 1976, p. 49.

ANNEX III

CONDITIONALLY PERMITTED PRESERVATIVES AND ANTIOXIDANTS

A. Sorbates, benzoates and p-hydroxybenzoates

EEC No	Name	Abbreviations
E 200	Sorbic acid	Sa
E 202	Potassium sorbate	
E 203	Calcium sorbate	
E 210	Benzoic acid	Ba (1)
E 211	Sodium benzoate	
E 212	Potassium benzoate	
E 213	Calcium benzoate	
E 214	Ethyl p-hydroxybenzoate	PHB
E 215	Sodium ethyl p-hydroxybenzoate	
E 216	Propyl p-hydroxybenzoate	
E 217	Sodium propyl p-hydroxybenzoate	
E 218	Methyl p-hydroxybenzoate	
E 219	Sodium methyl p-hydroxybenzoate	

(1) Benzoic acid may be present in certain fermented products resulting from fermentation processes following good manufacturing practice.

Notes

1. The levels of all substances mentioned above are calculated as the free acid.
2. The abreviations used in the table mean the following:
   - Sa + Ba: Sa and Ba used singly or in combination
   - Sa + PHB: Sa and PHB used singly or in combination
   - Sa + Ba + PHB: Sa, Ba and PHB used singly or in combination.
3. The maximum levels of use indicated refer to foodstuffs ready for consumption prepared following manufacturers' instructions.

Foodstuffs	Maximum level (in mg/kg or mg/l as appropriate)					
	Sa	Ba	PHB	Sa + Ba	Sa + PHB	Sa + Ba + PHB
Dairy-based flavoured drinks	—	200	—	300 (of which 200 Ba maximum)	—	—
Wine-based flavoured drinks	100	—	—	—	—	—
Water-based or fruit-juice-based drinks	500 (1)	200	—	200 Sa + 200 Ba (1)	—	—
Liquid tea concentrates and liquid fruit and herbal infusions concentrates	—	—	—	600	—	—
Alcohol-free wine	—	—	—	300	—	—
Grape juice, unfermented, for sacramental use	—	—	—	2 000	—	—
Wines	200	—	—	—	—	—
Fermented fruit juices	500 (1)	200	—	200 Sa + 200 Ba (1)	—	—
Mead	300	—	—	—	—	—
Spirituous beverages with not more than 15 % alcohol content	—	—	—	250	—	—

(1) Either use Sa or a combination of Sa + Ba.

Foodstuffs	Maximum level (in mg/kg or mg/l as appropriate)					
	Sa	Ba	PHB	Sa + Ba	Sa + PHB	Sa + Ba + PHB
Fillings of ravioli and similar products	1 000	—	—	—	—	—
Jams, jellies, marmalades and similar products, energy-reduced or sugar-free and other fruit based spreads	—	—	—	1 500	—	—
Candied fruit	—	—	—	1 000	—	—
Dried fruit	1 000	—	—	—	—	—
Fruit-based desserts	—	—	—	1 000	—	—
Fruit and vegetable preparations and fruit syrups	—	—	—	1 500	—	—
Vegetables in vinegar, brine or oil	—	—	—	2 000	—	—
Potato dough	2 000	—	—	—	—	—
Meat products, cooked or cured or dried, surface treatment only (gelatin coatings included)	—	—	—	—	—	*Quantum satis*
Semi-preserved fish products	—	—	—	4 000	—	—
Fish-roe products	—	—	—	4 000	—	—
Shrimps, cooked	—	—	—	4 000	—	—
Crangon crangon and *Crangon vulgaris* (Brown shrimp), cooked	—	—	—	8 000	—	—
Milk, heat-treated fermented	—	—	—	300	—	—
Milk, renneted	—	—	—	1 000	—	—
Cheese, prepacked sliced	1 000	—	—	—	—	—
Unripened cheese	1 000	—	—	—	—	—
Processed cheese	2 000	—	—	—	—	—
Dairy-based desserts	—	—	—	1 000	—	—
Liquid egg (white, yolk or whole egg)	—	—	—	10 000	—	—
Prepacked sliced bread and rye-bread	2 000	—	—	—	—	—
Prebaked bakery wares intended for retail sale	2 000	—	—	—	—	—
Fine bakery wares with a water activity of more than 0,65	2 000	—	—	—	—	—
Cereal or potato based snacks and coated nuts	—	—	—	—	1 000 (of which 300 PHB maximum)	—
Cake mixes	—	—	—	—	2 000 (of which 300 PHB maximum)	—
Batters	2 000	—	—	—	—	—
Sugar, nut or fat-based confectionery	—	—	—	—	—	2 000 (of which 300 PHB maximum
Cocoa-based confectionery (excluding chocolate)	—	—	—	1 500	—	—
Chewing gum	—	—	—	1 500	—	—
Sugar toppings (syrups for pancakes etc)	—	—	—	1 500	—	—

Foodstuffs	Maximum level (mg/kg or mg/l as appropriate)					
	S_2	B_2	PHB	S_2 + B_2	S_2 + PHB	S_2 + B_2 + PHB
Fat emulsions	—	—	—	2 000	—	—
Emulsified sauces	—	—	—	2 000	—	—
Non-emulsified sauces	—	—	—	1 200	—	—
Salads	—	—	—	1 500	—	—
Mustard	—	—	—	1 000	—	—
Seasonings, condiments and mixed spices	—	—	—	1 000	—	—
Soups and broths	—	—	—	500	—	—
Dietary food supplements	—	—	—	2 000	—	2 000
Dietetic foods intended for special medical purposes — Dietetic formula for weight control intended to replace total daily food intake or an individual meal	—	—	—	1 500	—	—

B. Sulphur dioxide and sulphites

EEC No	Name
E 220	Sulphur dioxide
E 221	Sodium sulphite
E 222	Sodium hydrogen sulphite
E 223	Sodium metabisulphite
E 224	Potassium metabisulphite
E 226	Calcium sulphite
E 227	Calcium hydrogen sulphite
E 228	Potassium hydrogen sulphite

Notes

1. Maximum levels are expressed as SO_2 in mg/kg or mg/l as appropriate and relate to the total quantity, available from all sources.
2. An SO_2 content of not more than 10 mg/kg or 10 mg/l is not considered to be present.

Foodstuffs	Maximum level expressed as SO_2 (mg/kg or mg/l as appropriate)
'Burger meat' with a minimum vegetable and/or cereal content of 4 %	450
'Breakfast sausages' with a minimum cereal content of 6 %	450
'Longaniza fresca' and 'butifarra fresca'	450
Dried cod	200
Crustaceans and cephalopods	
— fresh and frozen	100
— cooked	30 } in edible parts
Fine bakery wares	50
Starches (excluding starches for weaning foods, follow-on formula)	50
Starches and modified starches for weaning foods, follow-on formula and infant formula	10

Foodstuffs	Maximum level expressed as SO_2 (mg/kg or mg/l as appropriate)
Sago	30
Pearled barly	30
Dehydrated granulated potatoes	500
Cereal and potato based snacks	100
Peeled potatoes	50
Processed potatoes (including frozen potatoes)	100
Potato dough	100
White vegetables, dried	500
White vegetables, processed (including frozen white vegetables)	50
White cardamom, cumin and caraway seed	500
Dried ginger	500
Dried tomatoes	500
Horseradish pulp	1 000
Onion, garlic and shallot pulp	300
Onions in vinegar	300
Other vegetables and fruits in vinegar, oil or brine	100
Processed mushrooms (including frozen mushrooms)	100
Dried fruits	
— apricots, peaches, pears, grapes, prunes and figs	2 000
— bananas	1 000
— apples	1 500
— other (including shell nuts)	500
Dried coconut	50
Peeled fruit and citrus peel	100
Candied fruit and candied citrus peel	100
Jam, jelly and marmalade as meant in Directive 79/693/EEC (1)	50
Energy reduced jam, jelly and marmalade	50
Other fruit based sandwich spreads	50
Fruit preparations	200
Citrus juice based seasonings	300
Concentrated grape juice for home wine making	2 000
Fruit mustard, fruit curd and fruit chutney	100
Jellying fruit extract, liquid pectin	
— for sale to the final consumer	800
Canned and bottled fruit (with heart cherries, mixtures with white heart cherries, rehydrated dried fruit and lychees and sliced lemon)	100
Sugars as meant in Directive 73/437/EEC (2)	15
— except glucose syrup, whether or not dehydrated:	20
Other sugars	40
Sugar toppings (syrups for pancakes etc.)	40

(1) OJ No L 205, 13. 8. 1979, p. 5.
(2) OJ No L 356, 27. 12. 1973, p. 71.

Foodstuffs	Maximum level expressed as SO_2 (mg/kg or mg/l as appropriate)
Concentrates of citrus fruit juice, apple juice and pineapple juice	350
Orange, grapefruit, apple and pineapple juice	50
Lime and lemon juice	350
Concentrates based on fruit juice and containing not less than 0,5 % barley on a ready to drink basis	350
Other concentrates based on fruit juice or comminuted fruit	250
Non-alcoholic fruit juice based drinks	20 (carry-over from concentrates only)
Water based flavoured drinks containing glucose syrup as the main carbohydrate	50
Grape juice, unfermented, for sacramental use	70
Grape juice	15
Glucose-based confectionery	50
Beer, including low and alcohol free beer	30
Cask-conditioned beer	50
Wines	as in Regulation (EEC) No 822/87 (1)
Alcohol-free wine	200
Cider, perry, fruit wine, sparkling fruit wine	200
Mead	100
Fermentation vinegar	170
Mustard, excluding Dijon mustard	250
Dijon mustard	500
Gelatin	50
Vegetable and cereal proteins	200
Vegetable and cereal protein-based meat, fish and crustacean analogues	200

(1) OJ No L 84, 27. 3. 1987, p. 1.

C. Other preservatives

EEC No	Name	Foodstuffs	Maximum level
E 230	Biphenyl, diphenyl	Surface treatment of citrus fruit	70 mg/kg
E 231	Orthophenyl phenol	Surface treatment of citrus fruit	12 mg/kg singly or in combination expressed as orthophenyl phenol
E 232	Sodium orthophenyl phenol		
E 233	Thiabendazole	Surface treatment of	
		— citrus fruit	6 mg/kg
		— bananas	3 mg/kg
E 234	Nisin	Semolina and tapioca puddings	1 mg/kg
		Cheese and processed cheese	12,5 mg/kg
E 235	Natamycin	Surface treatment of	
		— hard, semi-hard and semi-soft cheese	1 mg/dm² surface (not present at a depth of 5 mm)
		— dried, cured sausages	
E 236	Formic acid	Sauces	200 mg/kg
E 237	Sodium formate	Non-alcoholic water based flavoured drinks	100 mg/l
E 238	Calcium formate	Preserves of gherkins	1 000 mg/kg (expressed as formic acid)

EEC No	Name	Foodstuffs	Maximum level
E 239	Hexamethylene tetramine	'Provolone' cheese	25 mg/kg (residual amount, expressed as formaldehyde)
E 242	Dimethyl dicarbonate	Non-alcoholic water based and fruit juice based flavoured drinks	250 mg/l
		Canned liquid tea and herbal infusions	250 mg/l
		Alcohol free wine	250 mg/l (ingoing amount, residues not detectable)
	Boric acid and sodium tetraborate (borax)	Caviar	4 g/kg (expressed as boric acid)

EEC No	Name	Foodstuffs	Ingoing amount (in mg/kg)	Residual amount (in mg/kg)
E 249	Potassium nitrite (1)	Non-heat treated, cured, dried meat products	150 (2)	50 (3)
E 250	Sodium nitrite (1)	Other cured meat products	150 (2)	100 (3)
		Cured bacon		175 (4)
E 251	Sodium nitrate	Cured meat products	300 (2)	
E 252	Potassium nitrate	Hard and semi-hard cheese and analogues based on vegetable fat or vegetable protein		50 (3)
		Pickled herring and sprat		200 (4)

(1) When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.
(2) Residual amount at point of sale to the final consumer, expressed as $NaNO_3$.
(3) Expressed as $NaNO_3$.
(4) Residual amount, nitrite formed from nitrate included, expressed as $NaNO_3$.
(5) Espressed as $NaNO_3$.

EEC No	Name	Foodstuffs	Maximum level
E 280	Propionic acid (1)	Prepacked sliced bread	1 000 mg/kg (expressed as propionic acid)
E 281	Sodium propionate (1)	Energy reduced bread	
E 282	Calcium propionate (1)	Partially baked and packed bread	
		Prepacked fine bakery wares (including flour confectionery) with a water activity of more than 0,65	
E 283	Potassium propionate (1)	Rye bread	3 000 mg/kg (expressed as propionic acid)
E 1105	Lysozyme	Cheese	*Quantum satis*

(1) Propionic acid and its salts may be present in certain fermented products resulting from the fermentation process following good manufacturing practice.

D. Other antioxidants

Notes

1. Maximum levels are expressed in mg/kg and relate to the levels at the point of sale to the final consumer.
2. The * in the table refers to the proportionality rule: when combinations of gallates, BHA and BHT are used, the individual levels must be reduced proportionally.

EEC No	Name	Foodstuffs	Maximum level
E 310 E 311 E 312 E 320 E 321	Propyl gallate Octyl gallate Dodecyl gallate Butylated hydroxyanisole (BHA) Butylated hydroxytoluene (BHT)	Fats and oils for the professional manufacture of heat-treated foodstuffs Frying oil and frying fat Lard, tallow, fish oil, poultry and sheep fat	200* (gallates and BHA, singly or in combination) 100* (BHT) both
		Cereal-based snack foods Milk powder for vending machines Soups and broths Sauces Spices Preserved fish products and fish preserves	expressed on fat 200* (gallates and BHA, singly or in combination)
		Processed nuts	200 (gallates and BHA, singly or in combination)
		Dehydrated potato products Precooked cereals Breakfast cereals	25 (gallates and BHA singly or in combination)
		Chewing gum Dietary supplements	400 (gallates, BHA and BHT, singly or in combination)
E 315 E 316	Erythorbic acid Sodium erythorbate	Semi-preserved and preserved meat products Preserved and semi-preserved fish products Jams, jellies, marmalades, and similar products Primary egg products	500 1 500 200 1 000
E 1102	Glucose oxidase	Non-alcoholic water or fruit-juice-based drinks Sauces	*Quantum satis*

ANNEX IV

OTHER PERMITTED ADDITIVES

Notes

1. The maximum levels of use indicated refer to foodstuffs ready for consumption prepared following manufacturers' instructions.
2. The substances listed under number E 407 may be standardized with sugars, on condition that this is stated in addition to its numer and designation.

EEC No	Name	Foodstuffs	Maximum level
E 297	Fumaric acid	*Pro memoria:* Wine in respect of Regulation (EEC) No 1873/84 (1)	
		Fillings and toppings for fine bakery wares	4 g/kg
		Sugar confectionery	5 g/kg
		Desserts (jelly-like and fruit-flavoured)	4 g/kg
		Surimi, minced and creamed fish	1 g/kg
		Tea and herbal infusions, instant tea	5 g/kg
		Chewing gum	5 g/kg
In the following applications, phosphoric acid and the phosphates E 338, E 339, E 340, E 341, E 450, E 451 and E 452 may be used singly or in combination up to the maximum level, which is expressed as P_2O_5 in w/w.			
E 338	Phosphoric acid	Non-alcoholic flavoured drinks	700 mg/l (E 338 only)
E 339	Sodium phosphates	Sterilized and UHT milk	1 g/l
	(i) Monosodium phosphate	Partly dehydrated milk with less than 28 % solids	1 g/kg
	(ii) Disodium phosphate	Partly dehydrated milk with more than 28 % solids	1,5 g/kg
	(iii) Trisodium phosphate	Dried milk and dried skimmed milk	2,5 g/kg
E 340	Potassium phosphates	Sterilized and UHT creams	5 g/kg
	(i) Monopotassium phosphate	Whipped cream and vegetable fat analogues	5 g/kg
	(ii) Dipotassium phosphate	Unripened cheese	2 g/kg
	(iii) Tripotassium phosphate	Processed cheese	20 g/kg
		Meat products	5 g/kg
		Sport drinks and prepared table waters	0,5 g/l
E 341	Calcium phosphates	Dietary supplements	*Quantum satis*
	(i) Monocalcium phosphate	Milk or vegetable proteins	20 g/kg
	(ii) Dicalcium phosphate	Beverage whiteners	30 g/kg
	(iii) Tricalcium phosphate	Beverage whiteners for vending machines	50 g/kg
E 450	Diphosphates	Edible ices	1 g/kg
	(i) Disodium diphosphate	Desserts	3 g/kg
	(ii) Trisodium diphosphate	Fine bakery wares	10 g/kg
	(iii) Tetrasodium diphosphate	Flour	2,5 g/kg
	(iv) Dipotassium diphosphate	Flour, self-raising	20 g/kg
	(v) Tetrapotassium diphosphate	Soda bread	10 g/kg
	(vi) Dicalcium diphosphate	Liquid egg (white, yolk or whole egg)	10 g/kg
	(vii) Calcium dihydrogen diphosphate	Sauces	5 g/kg

(1) OJ No L 176, 3. 7. 1984, p. 6.

EEC No	Name	Foodstuffs	Maximum level
E 451	Triphosphates	Soups and broths	3 g/kg
	(i) Pentasodium triphosphate	Tea and herbal infusions	2 g/kg
	(ii) Pentapotassium triphosphate	Cider and perry	2 g/kg
E 452	Polyphosphates	Chewing gum	*Quantum satis* (1)
	(i) Sodium polyphosphate	Dried powdered foodstuffs	10 g/kg (2)
	(ii) Potassium polyphosphate	Chocolate and malt dairy based drinks	2 g/l
	(iii) Sodium calcium polyphosphate	Alcoholic drinks excluding wine and beer	1 g/l
	(iv) Calcium polyphosphate	Breakfast cereals	10 g/kg
		Other processed foodstuffs	5 g/kg
E 431	Polyoxyethylene(40)stearate	*Pro memoria:* wine in respect of Regulation (EEC) No 1873/84	
E 353	Metatartaric acid	Wine	As specified in Regulation (EEC) No 822/87 (3)
E 355	Adipic acid	Fillings and toppings for fine bakery wares	Expressed as adipic acid 5 g/kg
E 356	Sodium adipate	Desserts (jelly-like and fruit-flavoured)	5 g/kg
E 357	Potassium adipate	Powders for home preparation of drinks	10 g/kg
		Chewing gum	20 g/kg
E 363	Succinic acid	Desserts	6 g/kg
		Soups and broths	*Quantum satis*
		Minced and creamed fish	*Quantum satis*
		Powders for home preparation of drinks	*Quantum satis*
E 385	Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA)	Emulsified sauces	75 mg/kg
		Canned and bottled pulses, legumes, mushrooms and artichokes	250 mg/kg
		Canned and bottled crustaceans	250 mg/kg
		Canned and bottled fish	75 mg/kg
		Minarine	100 mg/kg
E 405	Propane-1,2-diol alginate	Fat emulsions	3 g/kg
		Fine bakery wares	2 g/kg
		Fillings, toppings and coatings for fine bakery wares and desserts	5 g/kg
		Sugar confectionery	5 g/kg
		Water based edible ices	3 g/kg
		Cereal and potato based snacks	3 g/kg
		Sauces	10 g/kg
		Beer	100 mg/l
		Chewing gum	10 g/kg
		Fruit and vegetable preparations	5 g/kg
		Non-alcoholic flavoured drinks	300 mg/l
		Emulsified liqueur	10 g/l
		Dietetic foods intended for special medical purposes — Dietetic formula for weight control intended to replace total daily food intake or an individual meal	1 g/kg
		Dietary food supplements	1 g/kg

(1) E 341 (ii) only.
(2) E 341 (iii) only.
(3) OJ No L 84, 27. 3. 1987, p. 1.

EEC N.	Name	Foodstuffs	Maximum level
E 407	Carrageenan	Patially dehydrated milk	150 mg/l
		Dried milk	5 g/kg
		Unripened cheese	5 g/kg
		Processed cheese	5 g/kg
		Reduced fat spreads	10 g/kg
		Desserts	20 g/kg
		Sauces	20 g/kg
		Diary based drinks	500 mg/l
		Other foodstuffs	15 g/kg
E 416	Karayagum	Cereal and potato-based snacks	5 g/kg
		Nut coatings	10 g/kg
		Fillings, toppings and coatings for fine bakery wares	5 g/kg
		Desserts	6 g/kg
		Emulsified sauces	20 g/kg
		Egg based liqueurs	10 g/kg
		Dietary food supplements	*Quantum satis*
E 420	Sorbitol	Foodstuffs in general excluiding water based flavoured non-alcoholic drinks	*Quantum satis* (for purposes other than sweetening)
	(i) Sorbitol		
	(ii) Sorbitol syrup		
E 421	Mannitol		
E 953	Isomalt		
E 959	Maltitol		
	(i) Maltitol		
	(ii) Maltitol syrup		
E 966	Lactitol		
E 969	Xylitol		
E 432	Polyoxyethylene sorbitan monolaurate (polysorbate 20)	Dairy-based drinks	5 g/kg
		Fine bakery wares	3 g/kg
E 433	Polyoxyethylene sorbitan monooleate (polysorbate 80)	Fat emulsions for baking purposes	10 g/kg
		Milk- and cream analogues	5 g/kg
E 434	Polyoxyethylene sorbitan monopalmitate (polysorbate 40)	Edible ices	1 g/kg
		Desserts	3 g/kg
E 435	Polyoxyethylene sorbitan monostearate (polysorbate 60)	Sugar confectionary	1 g/kg
		Emulsified sauces	5 g/kg
E 436	Polyoxyethylene sorbitan tristearate (polysorbate 65)	Soups	1 g/kg
		Chewing gum	20 g/kg
		Dietary food supplements	*Quantum satis*
		Dietetic foods intendet for special medical purposes — Dietetic formula for weight control intendet to replace total daily food intake or an individual meal	1 g/kg
E 442	Ammonium phosfatides	Chocolate and cocoa based confectionery	10 mg/l
E 445	Glycerol esters of wood rosins	Non-alcoholic cloudy drinks	100 mg/l
		Alcoholic cloudy drinks	200 mg/l

E No.	Name	Foodstuffs	Maximum level
			Singly or in combination
E 461	Methylcellulose	Fine bakery wares	10 g/kg
E 463	Hydroxy propylcellulose	Sterilized cream	2 g/kg
E 464	Hydroxy propylmethyl cellulose	Edible ices	5 g/kg
E 465	Ethylmethyl cellulose	Desserts	5 g/kg
E 466	Carboxymethyl cellulose	Flavoured water or dairy-based drinks	2 g/l
		Solid processed foodstuffs (bread, jam, jelly, marmalade and chocolate excluded)	5 g/kg
		Soups and broths	5 g/l
		Sauces	5 g/kg
		Jelly coatings for fish and meat products	5 g/kg
		Gluten-free bakery produkts	4 g/kg
		Vegetable and cereal protein-based meat, fish and crustacean analogues	20 g/kg
		Emulsified liquers	10 g/l
		Dietetic foods intendet for special medical purposes — Dietetic formula for weight control intendet to replace total daily food intake or an individual meal	1 g/kg
		Dietary food supplements	5 g/kg
			Singly or in combination
E 471	Sucrose esters of fatty acids	Canned liquid coffee	1 g/kg
E 474	Sucroglycerides	Heat treated meat products	5 g/kg on fat
		Fat emulsions for baking purposes	10 g/kg
		Beverage whiteners	20 g/kg
		Edible ices	5 g/kg
		Sugar confectionary	5 g/kg
		Desserts	5 g/kg
		Sauces	10 g/kg
		Soups and broths	2 g/kg
		Fresh fruits, surface treatment	*Quantum satis*
		Emulsified non-alcoholic anisette	5 g/l
		Spirituous beverages (excluding wine and beer)	5 g/l
		Dietary food supplements	*Quantum satis*
		Dietetic foods intendet for special medical purposes — Dietetic formula for weight control intendet to replace total daily food intake or an individual meal	5 g/kg
		Chewing gum	10 g/kg
E 475	Polyglycerol esters of fatty acids	Fine bakery wares	10 g/kg
		Emulsified liqueurs	5 g/kg
		Egg products	1 g/kg
		Beverage whiteners	0,5 g/kg
		Chewing gum	5 g/kg
		Fat emulsions	5 g/kg
		Milk- and cream analogues	5 g/kg
		Sugar confectionary	5 g/kg
		Desserts	10 g/kg
		Dietary food supplements	*Quantum satis*
		Dietetic foods intendet for special medical purposes — Dietetic formula for weight control intendet to replace total daily food intake or an individual meal	5 g/kg
E 476	Polyglycerol polyricinoleate	Low and very low-fat spreads and dressings	4 g/kg
		Chocolate and cocoa-based confectionary	5 g/kg

EEC No	Name	Foodstuffs	Maximum level
E 477	Propane-1,2-diol esters of fatty acids	Fine bakery wares	10 g/kg
		Fat emulsions for baking purposes	20 g/kg
		Milk and cream analogues	5 g/kg
		Beverage whiteners	1 g/kg
		Edible ices	3 g/kg
		Suger confectionery	5 g/kg
		Desserts	5 g/kg
		Whipped dessert toppings other than cream	30 g/kg
		Dietetic foods intended for special medical purposes — Dietetic formula for weight control intended to replace total daily food intake or an individual meal	1 g/kg
E 479a	Thermally oxidized soya-bean oil	Fat emulsions for baking and frying purposes	4 g/kg
E 479b	Thermally oxidized soya-bean oil interacted with mono- and diglycerides of fatty acids	Fat emulsions for baking and frying purposes	10 g/kg
			Singly or in combin
E 481	Sodium stearoyl-2-lactylate	Fine bakery wares	5 g/kg
E 482	Calcium stearoyl-2-lactylate	Quick-cooking rice	4 g/kg
		Breakfast cereals	5 g/kg
		Emulsified liqueur	8 g/kg
		Cereal-based snacks	2 g/kg
		Chewing gum	2 g/kg
		Fat emulsions	10 g/kg
		Desserts	5 g/kg
		Sugar confectionery	5 g/kg
		Beverage whiteners (without phosphates)	1 g/kg
		Cereal and potato-bases snacks	5 g/kg
		Meat products	1 g/kg
		Powders for the preparation of hot beverages	2 g/kg
		Dietetic foods intended for special medical purposes — Dietetic formula for weight control intended to replace total daily foor intake or an individuel meal	2 g/kg
		Bread	5 g/kg
E 483	Stearyl tartrate	Bakery wares	5 g/kg
		Desserts	5 g/kg
			Singly or in combina
E 491	Sorbitan monostearate	Fine bakery wares	10 g/kg
E 492	Sorbitan tristearate	Jelly marmalade	25 mg/kg (for E 493 only
E 493	Sorbitan monolaurate		
E 494	Sorbitan monooleate	Fat emulsions	10 g/kg
E 495	Sorbitan monopalmitate	Milk and cream analogues	5 g/kg
		Beverage whiteners	5 g/kg
		Liquid tea concentrates an liquid fruit and herbal infusions concentrates	0,5 g/kg
		Edible ices	0,5 g/kg
		Desserts	5 g/kg
		Sugar confectionery	5 g/kg
		Chocolate and cocoa-based confectionery	10 g/kg (for E 492 only

EEC No	Name	Foodstuffs	Maximum level
E 495	*(cont'd)*	Emulsified sauces	5 g/kg
		Dietary foor supplements	*Quantum satis*
		Yeasts for baking purposes	10 g/kg
		Dietetic foods intended for special medical purposes — Dietetic formula for weight control intended to replace total daily food intake or an individual meal	5 g/kg
		Chewing gum	5 g/kg
		Pro memoria: Wine in respect of Regulation (EEC) No 1873/84 — for E 491 only	
E 512	Stannous chloride	Canned and bottled white vegetables	25 mg/kg as Sn
E 520	Aluminium sulphate	Egg white	Singly or in combination 30 mg/kg as Al
E 521	Aluminium soldium sulphate	Candied fruit	200 mg/kg
E 522	Aluminium potassium sulphate		
E 523	Aluminium ammonium sulphate		
E 541	Sodium aluminium phosphate, acidic	Fine bakery wares (scones and sponge wares only)	2,6 g/kg as Al
E 535	Sodium ferrocyanide	Salt and salt substitutes	Singly or in combination 20 mg/kg as anhydrous potassium ferrocyanide
E 536	Potassium ferrocyanide		
E 538	Calcium ferrocyanide		
E 551	Silicon dioxide	Rice (for E 553b only)	*Quantum satis*
E 552	Calcium silicate	Dried powdered foodstuffs	10 g/kg
E 553a	(i) Magnesium silicate	Sodium chloride and salt substitutes	10 g/kg
	(ii) Magnesium trisilicate (1)	Dietary food supplements	*Quantum satis*
E 553b	Talc (1)	Foodstuffs in tables form	*Quantum satis*
E 554	Sodium aluminium silicate	Chewing gum	*Quantum satis* (for E 553b only)
E 555	Potassium aluminium silicate		
E 556	Calcium aluminium silicate		
E 558	Bentonite		
E 559	Aluminium silicate (Kalin)		
E 579	Ferrous gluconate	Black olives	150 mg/kg as Fe
E 585	Ferrous lactate		
E 626	Guanylic acid	Foodstuffs in general	500 mg/kg singly or in combination, expressed as guanylic acid
E 627	Disodium guanylate		
E 628	dipotassium buanylate		
E 629	Calcium guanylate		
E 630	Inosinic acid	Seasonings and condiments	*Quantum satis*
E 631	Disodium inosinate		
E 632	Dipotassium inosinate		
E 633	Calcium inosinate		
E 634	Calcium-5'-ribonucleotides		
E 635	Disodium-5'-ribonucleotide		

(1) Asbestos free.

EEC No	Name	Foodstuffs	Maximum level
E 636	Maltol	Chewing gum	300 mg/kg
E 637	Ethyl maltol	Chewing gum	300 mg/kg
E 900	Dimethyl polysiloxane	Foodstuffs in general	10 mg/kg
		Chewing gum	100 mg/kg
		Pro Memoria Wine (in respect of Council Regulation 84/1873/EEC)	
E 901	Bees wax, white and yellow	Confectionery and small products of fine bakery wares coated with chocolate (as glazing agents)	*Quantum satis*
E 902	Candelilla wax	Snacks (as glazing agents)	
E 903	Carnauba wax	Nuts (as glazing agents)	
E 904	Shellac	Coffee beans (as glazing agents)	
		Dietary food supplements	*Quantum satis*
		Fresh citrus fruits, melons, apples and pears, suface treatment only	*Quantum satis*
E 912	Montan acid esters	Fresh citrus fruits, surface treatment only	*Quantum satis*
E 914	Oxidized polyethylene wax		
E 927b	Carbamide	Sugar-free chewing gum	30 g/kg
E 950	Acesulfame-K	Chewing gum	(1)
E 951	Aspartame		800 mg/kg
E 957	Thaumatin		2 500 mg/kg
			10 mg/kg (as flavour enhan only)
E 959	Neohesperidine-DC	Chewing gum	150 mg/kg
		Margarine	5 mg/kg (as flavour enh only)
		Minarine	
		Meat products	
		Meat pates	
		Fruit jellies	
		Vegetable protein products	
E 999	Quillaia extract	Water based flavoured non-alcoholic drinks	200 mg/l
E 1103	Invertase	Sugar confectionera and filling for fine bakery wares	*Quantum sati*
E 1505	Triethyl citrate	Dried egg white	*Quantum sati*

(1) If E 950, E 951 and E 959 are used in combination levels, they are proportionally reduced.

ANNEX V

PERMITTED CARRIERS AND CARRIER SOLVENTS

Note

Not included in this list are:

1. substances generally considered as foodstuffs;
2. substances meant in Article 1 (4);
3. substances having primarily an acid or acidity regulator function, such as citric acid and ammonium hydroxide.

EEC No	Name	Restricted use
—	Propan-1,2-diol (propylene glycol)	Colours, emulsifiers, antioxidants and enzymes
E 422	Glycerol	
E 420	Sorbitol	
E 421	Mannitol	
E 953	Isomalt	
E 965	Maltitol	
E 966	Lactitol	
E 967	Xylitol	
E 400 to E 404	Alginic acid and it sodium, potassium calcium and ammonium salts	
E 405	Propan-1,2-diol alginate	
E 406	Agar	
E 407	Carrageenan	
E 410	Locust bean gum	
E 412	Guar gum	
E 413	Tragacanth	
E 414	Acacia gum (gum arabic)	
E 415	Xanthan gum	
E 440	Pectins	
E 460	Cellulose (microcrystalline or powdered)	
E 461	Methyl cellulose	
E 463	Hydroxypropyl cellulose	
E 464	Hydroxypropyl methyl cellulose	
E 465	Ethyl methyl cellulose	
E 466	Carboxy methyl cellulose	
	Sodium carboxy methyl cellulose	
E 322	Lecithins	Colours and fat-soluble Antioxidants only
E 432 to E 436	Polysorbates 20, 40, 60, 65 and 80	
E 470b	Magnesium salts of fatty cids	
E 471	Mono- and diglycerides of fatty acids	
E 472a	Acetic acid esters of mono- and diglycerides of fatty acids	
E 472c	Citric acid esters of mono- and diglycerides of fatty acids	
E 472e	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids	
E 473	Sucrose esters of fatty acids	
E 475	Polyglycerol esters of fatty acids	

EEC No	Name	Restricted use
E 491	Sorbitan esters	Colours and anti-foaming agents only
E 492		
E 493		
E 494		
E 495		
	Polyethylene glycol	Enzyme preparations only, maximum 10 %
E 1404	Oxidized starch	
E 1410	Monostarch phosphate	
E 1412	Distarch phosphate	
E 1413	Phosphated distarch phosphate	
E 1414	Acetylated distarch phosphate	
E 1420	Acetylated starch	
E 1422	Acetylated distarch adipate	
E 1440	Hydroxy propyl starch	
E 1442	Hydroxy propyl distarch phosphate	
E 1450	Starch sodium octenyl succinate	
E 170	Calcium carbonates	
E 501	Potassium carbonates	
E 504	Magnesium carbonates	
E 508	Potassium chloride	
E 509	Calcium chloride	
E 511	Magnesium chloride	
E 514	Sodium sulphate	
E 515	Potassium sulphate	
E 516	Calcium sulphate	
E 517	Ammonium sulphate	
E 341	Calcium phosphates	
E 263	Calcium acetate	
E 331	Sodium citrates	
E 332	Potassium citrates	
E 577	Potassium gluconate	
E 640	Glycine and its sodium salt	
E 1505	Triehtyl citrate	
E 1518	Glyceryl triacetate (triacetin)	
E 551	Silicon dioxide	Emulsifiers and colours, maximum 5 %
E 552	Calcium silicate	
E 553b	Talc	Colours only, maximum 5 %
E 558	Bentonite	
E 559	Aluminium silicate (Kaolin)	
E 901	Bees wax	Colours only
E 1200	Polydextrose	

ANNEX VI

FOOD ADDITIVES PERMITTED IN INFANT FORMULA, IN FOLLOW-ON FORMULA AND IN WEANING FOODS

Note

Formula and weaning foods for infants and young children may contain E 414 acacia gum (gum arabic) and E 551 silicon dioxide resulting from the addition of nutrient preparations containing not more than 10 g/kg of each of theses substances, as well as E 421 mannitol when used as a carrier for vitamin B 12 (not less than 1 part vitamin B 12 to 1 000 parts mannitol).

The maximum levels of use indicated refer to foodstuffs ready for consumption prepared following manufacturers' instructions.

I. Food additives permitted in infant formula for infants in good health

Notes

1. For the manufacture of infant formula, non-pathogenic L(+)-lactic acid producing cultures may be used.
2. If more than one of the substances E 322 and E 471 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substance in that foodstuff.

EEC No	Name	Maximum level
E 270	Lactic acid (L(+)-form only)	*Quantum satis*
E 330	Citric acid	*Quantum satis*
E 306	Tocopherol-rich extract	10 mg/l singly or in combination
E 307	Alpha-tocopherol	
E 308	Gamma-tocopherol	
E 309	Delta-tocopherol	
E 322	Lecithins	5 g/l
E 471	Mono- and diglycerides	4 g/l

II. Food additives permitted in follow-on formula for infants in good health

Notes

1. For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used.
2. If more than one of the substances E 322 and E 471 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substance in that foodstuff.
3. If more than one of the substances E 407, E 410 and E 412 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.

EEC No	Name	Maximum level
E 270	Lactic acid (L(+)-form only)	*Quantum satis*
E 330	Citric acid	*Quantum satis*
E 306	Tocopherol-rich extract	10 mg/l singly or in combination
E 307	Alpha-tocopherol	
E 308	Gamma-tocopherol	
E 309	Delta-tocopherol	
E 322	Lecithins	5 g/l
E 471	Mono- and diglycerides	4 g/l
E 407	Carrageenan	0,3 g/l
E 410	Locust bean gum	1 g/l
E 412	Guar gum	1 g/l

III. Food additives permitted in weaning foods for infants and young children in good health

EEC No	Name	Foodstuffs	Maximum level
E 170	Calcium carbonates	Weaning foods	*Quantum satis* (only for pH adjustment)
E 260	Acetic acid		
E 261	Potassium acetate		
E 262	Sodium acetates		
E 263	Calcium acetate		
E 270	Lactic acid (1)		
E 296	Malic acid		
E 325	Sodium lactate (1)		
E 326	Potassium lactate (1)		
E 327	Calcium lactate (1)		
E 330	Citric acid		
E 331	Sodium citrates		
E 332	Potassium citrates		
E 333	Calcium citrates		
E 500	Sodium carbonates		
E 501	Potassium carbonates		
E 503	Ammonium carbonates		
E 507	Hydrochloric acid		
E 524	Sodium hydroxide		
E 525	Potassium hydroxide		
E 526	Calcium hydroxide		
E 300	L-Ascorbic acid	Fruit and vegetable-based drinks, juices and baby foods	Singly or in combination, expressed as Ascorbic acid
E 301	Sodium L-Ascorbate		0,3 g/kg
E 302	Calcium L-Ascorbate	Fat containing cereal-based foods including biscuits and rusks	0,2 g/kg

(1) L(+) form only.

EEC No	Name	Foodstuffs	Maximum level
E 304 E 306 E 307 E 308 E 309	L-Ascorbyl palmitate Tocopherol-rich extract Alpha-tocopherol Gamma-tocopherol Delta-tocopherol	Fat containing cereals, biscuits, rusks and baby foods	0,1 g/kg singly or in combination
E 338	Phosphoric acid	Weaning foods	1 g/kg as P_2O_5 (only for pH adjustment)
E 339 E 340 E 341	Sodium phoshates Potassium phosphates Calcium phosphates	Cereals	1 g/kg singly or in combination, expressed as P_2O_5
E 322	Lecithins	Biscuits and rusks Cereal-based foods Baby foods	10 g/kg
E 471 E 472a E 472b E 472c	Mono- and diglycerides of fatty acids Acetic acid esters of mono- and diglycerides of fatty acids Lactic acid esters of mono- and diglycerides of fatty acids Citric acid esters of mono- and diglycerides of fatty acids	Biscuits and rusks Cereal based foods Baby foods	5 g/kg singly or in combination
E 400 E 401 E 402 E 404	Alginic acid Sodium alginate Potassium alginate Calcium alginate	Desserts Pudding	0,5 g/kg singly or in combination
E 410 E 412 E 414 E 415 E 440 E 460 (i)	Locust bean gum Guar gum Acacia gum (gum arabic) Xanthan gum Pectins Microcrystalline cellulose	Weaning foods Gluten free cereal based foods	10 g/kg singly or in combination) 20 g/kg singly or in combination
E 551	Silicon dioxide	Dry cereals	2 g/kg
E 334 E 335 E 336 E 450a E 575	Tartaric Sodium tartrate Potassium tartrate Disodium diphosphate Glucono-delta-lactone	Biscuits and rusks	5 g/kg as a residue

EEC No	Name	Foodstuffs	Maximum level
E 1404	Oxidized starch	Weaning foods	50 g/kg
E 1410	Monostarch phosphate		
E 1412	Distarch phosphate		
E 1413	Phosphated distarch phosphate		
E 1414	Acetylated distarch phosphate		
E 1420	Acetylated starch		
E 1422	Acetylated distarch adipate		
E 1450	Starch sodium octenyl succinate		

IV. Food additives permitted in infant formula, in follow-on formula and in weaning foods for special medical purposes

See corresponding tables of Annex VI.

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COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

(89/109/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 Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (3), as last amended by the act of Accession of Spain and Portugal (4), has been substantially amended on a number of occasions; whereas on making the new amendments to the said Directive, the opportunity should be taken to consolidate the provisions of the existing relevant texts with a view to ensuring legal clarity;

Whereas Directive 76/893/EEC was adopted on the grounds that the differences that existed at that time between the national laws relating to the aforesaid materials and articles impeded the free movement thereof, could create unequal conditions of competition and could thereby directly affect the establishment or functioning of the common market;

Whereas those laws had to be approximated if free movement was to be achieved for the aforesaid materials and articles, taking account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technological needs;

Whereas the chosen method was to lay down, in the first place, in a framework directive, general principles on the basis of which legal differences between certain groups of materials and articles had been and could subsequently be diminated by means of specific directives; whereas this method has proved itself and should therefore be retained;

Whereas covering or coating substances, all or part of which form part of foodstuffs, could not be considered to be simply in contact with these foodstuffs; whereas, in that case, account had to be taken of possible direct consumption by consumers; whereas the rules laid down in this Directive are therefore inappropriate in such circumstances;

Whereas the principle underlying this Directive should be that any material or article intended to come into contact or which is intentionally in contact either directly or indirectly with foodstuffs, must be sufficiently stable not to transfer substances to the foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic properties thereof;

Whereas, in order to achieve this objective, it may prove necessary to lay down various types of limitations, alone or in combination; whereas it is appropriate to retain in specific directives those limitations which are most appropriate to the desired objective, having regard to the technological characteristics peculiar to each group of materials and articles;

Whereas, in order to allow the informed use of the materials and articles, appropriate labelling should be provided for; whereas the methods used for such labelling may vary according to the user;

Whereas this Directive does not apply to the labelling of products which, by reason of their behaviour in the presence of foodstuffs, must not be designed to come into contact or be in contact with them;

Whereas the drafting of specific directives implementing the basic principles and of amendments thereto constitute technical implementing measures; whereas, in order to simplify and expedite the procedure, the adoption of these measures should be entrusted to the Commission;

Whereas the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (5), should be asked for its opinion before provisions liable to affect public health are adopted under specific directives;

(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 340, 9. 12. 1976, p. 19.
(4) OJ No L 302, 15. 11. 1985, p. 216.
(5) OJ No L 136, 20. 5. 1974, p. 1.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose, hereinafter referred to as 'materials and articles'.

Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to this Directive.

2. This Directive shall apply to materials and articles which are in contact with water which is intended for human consumption. It shall not, however, apply to fixed public or private water supply equipment.

3. This Directive shall not apply to antiques.

Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

— endanger human health,

— bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Article 3

1. The groups of materials and articles listed in Annex I and, where appropriate, combinations of these materials and articles shall be subject to specific directives.

2. The specific directives, including amendments to existing specific directives, shall be adopted in accordance with the procedure laid down in Article 8.

3. The specific directives may include:

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

(b) purity standards for such substances;

(c) special conditions of use for these substances and/or the materials and articles in which they are used;

(d) specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;

(e) an overall limit on the migration of constituents into or onto foodstuffs;

(f) if necessary, provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles;

(g) other rules to ensure compliance with Article 2;

(h) the basic rules necessary for checking compliance with the provisions of points (d), (e), (f) and (g);

(i) detailed rules concerning sample taking and the methods of analysis required to check compliance with the provisions of points (a) to (g).

Provisions liable to affect public health shall be adopted after consulting the Scientific Committee for Food. They must fulfill the criteria set out in Annex II.

Article 4

1. Notwithstanding Article 3, a Member State may, where a list of substances has been drawn up in accordance with paragraph 3 (a) of that Article, authorize the use within its territory of a substance not included in the list, subject to compliance with the following conditions:

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

(b) the Member State must carry out an official check on materials and articles manufactured from a substance of which it has authorized the use;

(c) materials and articles thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the two-year period provided for in paragraph 1 (a), the Member State may submit to the Commission a request for the inclusion in the list referred to

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

in Article 3 (3) (a) of the substance given national authorization in accordance with paragraph 1 of this Article. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which this substance is intended.

Within 18 months of the submission of the request, a decision shall be taken on the basis of information relating to public health, after consulting the Scientific Committee for Food and in accordance with the procedure laid down in Article 9 as to whether the substance in question may be included in the list referred to in Article 3 (a) or whether the national authorization should be revoked. If provisions prove necessary pursuant to Article 3 (3) (b), (c) and (d), these shall be adopted in accordance with the same procedure. Notwithstanding paragraph 1 (a) of this Article, the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be revoked, this decision shall apply to any other national authorization in respect of the substance in question. The decision may stipulate that the ban on the use of this substance shall extend to uses other than those referred to in the request for inclusion in the list.

Article 5

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific directives was adopted, has detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific directive, 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 within the Standing Committee on Foodstuffs the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take the appropriate measures.

3. If the Commission considers that amendments to the specific directives in question are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 9 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 6

1. Without prejudice to any exceptions provided for in the specific directives, materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by:

(a) — the words 'for food use',

— or a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon,

— or a symbol determined in accordance with the procedure laid down in Article 9;

(b) where appropriate, any special conditions to be observed when they are being used;

(c) — either the name or trade name and the address or registered office,

— or the registered trade mark,

of the manufacturer or processor, or of a seller established within the Community.

2. The particulars listed in paragraph 1 must be conspicuous, clearly legible and indelible:

(a) at the retail stage:

— on the materials and articles or on the packaging,

— or on labels affixed to the materials and articles or to their packaging,

— or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; in the case mentioned in paragraph 1 (c), however, the latter option shall only be open if these particulars or a label bearing them cannot, for technical reasons, be affixed to the said materials and articles at either the manufacturing or the marketing stage;

(b) at the marketing stages other than the retail stage:

— on the accompanying documents,

— on the labels or packaging,

— or on the materials and articles themselves.

3. However, the particulars provided for in paragraph 1 shall not be compulsory for materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

4. The particulars provided for in paragraph 1 (a) and (b) shall be confined to materials and articles which comply:

(a) with the criteria laid down in Article 2;

(b) with the specific directives, in the absence of such directives, with any national provisions.

5. The specific directives shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.

In the absence of specific directives, Member States may retain existing provisions or adopt provisions to this effect.

6. Member States shall ensure that retail trade in materials and articles is prohibited if the particulars required under paragraph 1 (a) and (b) are not given in a language easily understood by purchasers, unless the purchaser is informed by other means. This provision shall not preclude such particulars appearing in several languages.

Article 7

1. Member States shall not, for reasons relating to composition, behaviour in the presence of foodstuffs or labelling, prohibit or restrict either trade in or the use of materials and articles complying with this Directive or with the specific directives.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of the specific directives.

Article 8

Amendments made to existing specific directives in order to bring them into line with this Directive shall be adopted in accordance with the procedure laid down in Article 9.

Article 9

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 and apply them immediately.

Article 10

1. Directive 76/893/EEC is hereby repealed.

2. References to the Directive repealed under paragraph 1 shall be construed as references to this Directive.

References to the Articles of the repealed Directive should be read in accordance with the correlation table appearing in Annex III.

Article 11

1. Member States shall take all measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

— permit, not later than 18 months after notification (1), trade in and use of materials and articles complying with this Directive, without prejudice to the application of national provisions which, in the absence of specific directives, apply to certain groups of materials and articles;

— prohibit not later than 36 months after notification trade in and use of materials and articles which do not comply with this Directive.

2. Paragraph 1 shall not affect those national provisions which, in the absence of the specific directives, apply to certain groups of materials and articles intended to come into contact with foodstuffs.

Article 12

This Directive shall not apply to materials and articles intended for export outside the Community.

Article 13

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 10 January 1989.

ANNEX II

List of groups of materials and articles covered by specific directives

Plastics, including varnish and coatings
Regenerated cellulose
Elastomers and rubber
Paper and board
Ceramics
Glass
Metals and alloys
Wood, including cork
Textile products
Paraffin waxes and micro-crystalline waxes

ANNEX II

Health criteria to be applied in the drafting of specific directives

1. Where appropriate, positive lists of substances shall be established for materials and articles intended to come into contact with foodstuffs. The acceptability of a substance for inclusion in a positive list shall be determined by considering both the quantity of the substance which is liable to migrate into foodstuffs and the toxicity of the substance.

2. A substance shall only be included in a positive list where, under normal or foreseeable conditions of use of any material or article of which it forms a part, the substance is not liable to migrate into foodstuffs in a quantity likely to constitute a danger to human health.

3. For certain materials it may be inappropriate to establish a positive list because such a list would offer no tangible benefit in terms of safeguarding human health. In such circumstances, any substances for which specific migration limits need to be established in order to prevent their being transferred to foodstuffs in quantities likely to constitute a danger to health shall be identified. The criteria set out in paragraphs 1 and 2 shall also apply to these substances.

4. All substances shall be kept under review and reassessed whenever this is justified by fresh scientific data or a re-evaluation of existing scientific data.

5. Where an acceptable daily intake or a tolerable daily intake is established for a particular substance, the need to establish a specific migration limit in order that this intake is not exceeded shall be considered. Where such a specific migration limit is established for a substance, due regard shall be paid to other possible sources of exposure to the substance.

6. In certain circumstances, a specific migration limit on a substance may not be the most valid means of safeguarding human health. In such circumstances, the need to protect human health shall be the primary consideration in determining what action might be appropriate.

ANNEX III

CORRELATION TABLE

Directive 76/893/EEC	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article —
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article —	Article 8
Article 9	Article —
Article 10	Article 9
Article —	Article 10
Article 11	Article —
Article 12	Article 12
Article 13	Article 11
Article 14	Article —
Article 15	Article 13

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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE

of 23 February 1990

relating to plastics materials and articles intended to come into contact with foodstuffs

(90/128/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/109/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (1), and in particular Article 3 thereof,

Whereas Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs ;

Whereas, in order to achieve this objective in the case of plastics materials and articles, a suitable instrument is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC, the general provisions of which are also applicable to the case in question ;

Whereas the scope of this Directive must coincide with that of Council Directive 82/711/EEC (2) ;

Whereas since the rules established in this Directive are not suitable for ion-exchange resins, these materials and articles will be covered by a subsequent specific Directive ;

Whereas the establishment of a list of approved substances accompanied by a limit an overall migration and, where necessary, by other specific restrictions will be sufficient to achieve the objective laid down in Article 2 of Directive 89/109/EEC ;

Whereas the stage reached in the work at Community level does not yet permit adoption of a complete list of the authorized substances applicable to all types of plastics materials and articles and therefore the substances which are currently used in at least one Member State can continue to be used pending a decision on inclusion in the Community list ; whereas this Directive will accordingly be extended in due course to the substances and sectors provisionally excluded ;

Whereas the overall migration limit is a measure of the inertness of the material and prevents an unacceptable change in the composition of the foodstuffs, and, moreover, reduces the need for a large number of specific migration limits or other restrictions, thus giving effective control ;

Whereas Directive 82/711/EEC lays down the basic rules necessary for testing migration of the constituents of plastics materials and articles and Council Directive 85/572/EEC (3) establishes the list of simulants to be used in the migration tests ;

(1) OJ No L 40, 11. 2. 1989, p. 38.
(2) OJ No L 297, 23. 10. 1982, p. 26.
(3) OJ No L 372, 31. 12. 1985, p. 14.

Whereas Council Directive 78/142/EEC (1) lays down limits for the quantity of vinyl chloride present in plastics materials and articles prepared with this substance and for the quantity of vinyl chloride released by these materials and articles, and Directives 80/766/EEC (2) and 81/432/EEC (3) establish the Community methods of analysis for controlling these limits;

Whereas Commission Directive 80/590/EEC (4) determines the symbol that may accompany any material and article intended to come into contact with foodstuffs;

Whereas in view of potential liability, there is a need for the written declaration provided for in Article 6 (5) of Directive 89/109/EEC whenever professional use is made of plastics materials and articles which are not by their nature clearly intended for food use;

Whereas, in accordance with Article 3 of Directive 89/109/EEC, the Scientific Committee for Food has been consulted on the provisions liable to affect public health;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.

2. This Directive shall apply to plastics materials and articles and parts thereof:

(a) consisting exclusively of plastics, or

(b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, 'plastics' shall mean the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as plastics:

(i) varnished or unvarnished regenerated cellulose film covered by Council Directive 83/229/EEC (5), as amended by Directive 86/388/EEC (6);

(ii) elastomers and natural and synthetic rubber;

(iii) paper and paperboard, whether modified or not by the addition of plastics;

(iv) surface coatings obtained from:

— paraffin waxes, including synthetic paraffin waxes and/or micro-crystalline waxes,

— mixtures of the waxes listed in the first indent with each other and/or with plastics;

(v) ion-exchange resins.

4. This Directive shall not apply, until further action by the Commission, to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

Article 2

Plastics materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);

(b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

(c) caps, gaskets, stoppers or similar devices for sealing.

Article 3

1. Only those monomers and other starting substances listed in Annex II, Sections A and B may be used for the manufacture of plastics materials and articles subject to the restrictions specified.

2. From the date of notification of this Directive, the list in Annex II, Section A may be amended:

— either by adding substances listed in Annex 2, Section B, according to the criteria in Annex II of Directive 89/109/EEC, or

— by including 'new substances', i.e. substances which are listed neither in Section A nor in Section B of Annex 2, according to Article 3 of Directive 89/109/EEC.

(1) OJ No L 44, 15. 2. 1978, p. 15.
(2) OJ No L 213, 16. 8. 1980, p. 42.
(3) OJ No L 167, 24. 6. 1981, p. 6.
(4) OJ No L 151, 19. 6. 1980, p. 21.
(5) OJ No L 123, 11. 5. 1983, p. 31.
(6) OJ No L 228, 14. 8. 1986, p. 32.

3. From the date of notification of this Directive no Member State shall authorize any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC.

4. As from 1 January 1993, only those monomers and other starting substances listed in Annex II, Section A shall be used for the manufacture of plastics materials and articles, subject to the restrictions specified therein. However, before 1 January 1992 it may be decided that, in some justified cases, for certain substances listed in Annex II, section B, this time limit will be postponed.

5. However the lists appearing in Annex II, Sections A and B do not yet include monomers and other starting substances used only in the manufacture of :

— surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
— silicones,
— epoxy resins,
— products obtained by means of bacterial fermentation,
— adhesives and adhesion promoters,
— printing inks.

Article 4

The specific migration limits in the list set out in Annex II are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases :

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l ;

(b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuff in contact therewith.

In these cases, the limits set out in Annex II, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

Article 5

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC and the further provisions set out in Annex I.

2. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

Article 6

1. At the marketing stages other than the retail stages, the plastics materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC.

2. Paragraph 1 does not apply to plastics materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

Article 7

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1990. They shall forthwith inform the Commission thereof.

2. Member States shall :

— permit the trade in and use of plastics materials and articles complying with this Directive before 1 January 1991,
— prohibit trade in and use of plastics materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive as from 1 January 1993.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 23 February 1990.

For the Commission
Martin BANGEMANN
Vice-President

ANNEX I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE WITH THE MIGRATION LIMITS

General provisions

1. When comparing the results of the migration tests specified in the Annex to Directive 82/711/EEC, the specific gravity of all the simulants should conventionally be assumed to be 1. Milligrams of substance(s) released per litre of simulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in Directive 85/572/EEC, to milligrams of substance(s) released per kilogram of foodstuff.

2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m \cdot a_2}{a_1 \cdot q} \cdot 1\,000$$

Where:

M is the migration in mg/kg;

m is the mass in mg of substance released by the sample as determined by the migration test;

a_1 is the surface area in dm^2 of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm^2 of the material or article in real conditions of use;

q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.

The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.

The migration testing of caps, gaskets, stoppers or similar devices for sealing must be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.

It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in Article 5 of the present Directive, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.

5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in Directives 82/711/EEC and 85/572/EEC are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue.

If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.

The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.

Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determied. One of these possible modifications is described below.

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M_1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M_2 and M_3, respectively).

The material or article shall be deemed to be in compliance provided that either M_1 or $M_3 - M_2$ do not exceed the overall migration limit.

7. A material or article that exceeds the overall migration limit by an account not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Directive.

The following analytical tolerances have been observed.

— 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,

— 6 mg/kg or 1 mg/dm² in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

8. Without prejudice to the provisions of Article 3 (2) of Directive 82/711/EEC, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint.

In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However the sum of all specific migration determined shall not exceed the overall migration limit.

ANNEX II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

General introduction

1. This Annex contains the list of monomers or other starting substances. The list includes :

   — substances undergoing polymerization, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,

   — natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesize them are not included in the list,

   — substances used to modify existing natural or synthetic macromolecular substances.

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorized acids, phenols or alcohols which are also authorized. However, names containing '... acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term 'salts' is 'salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.

3. The list also does not include the following substances although they may be present :

   (a) substances which could be present in the finished product as :

      — impurities in the substances used,

      — reaction intermediates,

      — decomposition products ;

   (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesize them are included in the list.

   (c) mixtures of the authorized substances.

   The materials and articles which contain the substance indicated under (a), (b) and (c) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality.

5. The list contains the following information :

   — column 1 (PM/REF. No) : the EEC packaging material references number of the list,

   — column 2 (CAS No) : the CAS (Chemical Abstracts Service) registry number,

   — column 3 (Name) : the chemical name,

   — column 4 (Restrictions). These may include :

      — specific migration limit (SML),

      — maximum permitted quantity of the 'residual', substance in the material or article (QM),

      — any other restriction specifically mentioned.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in Einecs and the CAS registry, the CAS number in the CAS registry shall apply.

8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows :

DL =	detection limit of the method of analysis ;
FP =	finished material or article ;
NCO =	isocyanate moiety ;
QM =	maximum permitted quantity of the 'residual' substance in the material or article ;
QM (T) =	maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated ;
SML =	specific migration limit in food or in food simulant, unless it is specified otherwise ;
SML (T) =	specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated.

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COMMISSION DIRECTIVE 93/9/EEC

of 15 March 1993

amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/109/EEC (1) of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs, and in particular Article 3 thereof,

After consulting the Scientific Committee for Food,

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually, and whereas furthermore their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Commission Directive 90/128/EEC (2), as amended by Directive 92/39/EEC (3), and in particular Article 3 (4) thereof, provides for the revision of Annex II and particularly Section B;

Whereas, on the basis of the available information, certain substances provisionally admitted at national level may be included in the Community list, while others must be definitively prohibited;

Whereas certain substances provisionally admitted at national level may continue to be permitted for a further specified period since the data requested by the Scientific Committee for Food are not yet available but the required studies are ongoing or are planned;

Whereas other substances have been requested for use following the adoption of Directive 90/128/EEC and the technical data supplied permit their inclusion in the Community list;

Whereas, for certain substances, the restrictions already set out should be amended according to the available information;

Whereas it is necessary to permit the continued use of certain well-defined substances contained in those groups of substances which are not well-defined and are now deleted, pending a decision on their inclusion in the Community list;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/128/EEC is amended as follows:

1. The following paragraph 3 is added to Article 5:

'3. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.'

2. Annex II is amended as follows:

(a) Point 8 is hereby amended as follows:

— the following text is inserted after 'QM (T) = maximum permitted quantity of the "residual" substance in the material or article expressed as total of moiety or substance(s) indicated':

'For the purpose of this Directive "QM (T)" means that the maximum permitted quantity of the "residual" substance in the material or article should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.'

— the following text is inserted after 'SML (T) = specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated':

'For the purpose of this Directive "SML (T)" means that the specific migration of the substances should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.'

(1) OJ No L 40, 11. 2. 1989, p. 38.
(2) OJ No L 75, 21. 3. 1990, p. 19, rectified by OJ No L 349, 13. 12. 1990, p. 26.
(3) OJ No L 168, 23. 6. 1992, p. 2.

(b) Section A :

— the substances appearing in Annex I to this Directive are added,

— the content of the column 'Restrictions' for the substances appearing in Annex II to this Directive is amended as indicated therein ;

(c) Section B :

— the substances appearing in Annex III to this Directive are added, as a replacement for those groups of substances which are not well defined and which are deleted by this Directive,

— the substances appearing in Annex IV to this Directive are deleted ;

(d) the substances appearing in Annex V to this Directive are transferred from Section B to A and are now subject to the restrictions, if any, specified.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 April 1994. They shall immediately inform the Commission thereof.

Member States shall :

— permit, as from 1 April 1994, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs complying with this Directive,

— prohibit, as from 1 April 1996, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX I

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES ADDED TO SECTION A

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15820	000345-92-6	4,4'-Difluorobenzophenone	SML = 0,05 mg/kg
17160	000097-53-0	Eugenol	SML = 0,01 mg/kg
22390	000840-65-3	2,6-Naphtalenedicarboxylic acid, dimethyl ester	SML = 0,05 mg/kg
24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as pyromellitic acid)
24475	001313-82-2	Sodium sulphide	
24540	009005-25-8	Starch, edible	
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg

ANNEX II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES IN SECTION A FOR WHICH THE CONTENT OF THE COLUMN 'RESTRICTIONS' IS MODIFIED

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
12788	002432-99-7	11-Aminoundecanoic acid	SML = 5 mg/kg

ANNEX III

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES ADDED TO SECTION B

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	
10599/91	061788-89-4	Acids, fatty, unsaturated (C 18), dimers, non-distilled	
10599/92A	068783-41-5	Acids, fatty, unsaturated (C 18), dimers, hydrogenated, distilled	
10599/93	068783-41-5	Acids, fatty, unsaturated (C 18), dimers, hydrogenated, non-distilled	

ANNEX IV

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES DELETED

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10599/90	061788-89-4	Acids, fatty, unsaturated (C 18), dimers	
10599/92	068783-41-5	Acids, fatty, unsaturated (C 18), dimers, hydrogenated	
10600	—	Acids, linear, with an even number of carbon atoms (C 8-C 22), and the dimers and trimers of the unsaturated acids	
10720	000999-55-3	Acrylic acid, allyl ester	
10775	084100-23-2	Acrylic acid, 4-tert-butylcyclohexyl ester	
10990	002156-96-9	Acrylic acid, decyl ester	
11005	012542-30-2	Acrylic acid, dicyclopentenyl ester	
11010	024447-78-7	Acrylic acid, diester with 2,2-bis (4-hydroxyphenyl)propane (2-hydroxyethyl) ether	
11020	019485-03-1	Acrylic acid, diester with 1,3-butanediol	
11080	004074-88-8	Acrylic acid, diester with diethyleneglycol	
11110	002274-11-5	Acrylic acid, diester with ethyleneglycol	
11140	013048-33-4	Acrylic acid, diester with 1,6-hexanediol	
11170	026570-48-9	Acrylic acid, diester with polyethyleneglycol	
11200	002426-54-2	Acrylic acid, 2-(diethylamino) ethyl ester	
11230	002439-35-2	Acrylic acid, 2-(dimethylamino) ethyl ester	
11260	000106-90-1	Acrylic acid, 2,3-epoxypropyl ester	
11532	002761-08-2	Acrylic acid, 3-hydroxypropyl ester	
11860	—	Acrylic acid, monoester with propyleneglycol	
11875	004813-57-4	Acrylic acid, octadecyl ester	
12640	000106-92-3	Allyl 2,3-epoxypropyl ether	
13210	001761-71-3	Bis (4-aminocyclohexyl) methane	
14008	000098-52-2	4-tert-Butylcyclohexanol	
14035	001746-23-2	4-tert-Butylstyrene	
14560	000126-99-8	2-Chloro-1,3-butadiene	
14650	000079-38-9	Chlorotrifluoroethylene	
14833	000623-43-8	Crotonic acid, methyl ester	
14980	001631-25-0	N-Cyclohexylmaleimide	
15030	000931-88-4	Cyclooctene	
15060	000142-29-0	Cyclopentene	
15260	000646-25-3	1,10-Diaminodecane	
15270	002783-17-7	1,12-Diaminododecane	
15295	000373-44-4	1,8-Diaminooctane	
16120	000110-97-4	Diisopropanolamine	
16180	005205-93-6	N-(Dimethylaminopropyl) methacrylamide	
16252	000110-03-2	2,5-Dimethyl-2,5-hexanediol	
16510	000138-86-3	Dipentene	
16719	003813-52-3	Endomethylenetetrahydrophthalic acid	
16900	013036-41-4	N-(Ethoxymethyl)acrylamide	
17116	005877-42-9	4-Ethyl-1-octyn-3-01	
17150	000078-27-3	1-Ethynylcyclohexanol	
17305	000141-02-6	Fumaric acid, bis (2-ethylhexyl) ester	
17320	002807-54-7	Fumaric acid, diallyl ester	
17380	000623-91-6	Fumaric acid, diethyl ester	
17398	007283-68-3	Fumaric acid, dioctadecyl ester	

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
17800	—	Glucosides obtained from glucose and pentaerythritol	
17830	—	Glucosides obtained from glucose and polyethyleneglycol (molecular weight greater than 200)	
17860	—	Glucosides obtained from glucose and polypropyleneglycol (molecular weight greater than 400)	
18436	001687-30-5	Hexahydrophthalic acid	
18490	015511-81-6	Hexamethylenediamine adipate	
18610	006422-99-7	Hexamethylenediamine sebacate	
18850	000107-41-5	Hexyleneglycol	
18865	003031-66-1	3-Hexyn-2,5-diol	
19140	026952-21-6	Isooctanol	
19480	002146-71-6	Lauric acid, vinyl ester	
19660	000141-05-9	Maleic acid, diethyl ester	
19690	014234-82-3	Maleic acid, diisobutyl ester	
19720	001330-76-3	Maleic acid, diisooctyl ester	
19750	000624-48-6	Maleic acid, dimethyl ester	
19915	000925-21-3	Maleic acid, monobutyl ester	
20095	046729-07-1	Methacrylic acid, 4-tert-butylcyclohexyl ester	
20200	001888-94-4	Methacrylic acid, 2-chloroethyl ester	
20320	003179-47-3	Methacrylic acid, decyl ester	
20455	006606-59-3	Methacrylic acid, diester with 1,6-hexanediol	
20560	000142-90-5	Methacrylic acid, dodecyl ester	
20830	—	Methacrylic acid, ester with 1,2-propanediol	
20920	000688-84-6	Methacrylic acid, 2-ethylhexyl ester	
20945	004664-49-7	Methacrylic acid, 2-hydroxyisopropyl ester (= methacrylic acid, 2-hydroxy-1-methylethyl ester)	
20965	002761-09-3	Methacrylic acid, 3-hydroxypropyl ester	
20980	007534-94-3	Methacrylic acid, isobornyl ester	
21040	029964-84-9	Methacrylic acid, isodecyl ester	
21070	028675-80-1	Methacrylic acid, isooctyl ester	
21170	000997-46-6	Methacrylic acid, monoester with 1,4-butanediol	
21250	002157-01-9	Methacrylic acid, n-octyl ester	
21430	004245-37-8	Methacrylic acid, vinyl ester	
21670	000563-46-2	2-Methyl-1-butene	
21733	000115-19-5	2-Methyl-3-butyn-2-ol	
21736	002549-61-3	alpha-Methyl-epsilon-caprolactone	
21739	002549-60-2	beta-Methyl-epsilon-caprolactone	
21742	002549-58-8	delta-Methyl-epsilon-caprolactone	
21745	002549-59-9	epsilon-Methyl-epsilon-caprolactone	
21748	002549-42-0	gamma-Methyl-epsilon-caprolactone	
21850	000095-71-6	Methylhydroquinone	
21880	000717-27-1	Methylhydroquinone diacetate	
22465	000112-05-0	Nonanoic acid	
22690	001806-26-4	4-Octylphenol	
22811	000591-93-5	1,4-Pentadiene	
22842	002590-16-1	Pentaerythritol diallyl ether	
22858	005343-92-0	1,2-Pentanediol	
22861	000111-29-5	1,5-Pentanediol	
22901	000109-68-2	2-Pentene	
22935	003823-94-7	Perfluoromethyl vinyl ether	
22940	006996-01-6	Perfluoropropyl vinyl ether	
23140	000092-69-3	4-Phenylphenol	
25158	000088-98-2	1,2,3,6-Tetrahydrophthalic acid	
25630	037275-47-1	1,1,1-Trimethylolpropane diacrylate	

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
25645	000682-09-7	1,1,1-Trimethylolpropane diallyl ether	
25780	025723-16-4	1,1,1-Trimethylolpropane, propoxylated	
25930	001067-53-4	Tris (2-methoxyethoxy) vinylsilane	
26200	002867-48-3	N-Vinyl-N-methylformamide	
26260	001184-84-5	Vinylsulphonic acid	

ANNEX V

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES TRANSFERRED TO SECTION A

PM/REF No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10750	002495-35-4	Acrylic acid, benzyl ester	
11890	002499-59-4	Acrylic acid, n-octyl ester	
15095	000334-48-5	Decanoic acid	
15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg
19210	001459-93-4	Isophtalic acid, dimethyl ester	SML = 0,05 mg/kg
20080	002495-37-6	Methacrylic acid, benzyl ester	
21280	002177-70-0	Methacrylic acid, phenyl ester	
24940	000100-20-9	Terephtalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as terephtalic acid,
25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg

ภาคผนวก ฉ

COUNCIL DIRECTIVE

of 14 June 1989

on the official control of foodstuffs

(89/397/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 (1),

In cooperation with the European Parliament (2),

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

Whereas trade in foodstuffs is one of the most important aspects of the common market; whereas all the Member States must endeavour to protect the health and economic interests of their citizens; whereas the protection of health must be given unconditional priority and whereas, therefore, official control of foodstuffs must be harmonized and made more effective;

Whereas, however, the differences between national legislations with respect to this type of control are such as to represent barriers to the free movement of goods;

Whereas it is therefore necessary to approximate these legislations;

Whereas, first of all, the general principles governing the carrying-out of such control must be harmonized;

Whereas specific provisions, in addition to the general principles, may, if necessary, be adopted subsequently;

Whereas the subject of this Directive is verification of the compliance of foodstuffs with legislation on foodstuffs; whereas such legislation contains provisions on health, rules on composition and rules on quality designed to protect consumers' economic interests as well as provisions on consumer information and fair commercial transactions;

Whereas, at the same time as foodstuffs, materials and articles intended to come into contact with such foodstuffs should be controlled;

Whereas for the purposes of the completion of the internal market, foodstuffs intended to cross intra-Community frontiers must be inspected with the same care as those intended for marketing in the Member State of production;

Whereas inspection must therefore be based in principle on the provisions in force in the Member State of production; whereas, however, such a principle should not apply where it has been established to the the satisfaction of the inspecting authority by appropriate means, including the submission of commercial documents, that the product in question is intended for consignment to another Member State and that it complies with the provisions in force in that Member State;

Whereas, to be effective, inspections must be carried out regularly; whereas they must not be limited as to the subject, stage or monient at which it is convenient to carry them out, and whereas they must take the most suitable forms to guarantee their effectiveness;

Whereas in order to ensure that inspection procedures are not evaded, it is necessary to provide that Member States shall not exclude a product from appropriate inspection on the grounds that it is intended for export outside the Community;

Whereas the inspectors must be granted adequate powers;

Whereas although, on the one hand, undertakings should not have the right to oppose the inspections, on the other hand their legitimate rights must be preserved, in particular the right to manufacturing secrecy and the right of appeal;

Whereas the authorities made responsible for the control of foodstuffs may differ from one Member State to another; whereas it is, therefore, desirable to publish a list of the competent authorities in the field in each Member State, with an indication of the territories for which they are competent, and approved laboratories for the analyses to be carried out in connection with such control;

Whereas official controls should contribute effectively to the prevention of food law infringements; whereas to that end programmes should be drawn up on the basis of appropriate criteria;

Whereas, although it is primarily for Member States to lay down their inspection programmes, it is necessary, with a view to the completion and operation of the internal market, to arrange also for coordinated programmes at Community level;

Whereas simultaneous implementation of national programmes and coordinated programmes will provide

(1) OJ No C 20, 27. 1. 1987, p. 6, OJ No C 88, 5. 4. 1987, p. 14, and OJ No C 131, 27. 5. 1989, p. 6.
(2) OJ No C 345, 21. 12. 1987, p. 80, and OJ No C 120, 16. 5. 1989.
(3) OJ No C 347, 22. 12. 1987, p. 1.

experience which is still widely lacking at present; whereas, in the light of that experience, it may prove necessary to revise this Directive to improve the arrangements which it introduces;

Whereas Member States should be allowed a certain degree of freedom as to the practical means of carrying out inspections so as not to interfere with systems of proven worth which are best suited to the particular situation in each Member State,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down the general principles for the performance of official control of foodstuffs.

2. For the purposes of this Directive 'official control of foodstuffs' — hereinafter called 'control' — means an inspection by the competent authorities of the compliance;

— of foodstuffs,

— of food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such,

— of materials and articles intended to come into contact with foodstuffs,

with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information.

3. This Directive shall apply without prejudice to the provisions adopted in the context of more specific Community rules.

4. This Directive shall not apply to metrological control.

Article 2

1. Member States shall take all necessary measures to ensure that control is carried out in accordance with this Directive.

2. Member States shall ensure that products intended for consignment to another Member State are inspected with the same care as those intended for marketing on their own territory.

Article 3

Member States shall not exclude a product from appropriate control on the grounds that it is intended for export outside the Community.

Article 4

1. Inspections shall be carried out:

(a) regularly;

(b) where non-compliance is suspected.

2. Inspections shall be carried out using means proportionate to the end to be observed.

3. Inspection shall cover all stages of production, manufacture, import into the Community, processing, storage, transport, distribution and trade.

4. As a general rule, inspections shall be carried out without prior warning.

5. As a general rule, inspections shall, in each case, select the stage or stages which it considers the most appropriate for its examination from those listed in paragraph 3.

Article 5

Control shall comprise one or more of the following operations in accordance with the conditions laid down in Articles 6 to 9 and in the light of the examination to be carried out:

1. inspection;

2. sampling and analysis;

3. inspection of staff hygiene;

4. examination of written and documentary material;

5. examination of any verification systems set up by the undertaking and of the results obtained.

Article 6

1. The following shall be subject to inspection:

(a) the state and use which is made at the different stages enumerated in Article 4 (3) of the site, premises, offices, plant surroundings, means of transport, machinery and equipment;

(b) raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;

(c) semi-finished products;

(d) finished products;

(e) materials and articles intended to come into contact with foodstuffs;

(f) cleaning and maintenance products and processes and pesticides;

(g) processes used for the manufacture or processing of foodstuffs;

(h) labelling and presentation of foodstuffs;

(i) preserving methods.

2. The operations enumerated in paragraph 1 may, where necessary, be supplemented by:

— interviews with the head of the inspected undertaking and with persons working for that undertaking,

— the reading of values recorded by measuring instruments installed by the undertaking,

— inspections carried out by the competent authority, with its own instruments, of measurements taken with the instruments installed by the undertaking.

Article 7

1. Samples of the products enumerated in Article 6 (1) (b) to (f) may be taken for the purposes of analysis.

Member States shall take the necessary steps to ensure that those subject to inspection may apply for a second opinion.

2. The analyses shall be carried out by official laboratories.

Member States may also empower other laboratories to carry out these analyses.

Article 8

Persons who, in the exercise of their activity, come into contact, whether directly or indirectly, with the materials and products referred to in Article 6 (1) (b) to (f) shall be subject to the hygiene inspection referred to in Article 5 (3).

The purpose of this inspection shall be to check that the health standards concerning personal cleanliness and clothing are respected. It shall be carried out without prejudice to medical examinations.

Article 9

1. Inspectors may take note of written and documentary material held by the natural and legal persons at the various stages enumerated in Article 4 (3).

2. Inspectors may also make copies or take extracts of written and documentary material submitted to them for examination.

Article 10

Where inspectors discover or suspect an irregularity, they shall take the requisite measures.

Article 11

1. Member States shall ensure that inspectors have the right to carry out the operations provided for in Articles 6 to 10.

2. Member States shall prescribe that the natural and legal persons concerned shall be obliged to undergo any inspection carried out in accordance with this Directive and to assist inspectors in the accomplishment of their tasks.

Article 12

1. Member States shall take the measures necessary to ensure that natural and legal persons concerned by the inspection have a right of appeal against measures taken by the competent authority for the purpose of inspection.

2. They shall prescribe that inspectors shall be bound by professional secrecy.

Article 13

In order to ensure that the application of this Directive is uniform throughout the Member States, the Commission shall, within one year of its adoption, make a report to the European Parliament and to the Council on:

(a) the current standard of training provision for food inspectors in the Member States;

(b) the possibility of establishing Community provisions on what should constitute the basic and further training of inspectors;

(c) the possibility of establishing Community quality standards for all laboratories involved in inspection and sampling under this Directive;

(d) the possibility of establishing a Community inspection service, including opportunities for all institutions and persons involved in the inspections to exchange information.

Article 14

1. The competent authority or authorities of the Member States shall draw up forward programmes laying down the nature and frequency of the inspections to be carried out regularly in accordance with Article 4 (1) (a) over a specific period.

2. By 1 May of each year the Member States shall send to the Commission all the necessary information on implementation during the previous year of the programmes referred to in paragraph 1, specifying:

— the criteria applied in drawing up these programmes,

— the number and type of inspections carried out,

— the number and type of infringements established.

3. By 16 October of each year, and for the first time in 1991, the Commission shall transmit to the Member States, after having consulted them within the framework of the Standing Committee for Foodstuffs, a recommendation concerning a coordinated programme of inspections for the following year. This recommendation may be subsequently adjusted as required during implementation of the coordinated programme.

The coordinated programme shall set out in particular the priority criteria to be applied in its implementation.

The information provided for in paragraph 2 shall contain a special, separate section on implementation of the coordinated programme.

4. Five years after notification of this Directive the Commission shall transmit to the Council a report on the application of this Article, accompanied, if necessary, by any appropriate proposals.

Article 15

Each Member State shall communicate to the Commission the names of:

— the competent authority or authorities and the extent of their territorial responsibility and functions,

— the official laboratories or laboratories authorized by the competent authorities, which are responsible for carrying out analyses in connection with the control.

These lists shall be published in the 'C' series of the *Official Journal of the European Communities*.

Article 16

Member States shall adopt and publish, not later than 12 months after notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive not later than 24 months after its notification (1). They shall forthwith inform the Commission thereof.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 4 June 1989.

For the Council
The President
P. SOLBES

(1) This Directive was notified to the Member States on 20 June 1989.

COUNCIL DIRECTIVE 79/111, OF JANUARY 24, 1979
AMENDING DIRECTIVE 64/432 AS REGARDS BRUCELLOSIS

ARTICLE 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive and shall forthwith inform the Commission thereof. C1-999/225

ARTICLE 8

This Directive is addressed to the Member States.

Done at Brussels, January 24, 1979.

ภาคผนวก ข

Council Directive 79/112 of December 18, 1978 C1-999/226

On the Approximation of the Laws of the Member States Relating to the Labelling, Presentation and Advertising of Foodstuffs for Sale to the Ultimate Consumer

(O.J. 1979, L33/1)

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 227 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas differences which exist at present between the laws, regulations and administrative provisions of Member States on the labelling of foodstuffs impede the free circulation of these products and can lead to unequal conditions of competition;

Whereas, therefore, approximation of these laws would contribute to the smooth functioning of the common market;

Whereas the purpose of this Directive should be to enact Community rules of a general nature applicable horizontally to all foodstuffs put on the market;

Whereas rules of a specific nature which apply vertically only to particular foodstuffs should be laid down in provisions dealing with those products;

Whereas, moreover, the field of application of this Directive should be limited to foodstuffs intended for sale to the ultimate consumer, and the rules governing the labelling of products intended for subsequent processing or preparation should be fixed at a later stage;

Whereas the prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer;

Whereas, therefore, a list should be drawn up of all information which should in principle be included in the labelling of all foodstuffs; C1-999/227

Whereas, however, the horizontal nature of this Directive does not allow, at the initial stage, the inclusion in the compulsory indications of all the indications which must be added to the list applying in principle to the whole range of foodstuffs; whereas, during the second stage, Community provisions should be adopted, aimed at supplementing the existing rules; whereas it would accordingly seem necessary to adopt as a matter of priority Community provisions regarding the indication of certain ingredients in the sales description or by indicating a quantity; C1-999/227

Whereas, furthermore, if in the absence of Community rules of a specific nature Member States should retain the right to lay down certain
C1-999/227 national provisions which may be added to the general provisions of this Directive, nevertheless these provisions should be subject to a Community procedure;

Whereas the said Community procedure may consist simply in informing the Commission and the Member States when the matter concerns the maintenance of national provisions that precede this Directive, but must be that of a Community Decision when a Member State wishes to enact new legislation;

Whereas provision should also be made for the Community legislator to derogate, in exceptional cases, from certain obligations that have been fixed generally;

Whereas the rules on labelling should also prohibit the use of information that would mislead the purchaser or attribute medicinal properties to foodstuffs; whereas, to be effective, this prohibition should also apply to the presentation and advertising of foodstuffs;

Whereas Member States should retain the right, depending on local conditions and circumstances, to lay down rules in respect of the labelling of foodstuffs sold in bulk; whereas, in such cases, information should nevertheless be provided for the consumer;

C1-999/228 Whereas, with the aim of simplifying and accelerating the procedure, the Commission should be entrusted with the task of adopting implementing measures of a technical nature;

Whereas in all cases where the Council makes the Commission responsible for implementing rules laid down in respect of foodstuffs, provision should be made for a procedure instituting close co-operation between Member States and the Commission within the Standing Committee on Foodstuffs, set up by Decision 69/414 (J.O. 1969, L291/9);

Whereas foodstuffs in Greenland are manufactured and marketed under conditions fundamentally different from those prevailing in the other parts of the Community because of the island's general situation and, in particular, because of its commercial structures, low population, considerable area and special geographical situation,

HAS ADOPTED THIS DIRECTIVE:

C1-999/229

ARTICLE 1

1. This Directive concerns the labelling of foodstuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof.

2. Without prejudice to the Community provisions to be adopted in this field, this Directive shall apply also to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers, in so far as the Member States shall so decide.

3. For the purpose of this Directive,

(*a*) "labelling" shall mean any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff;

(*b*) "pre-packaged foodstuff" shall mean any single item for presentation as such to the ultimate consumer, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case

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in such a way that the contents cannot be altered without opening or changing the packaging. C1–999/229

ARTICLE 2

1. The labelling and methods used must not:
   (*a*) be such as could mislead the purchaser to a material degree, particularly:
      (i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production,
      (ii) by attributing to the foodstuff effects or properties which it does not possess,
      (iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;
   (*b*) subject to the provisions applicable to foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties; Community provisions or, where there are none, national provisions may derogate from this rule in the case of natural mineral waters.

   The procedure laid down in Article 16 shall apply to any such national provisions.

2. The Council, in accordance with the procedure laid down in Article 100 of the Treaty, shall draw up a non-exhaustive list of the claims within the meaning of paragraph 1, the use of which must at all events be prohibited or restricted.

3. The prohibitions or restrictions referred to in paragraphs 1 and 2 shall also apply to:
   (*a*) the presentation of foodstuffs, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;
   (*b*) advertising.

ARTICLE 3 C1–999/230

1. In accordance with Articles 4 to 14 and subject to the exceptions contained therein, indication of the following particulars alone shall be compulsory on the labelling of foodstuffs:
   (1) the name under which the product is sold,
   (2) the list of ingredients,
   (3) in the case of prepackaged foodstuffs, the net quantity,
   (4) the date of minimum durability,
   (5) any special storage conditions or conditions of use,
   (6) the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

   However, the Member States shall be authorised in respect of butter produced in their territory, to require only an indication of the manufacturer, packager or seller.

   Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph, C1–999/230

—carbonated water, the description of which indicates that it has been carbonated,
—fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added; C1–999/232

(*b*) —cheese,
—butter,
—fermented milk and cream,
provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese;

(*c*) products consisting of a single ingredient.

3. In the case of beverages containing more than 1·2 per cent. by volume of alcohol, the Council, acting on a proposal from the Commission, shall, before the expiry of a period of four years following notification of this Directive, determine the rules for labelling ingredients [. . .]

4. (*a*) "Ingredient" shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

(*b*) Where an ingredient of the foodstuff is itself the product of several ingredients, the latter shall be regarded as ingredients of the foodstuff in question.

(*c*) The following shall not be regarded as ingredients:

(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) —additives:
—whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product,
—which are used as processing aids;
—substances used in the quantities strictly necessary as solvents or media for additives or flavouring.

(*d*) In certain cases Decisions may be taken in accordance with the procedure laid down in Article 17 as to whether the conditions described in (*c*) (ii) are satisfied.

5. (*a*) The list of ingredients shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word "ingredients." C1–999/233

However:

—added water and volatile products shall be listed in order of their weight in the finished product; the amount of water added as an ingredient in a foodstuff shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount need not be taken into consideration if it does not exceed five per cent. by weight of the finished product;

—ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration;

—in the case of concentrated or dehydrated foods which C1–999/233

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(7) particulars of the place of origin or provenance in the cases where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff,
(8) instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions.
[(9) with respect to beverages containing more than 1,2 per cent. by volume of alcohol, the actual alcoholic strenghth by volume.]

2. Notwithstanding the previous paragraph, Member States may retain national provisions which require indication of the factory or packaging centre, in respect of home production.

3. The provisions of this Article shall be without prejudice to more precise or more extensive provisions regarding weights and measures.

AMENDMENT
In para. (1) point (9) was inserted by Dir. 86/197, Art. 1 (O.J. 1986, L144/38).

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ARTICLE 4

1. Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide for derogations, in exceptional cases, from the requirements laid down in Article 3(1), points 2 and 4, provided that this does not result in the purchaser being inadequately informed.

2. Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars in addition to those listed in Article 3 must appear on the labelling.

Where there are no Community provisions, Member States may make provision for such particulars in accordance with the procedure laid down in Article 16.

ARTICLE 5

1. The name under which a foodstuff is sold shall be the name laid down by whatever laws, regulations or administrative provisions apply to the foodstuff in question or, in the absence of any such name, the name customary in the Member State where the product is sold to the ultimate consumer, or a description of the foodstuff and, if necessary, of its use, that is sufficiently precise to inform the purchaser of its true nature and to enable it to be distinguished from products with which it could be confused.

2. No trade mark, brand name or fancy name may be substituted for the name under which the product is sold.

3. The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (*e.g.* powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser.

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ARTICLE 6

1. Ingredients shall be listed in accordance with this Article and the Annexes.

2. Ingredients need not be listed in the case of:

C1–999/230
(*a*) —fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated,

—carbonated water, the description of which indicates that it has been carbonated,
—fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added; C1–999/232

(*b*) —cheese,
—butter,
—fermented milk and cream,
provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese;

(*c*) products consisting of a single ingredient.

3. In the case of beverages containing more than 1·2 per cent. by volume of alcohol, the Council, acting on a proposal from the Commission, shall, before the expiry of a period of four years following notification of this Directive, determine the rules for labelling ingredients [. . .]

4. (*a*) "Ingredient" shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

(*b*) Where an ingredient of the foodstuff is itself the product of several ingredients, the latter shall be regarded as ingredients of the foodstuff in question.

(*c*) The following shall not be regarded as ingredients:

(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) —additives:
—whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product,
—which are used as processing aids;
—substances used in the quantities strictly necessary as solvents or media for additives or flavouring.

(*d*) In certain cases Decisions may be taken in accordance with the procedure laid down in Article 17 as to whether the conditions described in (*c*) (ii) are satisfied.

5. (*a*) The list of ingredients shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word "ingredients." C1–999/233

However:

—added water and volatile products shall be listed in order of their weight in the finished product; the amount of water added as an ingredient in a foodstuff shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount need not be taken into consideration if it does not exceed five per cent. by weight of the finished product;

—ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration;

—in the case of concentrated or dehydrated foods which C1–999/233

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are intended to be reconstituted by the addition of water, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression such as "ingredients of the reconstituted product," or "ingredients of the ready-to-use product";

—in the case of mixtures of fruit or vegetables where no particular fruit or vegetable significantly predominates in proportion by weight, those ingredients may be listed in another order provided that that list of ingredients is accompanied by an expression such as "in variable proportion";

—in the case of mixtures of spices or herbs, where none significantly predominates in proportion by weight, those ingredients may be listed in another order provided that that list of ingredients is accompanied by an expression such as "in variable proportion";

(*b*) ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in Article 5. However:

—ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff need only be designated by the name of that category;

—ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EEC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated; amendments to this Annex based on advances in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 17;

—flavouring matter shall be described in accordance with the national provisions applicable thereto, until the entry into force of the Community provisions;

—the Community provisions or, where there are none, the national provisions applicable to certain specified foodstuffs, many also provide for categories additional to those specified in Annex I. Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this indent.

C1–999/234 6. Community provisions or, where there are none, national provisions may lay down that the name under which a specific foodstuff is sold is to be accompanied by mention of a particular ingredient or ingredients.

The procedure laid down in Article 16 shall apply to any such national provisions.

7. In the case referred to in paragraph 4(*b*), a compound ingredient may be included in the list of ingredients, under its own designation in so far as this is laid down by law or established by custom, in terms of its overall weight, provided that it is immediately followed by a list of its ingredients.

C1–999/233 Such a list, however, shall not be compulsory:

—where the compound ingredient constitutes less than 25 per cent. of the finished product; however, this exemption shall not apply

in the case of additives, subject to the provisions of paragraph 4(*c*),
—where the compound ingredient is a foodstuff for which a list of ingredients is not required under Community rules. C1–999/234

8. Notwithstanding paragraph 5(*a*), the water content need not be specified:

(*a*) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form;

(*b*) in the case of a liquid medium which is not normally consumed.

AMENDMENT

Para. (3) has been amended by Dir. 86/197, Art. 1 (O.J. 1986, L144/38).

ARTICLE 7

C1–999/235

1. Where the labelling of a foodstuff places emphasis on the presence or low content of one or more ingredients which are essential to the specific properties of the foodstuff, or where the description of the foodstuff has the same effect, the minimum or maximum percentage, as the case may be, used in the manufacture thereof shall be stated.

This information shall appear either immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient in question.

In accordance with the procedure laid down in Article 17, it may be decided that, in the case of certain ingredients, the percentage referred to in this paragraph shall be expressed in absolute terms.

2. Paragraph 1 shall not apply:

(*a*) in the case of labelling which is intended to characterise a foodstuff in accordance with Article 5(1) or which is required under Community provisions or, where there are none, under national provisions applicable to certain foodstuffs;

(*b*) in the case of ingredients used in small quantities only as flavourings.

3. Community provisions or, where there are none, national provisions may stipulate for certain foodstuffs, as well as in the case referred to in paragraph 2(*a*), that quantities of certain ingredients must be indicated either in absolute terms or as percentages and that, where appropriate, mention should be made of any alteration in the quantities of these ingredients.

The procedure laid down in Article 16 shall apply to any such national provisions.

ARTICLE 8

C1–999/236

1. The net quantity of prepackaged foodstuffs shall be expressed:
—in units of volume in the case of liquids,
—in units of mass in the case of other products,
using the litre, centilitre, millilitre, kilogram or gram, as appropriate.

Community provisions or, where there are none, national provisions applicable to certain specified foodstuffs may derogate from this rule.

The procedure laid down in Article 16 shall apply to any such national provisions.

2. (*a*) where the indication of a certain type of quantity (*e.g.* nominal quantity, minimum quantity, average quantity) is required by C1–999/236

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Community provisions or, where there are none, by national provisions, this quantity shall be regarded as the net quantity for the purposes of this Directive.

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this point.

(*b*) Community provisions or, where there are none, national provisions may, for certain specified foodstuffs classified by quantity in categories, require other indications of quantity.

The procedure laid down in Article 16 shall apply to any such national provisions.

(*c*) Where a prepackaged item consists of two or more individual prepackaged items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. Indication of these particulars shall not, however, be compulsory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.

(*d*) Where a prepackaged item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages. Community provisions or, where there are none, national provisions need not, in the case of certain foodstuffs, require indication of the total number of individual packages.

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this point.

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3. In the case of foodstuffs normally sold by number, Member States need not require indication of the net quantity provided that the number of items can clearly be seen and easily counted from the outside or, if not, is indicated on the labelling.

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph.

4. Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labelling.

For the purposes of this paragraph, "liquid medium" shall mean the following products, possibly in mixtures, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, salt water, brine, vinegar, acqueous solutions of sugars, and fruit or vegetable juices in the case of tinned fruit or vegetables.

Methods of checking the drained net weight shall be determined in accordance with the procedure laid down in Article 17.

5. It shall not be compulsory to indicate the net quantity in the case of foodstuffs:

(*a*) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser;

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(*b*) the net quantity of which is less than 5g or 5ml; however, this provision shall not apply to spices and herbs.

Community provisions or, where there are none, national provisions applicable to specified foodstuffs may in exceptional cases lay down thresholds which are higher than 5g or 5ml provided that this does not result in the purchaser being inadequately informed. C1–999/237

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph.

6. Until the end of the transitional period during which the use of the imperial units of measurement contained in Chapter D of the Annex to Directive 71/354 of October 18, 1971 (J.O. 1971, L243/29), on the approximation of the laws of the Member States relating to units of measurement, as last amended by Directive 76/770 (O.J. 1976, L262/204), is authorised in the Community, Ireland and the United Kingdom may permit the quantity to be expressed only in imperial units of measurement calculated on the basis of the following conversion rates: C1–999/238

—1 ml = 0·0352 fluid ounces,
—1 l = 1·760 pints or 0·220 gallons,
—1 g = 0·353 ounces (avoirdupois)
—1 kg = 2.205 pounds.

ARTICLE 9 C1–999/239

1. The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored.

It shall be indicated in accordance with the provisions of this Article.

2. The date shall be preceded by the words:

—"Best before . . . " when the date includes an indication of the day,

—"Best before end . . . " in other cases.

However, in the case of certain foodstuffs which, from the microbiological point of view, are highly perishable, Member States may require the words "use before . . . " to be indicated. Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this sub-paragraph.

Before the expiry of a period of six years from the date of notification of this Directive, the Council acting on a proposal from the Commission, shall decide on the common date-indication arrangements for highly perishable foodstuffs of the sort referred to in the second sub-paragraph.

3. The words referred to in paragraph 2 shall be accompanied by:

—either the date itself, or

—a reference to where the date is given on the labelling.

If need be, these particulars shall be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period.

4. The date shall consist of the day, month and year in uncoded chronological form.

However, in the case of foodstuffs:

—which will not keep for more than three months, an indication of the day and the month will suffice,

—which will keep for more than three months but not more than 18 months, an indication of the month and year will suffice,

—which will keep for more than 18 months, an indication of the year will suffice.

The manner of indicating the date may be specified according to the procedure laid down in Article 17. C1–999/239

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5. In their own territories the Member States may permit the minimum durability period to be expressed otherwise than in terms of the date of minimum durability.

Without prejudice to the notification provided for in Article 22, Member States shall notify the Commission and the other Member States of any measure taken under this paragraph.

6. Subject to the Community provisions governing the products below, an indication of the date of minimum durability shall not be required for:

—fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated,

—wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines,

—beverages containing 10 per cent. or more by volume of alcohol,

—bakers' or pastry-cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture,

—vinegar,

—cooking salt,

—solid sugar,

—confectionery products consisting of flavoured and/or coloured sugars.

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ARTICLE 10

1. The instructions for use of a foodstuff shall be indicated in such a way as to enable appropriate use to be made thereof.

2. Community provisions or, where there are none, national provisions may, in the case of certain foodstuffs, specify the way in which the instructions for use should be indicated.

The procedure laid down in Article 16 shall apply to such national provisions.

[ARTICLE 10A

The rules concerning indication of the alcoholic strength by volume shall, in the case of products covered by tariff heading Nos 22.04 and 22.05, be those laid down in the specific Community provisions applicable to such products.

In the case of other beverages containing more than 1,2 percent. by volume of alcohol, these rules shall be laid down in accordance with the procedure provided for in Article 17.]

AMENDMENT

This article was inserted by Dir. 86/197, Art. 1 (O.J. 1986, L144/38).

ARTICLE 11

1. (*a*) When the foodstuffs are prepackaged, the particulars provided for in Article 3 and Article 4(2) shall appear on the prepackaging or on a label attached thereto.

(*b*) Notwithstanding point (*a*) and without prejudice to Community provisions on nominal amounts, Member States may authorise that all or some of the particulars provided for in Article 3 and Article 4(2) be given only on the relevant trade documents

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when the foodstuffs are prepackaged and marketed prior to their sale to the ultimate consumer. C1–999/240

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this point.

The Council, acting on a proposal from the Commission, shall lay down the provisions to apply subsequently in this connection not later than nine years after notification of this Directive.

2. These particulars shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. C1–999/241

They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.

3. [(*a*) The particulars listed in Article 3(1), points (1), (3) (4) and (9) shall be simultaneously visible.

(*b*) However, for glass bottles intended for re-use, upon which one of the particulars listed in point (*a*) is indelibly marked, this requirement shall not apply for a period of 10 years following notification of this Directive.

4. Member States may:

(*a*) permit that only the particulars listed in Article 3(1), points 1, 3 and 4, be indicated on packaging or containers the largest surface of which has an area of less than 10 cm^2,

(*b*) require the indication of only some of the particulars listed in Article 3 in respect of milk or milk products in bottles intended for re-use; in this case they may also provide for derogations from paragraph 3(*a*).

Without prejudice to the notification provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph.

AMENDMENT

In para. (3) the words in square brackets were replaced by Dir. 88/197, Art. 1 (O.J. 1986, L144/38).

[THE NEXT PAGE IS C1999/490.]

ARTICLE 12

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Where foodstuffs are offered for sale to the ultimate consumer without prepackaging, or where foodstuffs are packaged on the sales premises at the consumer's request or prepackaged for direct sale, the Member States shall adopt detailed rules concerning the manner in which the particulars specified in Article 3 and Article 4(2) are to be shown.

They may decide not to require the provision of all or some of these particulars, provided that the consumer still received sufficient information.

ARTICLE 13

This Directive shall not affect the provisions of national laws which, in the absence of Community provisions, impose less stringent requirements for the labelling of foodstuffs presented in fancy packaging such as figurines or souvenirs.

ARTICLE 14

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Member States shall refrain from laying down requirements more detailed than those already contained in Articles 3 to 11 concerning the manner in which the particulars provided for in Article 3 and Article 4(2) are to be shown.

The Member State shall, however, ensure that the sale of foodstuffs within their own territories is prohibited if the particulars provided in Article 3 and Article 4(2) do not appear in a language 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 15

1. Member States may not forbid trade in foodstuffs which comply with the rules laid down in this Directive by the application of non-harmonized national provisions governing the labelling and presentation of certain foodstuffs or of foodstuffs in general.

2. Paragraph 1 shall not apply to non-harmonised national provisions justified on grounds of:

—protection of public health,
—prevention of fraud, unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,
—protection of industrial and commercial property rights, indications of provenance, registered designations of origin and prevention of unfair competition.

ARTICLE 16

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Where reference is made to this Article, the following procedure shall apply:

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(1) When a Member State maintains the provisions of its national laws, it shall inform the Commission and the other Member States thereof within a period of two years after notification of this Directive;

(2) Should a Member State deem it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on Foodstuffs if it considers such consultation to be useful or if a Member State so requests.

Member States may take such envisaged measures only three months after such notification and provided that the Commission's opinion is not negative.

In the latter event, and before the expiry of the abovementioned period, the Commission shall initiate the procedure provided for in Article 17 in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate modifications.

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ARTICLE 17

1. Where the procedure laid down in this Article is invoked, the matter shall be referred to the Standing Committee on Foodstuffs (hereinafter called "the Committee") by its chairman, either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall give its opinion on that draft within a time limit set by the chairman having regard to the urgency of the matter. Opinions shall be delivered by a majority of [54] votes, the votes of the Member States being weighted as provided for in Article 148(2) of the Treaty. The chairman shall not vote.

3. (*a*) Where the measures envisaged are in accordance with the opinion of the Committee, the Commission shall adopt them.

(*b*) Where 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 on the measures to be taken. The Council shall act by a qualified majority.

(*c*) If the Council has not acted within three months of the proposal being submitted to it, the proposed measures shall be adopted by the Commission.

AMENDMENT

In para. (2) the figure in square brackets was substituted by the Act of Accession of the Kingdom of Spain and the Portuguese Republic, Annex I, (X)(1).

ARTICLE 18

Article 17 shall apply [for a period of two years from the date on which the matter was first referred to the Committee after January 1, 1985] pursuant to Article 17.

AMENDMENT

The words in square brackets were replaced by Dir. 85/7, Art 1 (O.J. 1985 L2/22).

ARTICLE 19

C1–999/242

If temporary measures prove necessary to facilitate the application of this Directive, they shall be adopted in accordance with the procedure provided for in Article 17.

ARTICLE 20

C1–999/244

This Directive shall not affect Community provisions relating to the labelling and presentation of certain foodstuffs already adopted at the time of its notification.

Any amendments necessary to harmonize such provisions with the rules laid down in this Directive shall be decided in accordance with the procedure applicable to each of the provisions in question.

ARTICLE 21

This Directive shall not apply to products for export outside the Community.

ARTICLE 22

1. Member States shall make such amendments to their laws as may be necessary to comply with the provisions of this Directive and shall forthwith inform the Commission thereof; the laws thus amended shall be applied in such a way as to:

—permit trade in those products which comply with the provisions of this Directive no later than two years after its notification,

—prohibit trade in those products which do not comply with the provisions of this Directive four years after its notification.

2. However, Member States may:

(*a*) in the case of certain foodstuffs, reduce the period specified in the second indent of paragraph 1;

(*b*) in the case of certain foodstuffs which keep for a long time, extend the period specified in the second indent of paragraph 1;

(*c*) without prejudice to the first indent of Article 23(1)(*b*), in the case of foodstuffs which will keep for more than 12 months, extend to six years the period laid down in the second indent of paragraph 1 above as regards the obligation to indicate the date of minimum durability.

3. In the case referred to:

(*a*) in paragraph 2(*a*), the procedure laid down in Article 16(2) shall apply to any national provision;

(*b*) in paragraph 2(*b*) and (*c*), Member States shall inform the Commission and the other Member States of any measure taken pursuant to the said points.

4. Member States shall also ensure that the Commission receives the text of any essential provision of national law which they adopt in the field governed by this Directive.

ARTICLE 23

C1–999/245

1. By way of derogation from the second indent of Article 22(1), Member States may make implementation of the provisions relating to the following matters optional:

(*a*) the designation, provided for in the second indent of Article 6(5)(*b*), of the specific name or EEC number of the ingredients belonging to one of the categories listed in Annex II;

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(*b*) the indication provided for in Article 9, of the date of minimum durability in the case of:
—foodstuffs whose minimum durability exceeds 18 months,
—deep-frozen foodstuffs,
—ice-creams,
—chewing gums and similar chewing products,
—fermented cheese intended to ripen completely or partially in prepackaging;

(*c*) the information provided for in Annex I to supplement the designation "oil" or "fat."

2. Without prejudice to the information provided for in Article 22, Member States shall inform the Commission and the other Member States of any measure taken pursuant to paragraph 1.

3. After a period of five years following notification of this Directive, the Council shall, in accordance with the procedure laid down in Article 100 of the Treaty, decide upon the common rules to apply in the cases referred to in paragraph 1.

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ARTICLE 24

This Directive shall also apply to the French overseas departments.

ARTICLE 25

This Directive shall not apply to foodstuffs marketed in Greenland, intended for local consumption.

ARTICLE 26

This Directive is addressed to the Member States.
Done at Brussels, December 18, 1978.

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Annex 1

Categories of ingredients which may be designated by the name of the category rather than the specific name

Definition	*Designation*
Refined oils other than olive oil.	"Oil," together with —either the adjective "vegetable" or "animal," as appropriate, or —an indication of their specific vegetable or animal origin. The adjective "hydrogenated" must accompany the indication of a hydrogenated oil where the vegetable origin or the specific vegetable or animal origin is mentioned. However, in either case, Member States may lay down requirements which are more stringent in the case of foodstuffs consisting essentially of oils and fats, emulsified sauces or preparations where the oil serves as a liquid medium; in that case the procedure laid down is Article 16 shall apply.

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Definition	*Designation*
Refined fats.	" Fat," together with —either the adjective " vegetable " or " animal," as appropriate, or —an indication of their specific vegetable or animal origin. However, in either case, Member States may lay down requirements which are more stringent in the case of foodstuffs consisting essentially of oils and fats or emulsified sauces; in that case the procedure laid down in Article 16 shall apply.
Mixtures of flour obtained from two or more cereal species.	" Flour," followed by a list of the cereals from which it has been obtained in descending order by weight.
Starches, and starches modified by physical or enzymatic means.	Starch.
All species of fish where the fish constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific species of fish.	Fish.
All types of poultrymeat where such meat constitutes an ingredient of another foodstuff and provided that the name and presentation of such a foodstuff does not refer to a specific type of poultrymeat.	Poultrymeat.
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific type of cheese.	Cheese.
All spices and spice extracts not exceeding 2 per cent. by weight of the foodstuff.	Spice(s) or mixed spices.
All herbs or parts of herbs not exceeding 2 per cent. by weight of the foodstuff.	Herb(s) or mixed herbs.
All types of gum preparation used in the manufacture of gum base for chewing gum.	Gum base.
All types of crumbled baked cereal products.	Crumbs or rusks as appropriate.
All types of sucrose.	Sugar.
Anhydrous dextrose and dextrose monohydrate	Dextrose.
All types of caseinates.	Caseinates.
Press, expeller or refined cocoa butter.	Cocoa butter.
All crystallised fruit not exceeding 10 per cent. of the weight of the foodstuffs.	Crystallised fruit.

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Annex II

Categories of ingredients which must be designated by the name of the category to which they belong, followed by their specific name or EEC number

Colour
Preservative
Antioxidant
Emulsifier
Thickener
Gelling agent
Stabiliser
Flavour enhancer
Acid
Acidity regulator
Anticaking agent
Modified starches[1]
Artificial sweetener
Raising agent
Antifoaming agent
Glazing agent
Emulsifying salts[2]
Flour improvers

C1–999/249 GENERAL NOTE

With the exception of products for export outside the Community and foodstuffs presented in fancy packaging, foodstuffs for sale to the ultimate consumer must be packaged and labelled in accordance with Arts. 2–12 (Arts. 1, 13 and 21). Where such foodstuffs are not prepackaged or are packaged on the sales premises Member States are to introduce detailed rules as to how Arts. 3 and 4 (2) are to be applied (Art. 12). Member States may not forbid trade in foodstuffs which comply with the requirements of the Directive (Art. 15). Member States are forbidden to introduce more detailed rules than those laid down by the Directive, but shall ensure that the information required in Arts. 3 and 4 (2) is presented in a language with which purchasers will be familiar (Art. 14). The Directive must be implemented by Member States so as to permit trade in products complying with the Directive within two years of notification and to prohibit trade in products which do not comply with the Directive within four years of notification (Art. 22).

For implementation in England and Wales see S.I. 1980 No. 1849 and S.I. 1982 Nos. 1358 and 1359. For implementation in Scotland see S.I. 1981 No. 137. For further implementations see S.I. 1982 No. 117, S.I. 1982 No. 1779, S.I. 1984 No. 1314, S.I. 1984 No. 1315, S.I. 1984 No. 1316, S.I. 1984 No. 1317. See also Volume A of this Encyclopedia, Part A3.

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Council Directive 79/113 of December 19, 1978 On the Approximation of the Laws of the Member States Relating to the Determination of the Noise Emission of Construction Plant and Equipment

(O.J. 1979, L33/15)

The text of this Directive is printed under Transport and the Environment (Part C16).

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[1] Indication of specific name or EEC number is not required.
[2] Only for processed cheeses and processed cheese products.

ภาคผนวก ข

COUNCIL DIRECTIVE

of 14 June 1989

amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs for sale to the ultimate consume.

(89/395/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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 Council Directive 79/112/EEC (4), as last amended by Directive 86/197/EEC (5), makes provision for national derogations in a number of cases;

Whereas, with the dual aim of completing the internal market and providing improved information for all consumers in the Community, those derogations should be eliminated;

Whereas, in particular, experience acquired since the adoption of Directive 79/112/EEC enables it to be made applicable to restaurants, hospitals, canteens and other similar mass caterers throughout the Community;

Whereas the date of minimum durability has proved its worth; whereas, however, in the interests of a better protection of public health a stricter system of dating should be used in preference thereto in the case of foodstuffs which, from the microbiological point of view, are highly perishable and whereas in doubtful cases a Community procedure should be laid down;

Whereas this Directive is concerned only with labelling, presentation and advertising and not with the question of allowing or banning irradiation of foodstuffs or ingredients thereof;

Whereas, however, without prejudice to a decision on substance at Community level, the consumer's right to be informed of any irradiation treatment undergone by a foodstuff, where such treatment is allowed, must already be acknowledged; whereas to that end it should be specified that any foodstuff which has undergone such treatment must bear a corresponding indication; whereas, however, specific provisions concerning compound foodstuffs containing an ingredient previously treated with ionizing radiation will not be adopted until rules are adopted on irradiation treatment itself;

Whereas with a view to facilitating trade between Member States, it may be provided that, at stages prior to sale to the ultimate consumer, only information on the essential elements should appear on the outer packaging and whereas certain mandatory particulars that must appear on a prepackaged foodstuff need appear only on commercial documents referring thereto;

Whereas in all cases where the Council empowers the Commission to implement rules relating to foodstuffs intended for human consumption, 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 (6),

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 79/112/EEC is hereby amended as follows:

1. The title of the Directive shall be replaced by the following:

   'Council Directive of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs'.

2. Article 1 (2) shall be replaced by the following:

   '2. This Directive shall apply also to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as "mass caterers").'

3. In Article 1 (3) (b), 'to the ultimate consumer' shall be replaced by 'to the ultimate consumer and to mass caterers'.

(1) OJ No C 124, 28. 5. 1986, p. 5, and OJ No C 154, 12. 6. 1987, p. 10.
(2) OJ No C 99, 13. 4. 1987, p. 65, and OJ No C 120, 16. 5. 1989.
(3) OJ No C 328, 22. 12. 1986, p. 27.
(4) OJ No L 33, 8. 2. 1979, p. 1.
(5) OJ No L 144, 29. 5. 1986, p. 38.
(6) OJ No L 291, 19. 11. 1969, p. 9.

4. Article 2 (1) (b) shall be replaced by the following:

'(b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties'.

5. Article 3 (1) (4) shall be replaced by the following:

'4. The date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the "use by" date.'

6. The following paragraph shall be added to Article 4:

'3. The Community provisions referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure laid down in Article 17.'

7. In Article 5 (1), 'to the ultimate consumer' shall be replaced by 'to the ultimate consumer and to mass caterers'.

8. In Article 5 (3) the following text shall be added:

'Any foodstuff which has been treated with ionizing radiation must bear one of the following indications:

— in Spanish

"irradiado" or "tratado con radiacion ionizante"

— in Danish:

"bestrålet/ or "strålekonserveret" or "behandlet med ioniserende stråling" or "konserveret met ioniserende stråling"

— in German:

"bestrahlt" or "mit ionisierenden Strahlen behandelt"

— in Greek:

"επεξεργασμένο με ιονίζουσα ακτινοβολία" or "ακτινοβολημένο"

— in English:

"irradiated" or "treated with ionizing radiation"

— in French:

"traité par rayonnements ionisants" or "traité par ionisation"

— in Italian:

"irradiato" or "trattato con radiazioni ionizzanti"

— in Dutch:

"doorstraald" or "door bestraling behandeld" or "met ioniserende stralen behandeld"

— in Portuguese:

"irradiado" or "tratado por irradiação" or "tratado por radiação ionizante"'

9. The first indent of Article 6 (5) (b) shall be replaced by the following:

'— ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff may be designated by the name of that category only. Alterations to the list of categories in Annex I may be effected in accordance with the procedure laid down in Article 17,'.

10. The following shall be added to the third indent of Article 6 (5) (b):

'These provisions shall be adopted in accordance with the procedure laid down in Article 17,'.

11. The fourth indent of Article 6 (5) (b) shall be replaced by the following:

'— the specific Community provisions governing the indication of treatment of an ingredient with ionizing radiation shall be adopted subsequently in accordance with Article 100a of the Treaty.'

12. The following subparagraph shall be added to Article 6 (6):

'The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17.'

13. The following subparagraph shall be added to Article 7 (3):

'The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17.'

14. Article 8 (4) shall be replaced by the following:

'4. Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labelling.

For the purposes of this paragraph, "liquid medium" shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine; aqueous solutions of food acids, vinegar; aqueous solutions of sugars, aqueous solutions of other sweetening substances; fruit or vegetable juices in the case of fruit or vegetables.

This list may be supplemented in accordance with the procedure laid down in Article 17.

Methods of checking the drained net weight shall be determined in accordance with the procedure laid down in Article 17.'

15. The following paragraph shall be added to Article 8:

'7. The Community provisions referred to in paragraphs 1, 2 (b) and (d) and 5 shall be adopted in accordance with the procedure laid down in Article 17.'

16. The second and third subparagraphs of Article 9 (2) shall be deleted.

17. Article 9 (5) shall be replaced by the following:

'5. In their own territories the Member States may, until 31 December 1992, permit the minimum durability period to be expressed otherwise than in terms of the date of minimum durability. Without prejudice to the notification provided for in Article 22, Member States shall notify the Commission and the other Member States of any measure taken under this paragraph.'

18. Article 9 (6) shall be replaced by the following:

'6. Subject to Community provisions imposing other types of date indication, an indication of the durability date shall not be required for:

— fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts,

— wines, liqueur wines, sparkling wines, aromatized wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes 2206 00 91, 2206 00 93 and 2206 00 99 and manufactured from grapes or grape musts,

— beverages containing 10 % or more by volume of alcohol,

— soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers of more than five litres, intended for supply to mass caterers,

— bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture,

— vinegar,

— cooking salt,

— solid sugar,

— confectionery products consisting almost solely of flavoured and/or coloured sugars,

— chewing gums and similar chewing products,

— individual portions of ice-cream.'

19. The following Article shall be added:

'*Article 9a*

1. In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "use by" date.

2. The date shall be preceded by the words:

— in Spanish: "fecha de caducidad",

— in Danish: "sidste anvendelsesdato",

— in German: "verbrauchen bis",

— in Greek: "ανάλωση μέχρι",

— in English: "use by",

— in French: "à consommer jusqu'au",

— in Italian: "da consumare entro",

— in Dutch: "te gebruiken tot",

— in Portuguese: "a consumir até".

These words shall be accompanied by:

— either the date itself, or

— a reference to where the date is given on the labelling.

These particulars shall be followed by a description of the storage conditions which must be observed.

3. The date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form.

4. In some cases it may be decided by the procedure laid down in Article 17 whether the conditions laid down in paragraph 1 are fulfilled.'

20. The following subparagraph shall be added to Article 10 (2):

'The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 17.'

21. Article 11 shall be replaced by the following:

'*Article 11*

1. (a) When the foodstuffs are prepackaged, the particulars provided for in Articles 3 and 4 (2) shall appear on the prepackaging or on a label attached thereto.

(b) Notwithstanding point (a) and without prejudice to Community provisions on nominal quantities, where prepackaged foodstuffs are:

— intended for the ultimate consumer but marketed at a stage prior to sale to the ultimate consumer and where sale to a mass caterer is not involved at that stage,

— intended for supply to mass caterers for preparation, processing, splitting or retail sale,

the particulars required under Articles 3 and 4 (2) need appear only on the commercial documents referring to the foodstuffs where it can be guaranteed that such documents, containing all the labelling information, either accompany the foodstuffs to which they refer or were sent before or at the same time as delivery.

(c) In the cases referred to in (b), the particulars referred to in Article 3 (1) (1), (4) and (6) and, where appropriate, that referred to in Article

9a, shall also appear on the external packaging in which the foodstuffs are presented for marketing.

2. These particulars shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.

3. (a) The particulars listed in Article 3 (1), points 1, 3, 4 and 9 shall appear in the same field of vision.

This requirement may be extended to the particulars provided for in Article 4 (2).

(b) However, for glass bottles intended for re-use, upon which one of the particulars listed in point (a) is indelibly marked, this requirement shall not apply for a period of 10 years following notification of this Directive.

4. In the case of the glass bottles intended for re-use which are indelibly marked and which therefore bear no label, ring or collar and packaging or containers the largest surface of which has an area of less than 10 cm² only the particulars listed in Article 3 (1) (1), (3) and (4) need be given.

In this case, paragraph 3 (a) shall not apply.

5. Member States may, until 31 December 1996, refrain from requiring the minimum durability date or the "use by" date to be mentioned in respect of bottles referred to in paragraph 4.

6. Ireland, the Netherlands and the United Kingdom may derogate from Article 3 (1) and paragraph 3 (a) of this Article in the case of milk and milk products put up in glass bottles intended for re-use.

7. The Member States shall inform the Commission of any measure taken pursuant to paragraphs 5 or 6.'

22. In the first paragraph of Article 12, 'to the ultimate consumer' shall be replaced by 'to the ultimate consumer or to mass caterers'.

23. In the second paragraph of Article 12, 'consumer' shall be replaced by 'purchaser'.

24. Article 17 shall be replaced by the following:

'*Article 17*

Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee on Foodstuffs (hereinafter called "the Committee") by its chairman, either on his own initiative or at the request of a representative of a Member State.

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, on the expiry of a period three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.'

25. Article 18 shall be deleted.

26. Article 23 shall be deleted.

Article 2

Member States shall, where necessary, amend their laws, regulations and administrative provisions in such a way as to:

— permit trade in products complying with this Directive by not later than 20 December 1990,

— prohibit trade in products not complying with this Directive with effect from 20 June 1992.

They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1989.

For the Council

The President

P. SOLBES

ภาคผนวก ฉ

COUNCIL DIRECTIVE

of 24 September 1990

on nutrition labelling for foodstuffs

(90/496/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 (1),

In cooperation with the European Parliament (2),

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

Whereas it is important that measures should be adopted with a view to the progressive establishment of the internal market by 31 December 1992; whereas the internal market is an area without internal frontiers in which freedom of movement is ensured for goods, persons, services and capital;

Whereas there is growing public interest in the relationship between diet and health and in the choice of an appropriate diet to suit individual needs;

Whereas the Council and the Representatives of the Governments of the Member States meeting within the Council, in their resolution of 7 July 1986 on the European programme against cancer, considered the improvement of nutrition to be a priority;

Whereas knowledge of the basic principles of nutrition and appropriate nutrition labelling of foodstuffs would contribute significantly towards enabling the consumer to make this choice;

Whereas the provision of nutrition labelling should assist action in the area of nutrition education for the public;

Whereas, for the benefit of the consumer on the one hand, and to avoid any possible technical barriers to trade on the other, nutrition labelling should be presented in a standardized form applying throughout the Community;

Whereas foodstuffs bearing nutrition labelling should conform to the rules laid down in this Directive;

Whereas all other forms of nutrition labelling should be prohibited but foodstuffs bearing no nutrition labelling should be able to circulate freely;

Whereas, to appeal to the average consumer and to serve the purpose for which it is introduced, and given the current low level of knowledge on the subject of nutrition, the information provided should be simple and easily understood;

Whereas application of this Directive for a certain length of time will enable valuable experience on the subject to be gained and consumer reaction to the way in which nutrition information is presented to be evaluated thus enabling the Commission to review the rules and propose any appropriate amendments;

Whereas in order to encourage interested parties, especially small and medium-sized undertakings, to provide nutrition labelling for as many products as possible, measures to make information more complete and more balanced should be introduced gradually;

Whereas the rules laid down in this Directive should also take into account the *Codex Alimentarius* guidelines on nutrition labelling;

Whereas general labelling provisions and definitions are contained in Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (4), as last amended by Directive 89/395/EEC (5); whereas this Directive can therefore be confined to those provisions pertaining to nutrition labelling,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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1. This Directive concerns nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as 'mass caterers').

(1) OJ No C 282, 5. 11. 1988, p. 8 and OJ No C 296, 24. 11. 1989, p. 3.
(2) OJ No C 158, 26. 6. 1989, p. 250 and OJ No C 175, 16. 7. 1990, p. 76.
(3) OJ No C 159, 26. 6. 1989, p. 41.

(4) OJ No L 33, 8. 2. 1979, p. 1.
(5) OJ No L 186, 30. 6. 1989, p. 17.

2. This Directive shall not apply to :

— natural mineral waters or other waters intended for human consumption,

— diet integrators/food supplements.

3. This Directive shall apply without prejudice to the labelling provisions of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (1) and specific Directives as referred to in Article 4 of that Directive.

4. For the purposes of this Directive :

(a) 'nutrition labelling' means any information appearing on labelling and relating to :

(i) energy value ;

(ii) the following nutrients :

— protein,
— carbohydrate,
— fat,
— fibre,
— sodium,
— vitamins and minerals listed in the Annex and present in significant amounts as defined in that Annex.

Changes to the list of vitamins, minerals and their recommended daily allowances shall be adopted in accordance with the procedure laid down in Article 10 ;

(b) 'nutrition claim' means any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it

— provides,
— provides at a reduced or increased rate or
— does not provide,

and/or due to the nutrients it

— contains,
— contains in reduced or increased proportions or
— does not contain.

A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation.

In accordance with the procedure laid down in Article 10, it may be decided in certain cases whether the conditions described in this point are satisfied ;

(c) 'protein' means the protein content calculated using the formula : protein = total Kjeldahl nitrogen × 6,25 ;

(d) 'carbohydrate' means any carbohydrate which is metabolized in man, and includes polyols ;

(e) 'sugars' means all monosaccharides and disaccharides present in food, but excludes polyols ;

(f) 'fat' means total lipids, and includes phospholipids ;

(g) 'saturates' means fatty acids without double bond ;

(h) 'mono-unsaturates' means fatty acids with one *cis* double bond ;

(i) 'polyunsaturates' means fatty acids with *cis, cis*-methylene interrupted double bonds ;

(j) 'fibre' means the material to be defined in accordance with the procedure laid down in Article 10 and measured by the method of analysis to be determined in accordance with that procedure ;

(k) 'average value' means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary.

Article 2

1. Subject to paragraph 2, nutrition labelling shall be optional.

2. Where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling shall be compulsory.

Article 3

The only nutrition claims permitted shall be those relating to energy, to the nutrients listed in Article 1 (4) (a) (ii) and to substances which belong to or which are components of a category of those nutrients. Provisions restricting or prohibiting nutrition claims within the meaning of this Article may be adopted by the procedure laid down in Article 10.

Article 4

1. Where nutrition labelling is provided, the information to be given shall consist of either group 1 or group 2 in the following order :

Group 1

(a) energy value ;

(b) the amounts of protein, carbohydrate and fat.

Group 2

(a) energy value ;

(b) the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium.

2. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given shall consist of group 2.

(1) OJ No L 186, 30. 6. 1989, p. 27

3. Nutrition labelling may also include the amounts of one or more of the following :

— starch,
— polyols,
— mono-unsaturates,
— polyunsaturates,
— cholesterol,
— any of the minerals or vitamins listed in the Annex and present in significant amounts as defined in that Annex.

4. The declaration of substances which belong to or are components of one of the categories of nutrients referred to in paragraphs 1 and 3 shall be compulsory where a nutrition claim is made.

In addition, where the amount of polyunsaturates and/or mono-unsaturates and/or the cholesterol rate is given, the amount of saturates shall also be given, the declaration of the latter not constituting — in this case — a nutrition claim within the meaning of paragraph 2.

Article 5

1. The energy value to be declared shall be calculated using the following conversion factors :

— carbohydrate (except polyols)	4 kcal/g	— 17 kJ/g
— polyols	2,4 kcal/g	— 10 kJ/g
— protein	4 kcal/g	— 17 kJ/g
— fat	9 kcal/g	— 37 kJ/g
— alcohol (ethanol)	7 kcal/g	— 29 kJ/g
— organic acid	3 kcal/g	— 13 kJ/g

2. Provisions concerning the following points shall be adopted in accordance with the procedure laid down in Article 10 :

— amendments to the conversion factors mentioned in paragraph 1,

— the addition to the list in paragraph 1 of substances which belong to or are components of one of the categories of nutrients referred to in that paragraph and their conversion factors in order to calculate more precisely the energy value of foodstuffs.

Article 6

1. The declaration of the energy value and of the proportion of nutrients or their components shall be numerical. The units to be used are the following :

— energy — kJ and kcal — protein — carbohydrate — fat — fibre — sodium	grams (g)
— cholesterol — vitamins and minerals	milligrams (mg) the units specified in the Annex

2. Information shall be expressed per 100 g or per 100 ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated.

3. In accordance with the procedure laid down in Article 10 it may be decided that the information in paragraphs 1 and 2 may also be given in graphical form according to formats to be determined.

4. The amounts mentioned shall be those of the food as sold. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.

5. (a) Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance (RDA) given in the Annex for the amounts as specified in paragraph 2.

(b) The percentage of the recommended daily allowance (RDA) for vitamins and minerals may also be given in graphical form. Rules for implementing this subparagraph may be adopted in accordance with the procedure laid down in Article 10.

6. Where sugars and/or polyols and/or starch are declared, this declaration shall immediately follow the declaration of the carbohydrate content in the following manner :

— carbohydrate	g
of which :	
— sugars	g
— polyols	g
— starch	g

7. Where the amount and/or type of fatty acid and/or the cholesterol rate is declared, this declaration shall immediately follow the declaration of total fats in the following manner :

— fat	g
of which :	
— saturates	g
— mono-unsaturates	g
— polyunsaturates	g
— cholesterol	mg

8. The declared values shall, according to the individual case, be average values based on :

(a) the manufacturer's analysis of the food ;

(b) a calculation from the known or actual average values of the ingredients used ;

(c) a calculation from generally established and accepted data.

The rules for implementing the first paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure laid down in Article 10.

Article 7

1. The information covered by this Directive must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form.

It shall be printed in legible and indelible characters in a conspicuous place.

2. Member States shall ensure that the information covered by this Directive appears in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such information from being indicated in more than one language.

3. Member States shall refrain from laying down requirements more detailed than those already contained in this Directive concerning nutrition labelling.

Article 8

In the case of non-prepackaged foodstuffs put up for sale to the ultimate consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or prepackaged with a view to immediate sale, the extent of the information referred to in Article 4 and the manner of its communication may be determined by national provisions until the eventual adoption of Community measures in accordance with the procedure laid down in Article 10.

Article 9

Any measures likely to have an effect on public health shall be adopted after consultation of the Scientific Committee for Food set up by Decision 74/234/EEC (1).

Article 10

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee for Foodstuffs set up by Decision 69/414/EEC (2) (hereinafter referred to as 'the Committee') by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. 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.

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

(b) Where 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.

(c) If, on expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

1. Member States shall take the measures necessary to comply with this Directive and shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to:

— permit trade in products complying with this Directive by 1 April 1992,

— prohibit trade in products which do not comply with this Directive with effect from 1 October 1993.

2. Until .... (five years following notification of this Directive), the declaration in nutrition labelling, either on a voluntary basis or following a nutrition claim, of one or more of the following nutrients; sugars, saturates, fibre, sodium, shall not trigger the obligation set out in Article 4 (1) and (2) to declare all these nutrients.

3. The Commission shall, by .... (eight years after notification of this Directive), submit to the European Parliament and the Council a report on the application of

(1) OJ No L 136, 20. 5. 1974, p. 1.

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

this Directive. At the same time, it shall submit to the Council any appropriate proposals for amendment.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 24 September 1990.

For the Council
The President
V. SACCOMANDI

ANNEX

Vitamins and minerals which may be declared and their recommended daily allowances (RDAs)

Vitamin A µg	800	Vitamin B12 µg	1
Vitamin D µg	5	Biotin mg	0,15
Vitamin E mg	10	Pantothenic acid mg	6
Vitamin C mg	60	Calcium mg	800
Thiamin mg	1,4	Phosphorus mg	800
Riboflavin mg	1,6	Iron mg	14
Niacin mg	18	Magnesium mg	300
Vitamin B6 mg	2	Zinc mg	15
Folacin µg	200	Iodine µg	150

As a rule, 15 % of the recommended allowance specified in ths Annex supplied by 100 g or 100 ml or per package if the package contains only a single portion should be taken into consideration in deciding what constitutes a significant amount.

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(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 2377/90

of 26 June 1990

laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

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

Having regard to the opinion of the European Parliament (2),

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

Whereas the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;

Whereas as a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicines in foodstuffs at ever lower levels; whereas it is therefore necessary to establish maximum residue limits for pharmacologically active substances which are used in veterinary medicinal products in respect of all the various foodstuffs of animal origin, including meat, fish, milk, eggs and honey;

Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community;

Whereas the use of veterinary medicinal products plays an important part in agricultural production; whereas the establishment of maximum residue levels will facilitate the marketing of foodstuffs of animal origin;

Whereas the establishment of different maximum residue levels by Member States may hinder the free movement of foodstuffs and of veterinary medicinal products themselves;

Whereas it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality;

Whereas the need for the establishment of maximum residue levels throughout the Community is recognized in the Community rules relating to trade in foodstuffs of animal origin;

Whereas provisions must be adopted with a view to the systematic establishment of maximum residue levels for new substances capable of pharmacological action intended for administration to food-producing animals;

Whereas arrangements must also be made for the establishment of maximum residue levels for substances which are currently used in veterinary medicines administered to food-producing animals; whereas, however, in view of the complexity of this matter and the large number of substances involved, long transitional arrangements are required;

Whereas, after scientific assessment by the Committee for Veterinary Medicinal Products, maximum residue levels must be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee set up under Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (4), as last amended by Directive 87/20/EEC (5); whereas an urgent procedure is also required to ensure the swift review of any tolerance which might prove insufficient to protect public health;

(1) OJ No C 61, 10. 3. 1989, p. 5.
(2) OJ No C 96, 17. 4. 1990, p. 273.
(3) OJ No C 201, 17. 8. 1989, p. 1.

(4) OJ No L 317, 6. 11. 1981, p. 16.
(5) OJ No L 15, 17. 1. 1987, p. 34.

Whereas medicinally induced immunological responses are usually indistinguishable from those which arise naturally, and do not affect consumers of food of animal origin;

Whereas the information necessary to assess the safety of residues should be presented in accordance with the principles laid down by Directive 81/852/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'residues of veterinary medicinal products': means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered;

(b) 'maximum residue limit': means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or µg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects.

When establishing a maximum residue limit (MRL), consideration is also given to residues that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

2. This Regulation shall not apply to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity used in immunological veterinary medicinal products.

Article 2

The list of pharmacologically active substances used in veterinary medicinal products in respect of which maximum residue limits have been established shall be contained in Annex I, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex I shall be adopted in accordance with the same procedure.

Article 3

Where, following an evaluation of a pharmacologically active substance used in veterinary medicinal products, it appears that it is not necessary for the protection of public health to establish a maximum residue limit, that substance shall be included in a list in Annex II, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex II shall be adopted in accordance with the same procedure.

Article 4

A provisional maximum residue limit may be established for a pharmacologically active substance used in veterinary medicinal products on the date of entry into force of this Regulation, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer. A provisional maximum residue limit shall apply for a defined period of time, which shall not exceed five years. That period may be extended once only in exceptional cases for a period not in excess of two years if that proves expedient for the completion of scientific studies in progress.

In exceptional circumstances, a provisional maximum residue limit may also be established for a pharmacologically active substance not previously used in veterinary medicinal products on the date of entry into force of this Regulation provided that there are no grounds for supposing that residues of the substance concerned at the limit proposed present a hazard for the health of the consumer.

The list of pharmacologically active substances used in veterinary medicinal products in respect of which provisional maximum residue limits have been established shall be contained in Annex III, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex III shall be adopted in accordance with the same procedure.

Article 5

Where it appears that a maximum residue limit cannot be established in respect of a pharmacologically active substance used in veterinary medicinal products because residues of the substances concerned, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer, that substance shall be included in a list in Annex IV, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex IV shall be adopted in accordance with the same procedure.

The administration of the substances listed in Annex IV to food-producing animals shall be prohibited throughout the Community.

Article 6

1. In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals, and

— intended to be placed on the market of one or more Member States which have not previously authorized the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission. The application shall contain the information and particulars referred to in Annex V and shall comply with the principles laid down in Directive 81/852/EEC.

2. After verifying within a period of 30 days that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products set up under Article 16 of Directive 81/851/EEC. The Committee shall appoint one of its members to act as rapporteur and to undertake an initial evaluation of the application.

3. Within 120 days of referral of the application to the Committee for Veterinary Medicinal Products, and having regard to the observations formulated by the members of the Committee, the Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. The rapporteur shall update the evaluation report to take account of the additional information received.

4. Within 90 days of receipt of the additional information referred to in paragraph 3, the Commission shall prepare a draft of the measures to be taken, which shall forthwith be communicated to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the Committee for Veterinary Medicinal Products. The Commission may, at the request of the applicant, extend this time limit.

5. Within a further 60 days the Commission shall submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, set up under Article 2b of Directive 81/852/EEC, for the application of the procedure laid down in Article 8.

Article 7

1. Paragraphs 2 to 6 shall apply in respect of pharmacologically active substances which are authorized for use in veterinary medicinal products on the date of entry into force of this Regulation.

2. After consulting the Committee on Veterinary Medicinal Products, the Commission shall publish a timetable for the consideration of these substances, including time limits for submission of the information referred to in Annex V.

The persons responsible for marketing the veterinary medicinal products concerned shall ensure that all relevant information is submitted to the Commission in accordance with the requirements of Annex V and in conformity with the principles laid down in Directive 81/852/EEC before expiry of the relevant time limits. The competent authorities of the Member States shall bring any other relevant information to the attention of the Commission.

3. After verifying within 30 days that the information is submitted in correct form, the Commission shall forthwith submit the information for examination to the Committee for Veterinary Medicinal Products, which shall deliver its opinion within a renewable period of 120 days. That Committee shall appoint one of its members to act as rapporteur and to undertake an evaluation of the information.

4. Having regard to the observations formulated by the members of the Committee for Veterinary Medicinal Products, the Commission shall prepare, within a maximum period of 30 days, a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide additional information, within a specified period, for examination by the Committee. The rapporteur shall update the evaluation report to take account of the additional information received.

5. The draft of the measures to be taken shall be communicated forthwith by the Commission to the Member States and those persons responsible for marketing who have submitted information to the Commission before expiry of the time limit established in accordance with paragraph 2. These persons may, at their request, provide oral or written explanations to the Committee for Veterinary Medicinal Products.

6. The Commission shall forthwith submit the draft measures to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products for the application of the procedure laid down in Article 8.

Article 8

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit a draft of the measures to be adopted to the Committee for Adaptation to Technical Progress. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple majority.

Article 9

1. Where a Member State, as a result of new information or a reassessment of existing information, considers that the urgent amendment of a provision contained in Annexes I to IV is necessary in order to protect human or animal health, and therefore requires swift action to be taken, that Member State may temporarily suspend the operation of the provision concerned in its own territory. In that case, it shall immediately notify the other Member States and the Commission of the measures, attaching a statement of the reasons therefor.

2. The Commission shall as soon as possible examine the grounds given by the Member State concerned and, after consulting the Member States within the Committee for Veterinary Medicinal Products, it shall then deliver its opinion forthwith and take appropriate measures; the person responsible for marketing may be requested to provide the Committee with oral or written explanations. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council, acting by a qualified majority, may take a different decision within 30 days of the date on which the matter was referred to it.

3. If the Commission considers that it is necessary to amend the provision of Annex I to IV concerned in order to resolve the difficulties referred to 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 those amendments; the Member State which has taken measures under paragraph 1 may maintain them until the Council or the Commission has taken a decision in accordance with the abovementioned procedure.

Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged, where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If within 15 days of the proposals being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

Any changes which are necessary to adapt Annex V to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

Article 12

As soon as possible after the amendment of Annexes I, II, III or IV, the Commission shall publish a summary of the assessment of the safety of the substances concerned by the Committee for Veterinary Medicinal Products. The confidential nature of any proprietary data shall be respected.

Article 13

Member States may not prohibit or impede the putting into circulation within their territories of foodstuffs of animal origin originating in other Member States on the grounds that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit provided for in Annex I or III, or if the substance concerned is listed in Annex II.

Article 14

With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community, except in the case of clinical trials

accepted by the competent authorities following notification or authorization in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

Article 15

This Regulation shall in no way prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.

Nothing in this Regulation shall prejudice the measures taken by Member States to prevent the unauthorized use of veterinary medicinal products.

Article 16

This Regulation shall enter into force on 1 January 1992.

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

Done at Luxembourg, 26 June 1990.

For the Council
The President
M. O'KENNEDY

ANNEX I

List of pharmacologically active substances for which maximum residue levels have been fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX II

List of substances not subject to maximum residue levels

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which maximum residue levels have been fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX IV

Lists of pharmacologically active substances for which no maximum levels can be fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX V

Information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products

1. *Administrative particulars*

1.1. Name or corporate name and permanent address of the person responsible for placing the veterinary medicinal product(s) on the market.

1.2. Name of the veterinary medicinal product(s).

1.3. Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name recommended by the World Health Organization, where such name exists.

1.4. Manufacturing authorization, if any.

1.5. Marketing authorizations, if any.

1.6. Summary of the characteristics of the veterinary medicinal product(s) prepared in accordance with Article 5a of Directive 81/851/EEC.

2. *Identity of substance*

2.1. International non-proprietary name.

2.2. International Union of Pure and Applied Chemistry (IUPAC) name.

2.3. Chemical Abstract Service (CAS) name.

2.4. Classification:
- therapeutic
- pharmacological.

2.5. Synonyms and abbreviations.

2.6. Structural formula.

2.7. Molecular formula.

2.8. Molecular weight.

2.9. Degree of impurity.

2.10. Qualitative and quantitative composition of impurities.

2.11. Description of physical properties:
- fusion point
- boiling point
- vapour pressure
- solubility in water and organic solvents expressed in g/l, with indication of temperature
- density
- spectra of refraction, rotation, etc.

3. *Toxicological studies*

3.1. Short-term toxicological studies.

3.2. Long-term toxicological studies.

3.3. Studies on reproduction.

3.4. Studies on teratogenicity.

3.5. Studies on mutagenicity.

3.6. Studies for carcinogenicity.

3.7. Studies of immunological effects.

3.8. Studies of microbiological effects.

3.9. Observations in humans.

3.10. Other biological effects.

4. *Metabolic and residue studies*

4.1. Absorption, distribution, excretion and biotransformations.

4.2. Determination of residues, including methods of residue analysis.

4.3. Existing maximum permitted residue levels.

5. *Conclusions*

5.1. Level causing no toxicological effect.

5.2. Estimate of temporary acceptable daily intake for man.

5.3. Estimate of maximum residue levels in food with the specification of the residue concerned.

5.4. Methods of routine analysis that may be used by the competent authorities for the detection of residues.

5.5. Further work or information:
— required
— desirable.

6. *References*

7. *Experts report*

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COMMISSION REGULATION (EEC) No 675/92

of 18 March 1992

amending Annexes I and III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (1), and in particular Articles 7 and 8 thereof;

Whereas in accordance with Regulation (EEC) No 2377/90 maximum residue limits must be established progressively for all pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals;

Whereas maximum residue limits should be established only after the examination within the Committee for Veterinary Medicinal Products of all the relevant information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and the impact of residues on the industrial processing of foodstuffs;

Whereas, in establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify the animal species in which residues may be present, the levels which may be present in each of the relevant meat tissues obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

Whereas, for the control of residues, as provided for in appropriate Community legislation, maximum residue limits should usually be established for the target tissue of liver or kidney; whereas, however, the liver and kidney are frequently removed from carcases moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues;

Whereas, in the case of veterinary medicinal products intended for use in laying birds, lactating animals or honey bees, maximum residue limits must also be established for eggs, milk or honey;

Whereas the sulfonamide group of substances (in respect of residues in meat), ivermectin, benzylpenicillin, ampicillin, amoxicillin, oxacillin, cloxacillin and dicloxacillin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas dimetridazole, ronidazole, chloramphenicol, azaperone and carazolol, the nitrofurans group, trimethoprim, dapsone, compounds belonging to the tetracyclines group, spiramycin, febantel, fenbendazole, oxfendazole, levamisol and sulfonamide group (in respect of residues in milk) should be inserted into Annex III to Regulation (EEC) No 2377/90; whereas it is necessary to define the duration of the provisional maximum residue limits;

Whereas a period of 60 days should be allowed before the entry into force of this Regulation in order to allow Member States to make any adjustment which may be necessary to the authorizations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/CEE (2) to take account of the provisions of this Regulation;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and III of Regulation (EEC) No 2377/90 are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the 60 day following its publication in the *Official Journal of the European Communities*.

(1) OJ No L 224, 18. 8. 1990, p. 1.

(2) OJ No L 317, 6. 11. 1981, p. 1.

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

Done at Brussels, 18 March 1992.

For the Commission
Martin BANGEMANN
Vice-President

ANNEX

A. Annex I is hereby replaced by the following:

'ANNEX I

List of pharmacologically active substances for which maximum residue limits have been fixed

1. *Anti-infectious agents*

1.1. Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	All food producing species	100 µg/kg	Muscle, liver, kidney, fat	The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg

1.2. Antibiotics

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.1.1. Benzylpenicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.2. Ampicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.3. Amoxicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.4. Oxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.5. Cloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.6. Dicloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
				milk	

1.1.3. Nitrofurans

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the nitrofuran group	All residues with intact 5-nitro structure	All food producing species	5 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 July 1993 The combined total residues of all substances within this group should not exceed 5 µg/kg

1.1.4. Nitroimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.4.1. Dimetridazole	All residues with intact nitroimidazole structure	All food producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 January 1994
1.1.4.2. Ronidazole	All residues with intact nitroimidazole structure	All food producing species	2 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 January 1994

1.1.n. Other chemotherapeutics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.n.1. Dapsone	Parent drug	All food producing species	25 µg/kg 25 µg/kg	Muscle, liver, kidney, fat milk	Provisional MRL expires on 1 January 1994

1.2. Antibiotics

1.2.2. Tetracyclines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the tetracycline group	Parent drug	All food producing species	600 µg/kg 300 µg/kg 200 µg/kg 100 µg/kg 100 µg/kg	Kidney, liver eggs, muscle, milk	Provisional MRLs expires on 1 January 1994. The combined total residues of all substances within the tetracycline group should not exceed the limits indicated

1.2.3. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.3.1. Spiramycin	Parent drug	Bovine, porcine	300 µg/kg 200 µg/kg 50 µg/kg	Liver kidney muscle	Provisional MRLs expire on 1 July 1995
		bovine	150 µg/kg	milk	The MRLs for liver, kidney and muscle apply to both the bovine and porcine species

1.2.4. Chloramphenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.4.1. Chloramphenicol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on July 1994

2. *Antiparasitic agents*

2.1. Agents acting against endo-parasites

2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.1. Febantel 2.1.1.2. Fenbendazole 2.1.1.3. Oxfendazole	combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1 000 µg/kg 10 µg/kg 10 µg/kg	Liver muscle, kidney, fat milk	Provisional MRLs expire on 1 July 1995 The MRLs cover all residues of febantel, fenbendazole and oxfendazole

2.1.2. Tetra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.2.1. Levamisol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat, milk	Provisional MRL expires on 1 January 1995

2. *Antiparasitic agents*

2.1. Agents acting against endoparasites

2.1.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.1. Ivermectin	H2B1a – metabolite	Bovine, ovine, porcine, equine	15 µg/kg 20 µg/kg	Liver fat	The MRLs for liver and fat apply to all four species mentioned'

B. Annex III is hereby replaced by the following:

'ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1. *Anti-infectious agents*

1.1. Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	Cattle, sheep, goats	100 µg/kg	milk	Provisional MRL expires on 1 January 1994. The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg.

1.1.2. Diamino pyrimidine derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.2.1. Trimethoprim	Parent drug	All food producing	50 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 January 1996

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COMMISSION REGULATION (EEC) No 762/92

of 27 March 1992

modifying Annex V to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (1), as amended by Commission Regulation (EEC) No 675/92 (2), and in particular Article 11 thereof,

Whereas it is desirable in the interests of administrative efficiency that the information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products in accordance with Regulation (EEC) No 2377/90 should correspond as closely as possible to the information and particulars to be submitted to Member States in an application for authorization to place a veterinary medicinal product on the market submitted in accordance with Article 5 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (3), as amended by Directive 90/676/EEC (4);

Whereas it is necessary to amend Annex V to Regulation (EEC) No 2377/90 to take account of the changes to the requirements for the testing of veterinary medicinal products introduced by Commission Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products;

Whereas the provisions of this Regulation are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector established under Article 2b of Council Directive 81/852/EEC (5), as amended by Directive 87/20/EEC (6),

HAS ADOPTED THIS REGULATION:

Article 1

Annex V to Regulation (EEC) No 2377/90 is hereby replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the date 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 Brussels, 27 March 1992.

For the Commission

Martin BANGEMANN

Vice-President

(1) OJ No L 224, 18. 8. 1990, p. 1.
(2) OJ No L 73, 19. 3. 1992, p. 8.
(3) OJ No L 317, 6. 11. 1981, p. 1.
(4) OJ No L 373, 31. 12. 1990, p. 15.
(5) OJ No L 317, 6. 11. 1981, p. 16.
(6) OJ No L 15, 17. 1. 1987, p. 34.

ANNEX

'ANNEX V

Information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products

Administrative particulars

1 Name or corporate name and permanent address of the applicant.

2 Name of the veterinary medicinal product.

3 Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name recommended by the World Health Organization, where such name exists.

4 Manufacturing authorization, if any.

5 Marketing authorization, if any.

6 Summary of the characteristics of the veterinary medicinal product(s) prepared in accordance with Article 5a of Directive 81/851/EEC.

A. *Safety documentation*

A.0. Expert report

A.1. Precise identification of the substance concerned by the application

1.1 International non-proprietary name (INN).

1.2 International Union of Pure and Applied Chemistry (IUPAC) name.

1.3 Chemical Abstract Service (CAS) name.

1.4 Classification:

— therapeutic;

— pharmacological.

1.5 Synonyms and abbreviations.

1.6 Structural formula.

1.7 Molecular formula.

1.8 Molecular weight.

1.9 Degree of impurity.

1.10 Qualitative and quantitative composition of impurities.

1.11 Description of physical properties:

— melting point;

— boiling point;

— vapour pressure;

— solubility in water and organic solvents, expressed in grams per litre, with indication of temperature;

— density;

— refractive index, rotation, etc.

A.2. Relevant pharmacological studies

2.1 Pharmacodynamics.

2.2 Pharmacokinetics.

A.3. Toxicological studies

3.1 Single dose toxicity.

3.2 Repeated dose toxicity.

3.3 Tolerance in the target species of animal.

3.4 Reproductive toxicity, including teratogenicity.

3.4.1 Study of the effects on reproduction.

3.4.2 Embryotoxicity/fetotoxicity, including teratogenicity.

3.5 Mutagenicity.

3.6 Carcinogenicity.

A.4 Studies of other effects

4.1 Immunotoxicity

4.2 Microbiological properties of residues

4.2.1 On the human gut flora;

4.2.2 On the organisms and microorganisms used for industrial food-processing.

4.3 Observations in humans.

B. *Residue documentation*

B.0 Expert report

B.1. Precise identification of the substance concerned by the application

The substance concerned should be identified in accordance with point A.1. However, where the application relates to one or more veterinary medicinal products, the product itself should be identified in detail, including:

— qualitative and quantitative composition;
— purity;
— identification of the manufacturer's batch used in the studies; relationship to the final product;
— specific activity and radio-purity of labelled substances;
— position of labelled atoms on the molecule.

B.2. Residue studies

2.1 Pharmacokinetics
(absorption, distribution, biotransformation, excretion)

2.2 Depletion of residues

2.3 Elaboration of maximum residue limits (MRLS).

B.3. Routine analytical method for the detection of residues

3.1 Description of the method

3.2 Validation of the method

3.2.1 specificity;
3.2.2 accuracy, including sensitivity;
3.2.3 precision;
3.2.4 limit of detection;
3.2.5 limit of quantitation;
3.2.6 practicability and applicability under normal laboratory conditions;
3.2.7 susceptibility to interference.

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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 28 January 1991

concerning the animal health conditions governing the placing on the market of aquaculture animals and products

(91/67/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

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

Having regard to the opinion of the European Parliament (2),

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

Whereas aquaculture animals and products are included in the list in Annex II to the Treaty;

Whereas the breeding and rearing of aquaculture animals, and the placing on the market of aquaculture animals and products constitutes a source of income for persons working in the fisheries sector;

Whereas, in order to ensure the rational development of this sector and to increase productivity, health rules for this sector must be laid down at Community level;

Whereas in this context it is necessary to contribute to the completion of the internal market, avoiding the spread of infectious or contagious diseases;

Whereas the animal health situation for aquaculture animals is not the same throughout the territory of the Community; whereas reference must therefore be made to the concept of zones when dealing with parts of the territory concerned;

Whereas criteria and procedures should be laid down for the grant, maintenance, suspension, restoration and withdrawal of approval of such zones;

Whereas reference should also be made to the concept of farms enjoying a specific animal health status;

Whereas criteria and procedures should be laid down for the grant, maintenance, suspension, restoration and withdrawal of approval of such farms;

Whereas it is necessary to set Community requirements applicable to imports of aquaculture animals and products from third countries; whereas these requirements must provide for adequate protective measures;

Whereas a Community inspection system should be established in order to verify compliance with this Directive;

Whereas scientific studies should be undertaken so as to be able to supplement in the future the rules laid down by this Directive;

Whereas provision should be made for a procedure establishing close and efficient cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

General provisions

Article 1

This Directive defines the animal health conditions governing the placing on the market of aquaculture animals and products.

(1) OJ No C 84, 2. 4. 1990, p. 42.
(2) OJ No C 19, 28. 1. 1991.
(3) OJ No C 332, 31. 12. 1990.

This Directive shall apply without prejudice to Community or national provisions on the conservation of species

Article 2

For the purposes of this Directive:

1. 'aquaculture animals' means live fish, crustaceans or molluscs coming from a farm, including those from the wild intended for a farm;

2. 'aquaculture products' means products derived from aquaculture animals, whether intended for farming, such as eggs and gametes, or for human consumption;

3. 'fish, crustaceans or molluscs' means any fish, crustacean or mollusc at any stage of development;

4. 'farm' means any establishment or, in general, any geographically defined installation in which aquaculture animals are reared or kept with a view to their being placed on the market;

5. 'approved farm' means a farm complying, as the case may be, with the requirements of Annex C I, II or III, and approved as such in accordance with Article 6;

6. 'approved zone' means a zone complying, as the case may be, with the provisions of Annex B I, II or III, and approved as such in accordance with Article 5;

7. 'approved laboratory' means a laboratory located in the territory of a Member State, designated by the competent authority, under its responsibility, to carry out the diagnostic tests provided for in this Directive;

8. 'official service' means the veterinary service or any other service of equivalent level designated by the competent authority of the Member State or third country and responsible for carrying out the controls provided for in this Directive;

9. 'health inspection' means a visit by an official service or services for the purpose of conducting health checks on a farm or zone;

10. 'placing on the market' means holding or displaying for sale, offering for sale, selling, delivering, transferring or any other form of placing on the market in the Community, with the exception of retail sale.

CHAPTER 2

Placing on the market of Community aquaculture animals and products

Article 3

1. The placing on the market of aquaculture animals shall be subject to the following general requirements:

(a) they must show no clinical signs of disease on the day of loading;

(b) they must not be intended for destruction or slaughter under a scheme for the eradication of a disease listed in Annex A;

(c) they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in contact with animals from such a farm.

2. Aquaculture products being placed on the market for breeding purposes (eggs and gametes) must originate from animals which satisfy the requirements laid down in paragraph 1.

3. Aquaculture products being placed on the market for human consumption must originate from animals which satisfy the requirements laid down in paragraph 1 (a).

Article 4

Aquaculture animals must be dispatched in the shortest possible period to the place of destination, using means of transport that have been cleaned and, if necessary, disinfected in advance with a disinfectant that is officially authorized in the Member State of dispatch.

If water is used in overland transport, the vehicles shall be designed in such a way that water cannot escape from the vehicle during transport. Transport shall be carried out in such a way as to safeguard effectively the health of the animals, in particular by changing the water. Changes of water must be carried out in places complying with the requirements of Annex D. A list of these places and any subsequent amendments thereto must be notified by each Member State to the Commission, which shall forward that information to the other Member States.

Article 5

1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, of lists I and II, the status of approved zone, Member States shall submit to the Commission:

— all appropriate justifications concerning the conditions laid down, as the case may be, in Annex B under I B, II B or III B,

— the national rules ensuring compliance with the conditions laid down, as the case may be, in Annex B under I C, II C or III C.

2. The Commission shall scrutinize the information referred to in paragraph 1. The Commission may, in accordance with the procedure laid down in Article 26, approve or restore approval of zones, having regard to that information.

If, in accordance with Annex B under I D 5, II D or III D 5, the approval of a zone is withdrawn by the official service, the Commission shall revoke the decision concerning its approval.

3. The Commission shall draw up the list of approved zones. It shall amend this list in order to take account of new approvals or withdrawal of approvals. The Commission shall forward the list and any amendments thereto to the Member States.

Article 6

1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, of lists I and II, the status of approved farm situated in a non-approved zone, Member States shall submit to the Commission:

— all appropriate justifications concerning the conditions set out, as the case may be, in Annex C under I A, II A or III A,

— the national rules ensuring compliance with the conditions set out in Annex C under I B, II B or III B.

2. On receipt of the file relating to the request for approval or re-approval of a farm in a non-approved zone, the Commission shall have a month within which to examine that file. That examination shall be carried out in the light of the information mentioned in paragraph 1 and, where appropriate, of on-site inspections undertaken in accordance with the provisions set out in Article 17.

Should that examination lead to favorable conclusions, the Commission shall forward such conclusions to the Member States. The Member States shall have a period of two weeks within which to make known their remarks.

After expiry of that period, if no remarks have been made or if the Member States' remarks are not contrary to the Commission's conclusions, the Commission shall approve or re-approve the farm.

Should there exist major differences between the Commission's conclusions and the Member States' remarks, or should the Commission, after examining the file, consider that the approval or re-approval ought not be granted, the Commission shall have two months within which to refer the matter to the Standing Veterinary Committee and obtain its opinion. In that case, the approval or re-approval shall be granted in accordance with the procedure laid down in Article 26.

If in accordance with Annex C under I C, II C or III C, the approval of a farm is withdrawn by the official service, the Commission shall revoke the approval decision.

3. The Commission shall draw up the list of approved farms. It shall amend that list in order to take account of new approvals or withdrawal of approvals. The Commission shall forward the list and any amendments thereto to the Member States.

Article 7

1. The placing on the market of live fish belonging to the susceptible species referred to in Annex A, column 2 of lists I and II, their eggs or gametes, shall be subject to the following additional guarantees:

(a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come from an approved zone or an approved farm. Pending the outcome of the review provided for in Article 28, additional guarantees to be met for the introduction into an approved zone of fish coming from an approved farm situated in a non-approved zone shall be fixed in accordance with the procedure laid down in Article 26. Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty;

(b) where they are to be introduced into a farm which, although not situated in an approved zone, fulfils the conditions set out in Annex C I, they must in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come respectively from an approved zone or from a farm of the same health status as the farm of destination.

2. The Commission may, in accordance with the procedure laid down in Article 26, adapt or delete the additional guarantees referred to in paragraph 1, depending on the evolution of the animal health situation in the Community, in particular in order to take account of the results of the eradication measures for the disease referred to in Annex A, column 1 of list I.

Article 8

1. The placing on the market of live molluscs referred to in Annex A, column 2 of lists I and II, shall be subject to the following additional guarantees:

(a) if they are to be relaid in an approved coastal zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from an approved farm in a non-approved coastal zone, as the case may be;

(b) if they are to be relaid in a farm which although not situated in an approved coastal zone fulfils the conditions set out in Annex C III, they must, in

accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from a farm of the same health status as the farm of destination.

2. The Commission may, in accordance with the procedure laid down in Article 26, adapt or delete the additional guarantees referred to in paragraph 1, on the basis of the animal health situation existing in the Community.

Article 9

The placing on the market in an approved zone of aquaculture animals and products for human consumption originating in a non-approved zone shall be subject to the following requirements:

1. Fish susceptible to the diseases referred to in Annex A, column 1 of lists I and II, must be slaughtered and eviscerated prior to dispatch.

   However, pending the outcome of the review provided for in Article 28, the obligation to eviscerate shall not be required, if the fish come from an approved farm in a non-approved zone. Derogations from this principle may be adopted under the procedure provided for in Article 26.

   Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty.

2. Live molluscs susceptible to the diseases referred to in Annex A, column 1 of lists I and II must be delivered either for direct human consumption or to the preserving industry and shall not be relaid unless:

   — they originate in an approved farm in a non-approved coastal zone, or

   — they are temporarily immersed in storage ponds or purification centres which are specially equipped and approved for that purpose by the competent authority and include in particular a system for the treatment and disinfection of residual water. The conditions for such approval will be determined by the Commission in accordance with the procedure laid down in Article 26.

3. The Commission shall, in accordance with the procedure provided for in Article 26, take, if necessary, appropriate measures to ensure uniform compliance with this Article.

Article 10

1. Where a Member State draws up or has drawn up a programme designed to enable it subsequently to initiate the procedures provided for in Article 5 (1) and Article 6 (1), it shall submit its programme to the Commission specifying in particular:

   — the geographical zone and farm or farms concerned,

   — the measures to be taken by the official services to ensure that the programme is properly carried out,

   — the procedures followed by the approved laboratories, their number and location,

   — the prevalence of the disease or diseases listed in Annex A, column 1 of lists I and II,

   — the measures laid down to combat these diseases where detected.

2. The Commission shall scrutinize the programmes submitted by the Member States. The programmes shall be approved in accordance with the procedure laid down in Article 26. After the adoption of the programmes, the introduction of aquaculture animals and products into zones or farms covered by the programmes shall be subject to the rules set out in Articles 7 and 8.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 26. Under the same procedure the Commission may approve an amendment or addition to a programme which has been approved or to guarantees provided for by the rules referred to in paragraph 2.

Article 11

1. The movement documents referred to in Articles 7 and 8 must be drawn up by the official service at the place of origin within 48 hours before loading, in the official language or languages of the place of destination. They must be drawn up on a single sheet of paper, be made out for a single consignee. They shall be valid for 10 days.

2. Each consignment of aquaculture animals and products must be clearly identified in order to be able to trace back to the farm of origin, and to verify where appropriate the correlation of the animals or products with the information contained in the accompanying movement document. This information may figure directly on the container or on a label fixed to it or on the movement document.

Article 12

1. Where a Member State draws up or has drawn up a voluntary or compulsory control programme for one of the diseases referred to in Annex A, column 1 of list III, it shall submit the programme to the Commission, outlining in particular:

   — the distribution of the disease in the Member States,

   — the justification of the programme, taking into account, the importance of the disease and the programme's likely benefit in relation to its cost,

— the geographical area in which the programme will be implemented,

— the status of farms to be established, and the standards which must be achieved by the farms in each category, including test procedures,

— the rules applicable for entry of animals of a lower health status into the farm,

— the action to be taken if, for any reason, a farm loses its status,

— the procedures under which the programme is to be monitored.

2. The Commission shall scrutinize the programme presented by the Member States. These programmes may be approved in accordance with the procedure laid down in Article 26. The additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into officially checked zones or farms shall be defined in accordance with the same procedure.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 26. Under the same procedure, the Commission may approve an amendment or addition to a programme which has been approved or to guarantees which have been defined in accordance with paragraph 2.

Article 13

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases listed in Annex A, column 1 of list III, it shall submit to the Commission appropriate justifications, setting out in particular:

— the name of the disease and the previous history of its ocurrence in that Member State,

— the results of surveillance testing based on serological, virological, microbiological or pathological findings, as appropriate, and on the fact that the disease is compulsorily notifiable to the competent authorities,

— the period over which the surveillance was carried out,

— the control arrangements for verifying that the area concerned remains free from the disease.

2. The Commission shall examine such justifications. The additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into certain areas or farms shall be defined in accordance with the procedure provided for in Article 26.

3. The Member State concerned shall notify the Commission of any change in the particulars specified in paragraph 1 which relate to the disease. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure provided for in Article 27.

Article 14

1. Without prejudice to the requirements for diseases referred to in Annex A, column 1 of list III, established in accordance with the procedure laid down in Articles 12 and 13, the placing on the market of live farmed fish (molluscs or crustaceans) not belonging to the susceptible species referred to in Annex A, column 2 of lists I and II as well as their eggs and gametes shall be subject to the following additional requirements:

(a) where they are to be introduced into an approved zone, they must be accompanied in accordance with Article 11 by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status, from an approved farm in a non-approved zone or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish, molluscs or crustaceans belonging to the susceptible species referred to in Annex A, column 2 of lists I and II and is not connected with a watercourse or with coastal or estuarial waters.

However, pending the outcome of the review provided for in Article 28, Member States may, under the procedure laid down in Article 26, request a derogation from the preceding subparagraph, in particular so as to prohibit the introduction into an approved zone of fish, molluscs or crustaceans referred to in this paragraph, originating from an approved farm in a non-approved zone or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish, molluscs or crustaceans belonging to the susceptible species referred to in Annex A, column 2 of lists I and II and is not connected with a watercourse or with coastal or estuarial waters. In order to ensure uniform compliance with that provision, appropriate conditions and measures shall be fixed under the same procedure. Pending those decisions, national rules shall continue to apply subject to compliance with the general provisions of the Treaty;

(b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must be accompanied in accordance with Article 11 by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone, from a farm of the same health status or from a farm which may be situated in a non-approved zone, on condition that such a farm contains no fish, molluscs or crustaceans belonging to the susceptible species referred to in Annex A, column 2 of lists I and II and is not connected with a watercourse or with coastal or estuarial waters.

2. Without prejudice to the requirements for diseases referred to in Annex A, column 1 of list III established in accordance with the procedure laid down in Articles 12 and 13, the placing on the market of wild fish, molluscs or crustaceans, their eggs or gametes, shall be subject to the following additional requirements:

(a) where they are to be introduced into an approved zone, they must be accompanied in accordance with Article 11 by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status;

(b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must be accompanied in accordance with Article 11 by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone.

Article 15

Sampling plans and diagnostic methods to be applied for the detection and confirmation of the presence of the diseases referred to in Annex A, column 1, shall be established in accordance with the procedure laid down in Article 26. These sampling plans must take account of the presence of wild fish, crustaceans and molluscs in the aquatic environment.

Article 16

1. The rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (1) as regards aquaculture products for human consumption and Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (2) as regards aquaculture animals and products placed on the market shall apply, in particular as regards the organization of and the action to be taken following the inspections to be carried out by the Member State of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC is amended as follows:

(a) in Annex A, the following indent is added:

'— Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1)';

(b) in Annex B the following indent is deleted:

'— aquaculture products intended for human consumption.'

3. In Annex A, point I, of Directive 90/425/EEC the following reference is added:

'Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1)'.

Article 17

1. Commission veterinary experts may, where it is necessary for the uniform application of this Directive, carry out on-site inspections in conjunction with the competent authorities. The Member State in whose territory an inspection is carried out shall provide the experts with all the assistance necessary to complete their task. The Commission shall notify the Member States of the outcome of such inspections.

2. General provisions for the application of this Article shall be adopted in accordance with the procedure laid down in Article 26.

The rules to be followed during the inspection provided for in this Article shall be drawn up in accordance with the same procedure.

CHAPTER 3

Rules governing imports from third countries

Article 18

Aquaculture animals and products imported into the Community shall satisfy the conditions laid down in Articles 19, 20 and 21.

Article 19

1. Aquaculture animals and products must come from third countries or parts thereof appearing on a list drawn up by the Commission in accordance with the procedure laid down in Article 26. That list may be supplemented or amended in accordance with the same procedure.

2. In deciding whether a third country or part thereof may appear on the list referred to in paragraph 1, particular account shall be taken of:

(a) the state of health of the aquaculture animals, particular attention being paid to exotic diseases and the environmental health situation in the third country which might endanger the health of livestock in the Member States;

(1) OJ No L 395, 30. 12. 1989, p. 13.
(2) OJ No L 224, 18. 8. 1990, p. 29; as amended by Directive 90/539/EEC (OJ No L 303, 31. 10. 1990, p. 6).

Annexes A, B and C shall be amended only by the Council acting by a qualified majority on a proposal from the Commission, with a view in particular to adapting them to technological progress.

Article 26

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC (1), hereinafter referred to as 'the Committee', either on his own initiative or at the request of the representative of a Member State.

2. (a) 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.

(b) 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, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

Article 27

1. Where the procedure laid down in this Article is to be followed, the Chairman shall without delay, refer the matter to the Committee, either on his own initiative or at the request of the representative of a Member State.

2. (a) 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 two days. 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.

(b) 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, on the expiry of a period of 15 days from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

Article 28

Before 1 July 1992, in respect of the list of diseases set out in Annex A, and before 1 January 1997, in respect of the health status of approved farms in a non-approved zone, the Council shall, on the basis of a report from the Commission on the experience gained, prepared following an opinion from the Scientific Veterinary Committee and accompanied by any proposals, on which it will decide by a qualified majority, review the provisions of this Directive and in particular those concerning the marketing of live fish coming from approved farms in non-approved zones.

Article 29

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993.

2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 30

This Directive is addressed to the Member States.

Done at Brussels, 28 January 1991.

For the Council
The President
J.-C. JUNCKER

(1) OJ No L 255, 18. 10. 1968, p. 23.

(b) the regularity and rapidity of the information supplied by the country relating to the existence of infectious or contagious diseases of aquaculture animals in its territory, in particular those diseases mentioned in list B of the International Office of Epizootics;

(c) the rules of the third country on the prevention and control of diseases of aquaculture animals;

(d) the structure of the official services in the third country and their powers;

(e) the organization and implementation of measures to prevent and control infectious or contagious diseases of aquaculture animals;

(f) assurances which the third country may provide concerning the rules laid down in this Directive.

3. The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

Article 20

1. For each third country, aquaculture animals and products shall satisfy the health conditions adopted in accordance with the procedure laid down in Article 26.

2. Depending on the animal health situation in the third country concerned, the conditions referred to in paragraph 1 may include in particular:

— restriction to imports from a part of the third country,

— restriction to certain species at any stage of development,

— the prescription of a treatment to be applied to the products, such as the disinfection of eggs,

— prescription of the use to which these animals or products are to be put,

— the measures to apply following importation, such as quarantine or the disinfection of eggs.

Article 21

1. Aquaculture animals and products shall be accompanied by a certificate drawn up by the official services of the exporting third country. This certificate must:

(a) be issued on the day of loading of the consignment for dispatch to the Member State of destination;

(b) accompany the consignment in the original;

(c) attest that the aquaculture animals and certain fishery products meet the requirements of this Directive and those laid down pursuant thereto with regard to importation from the third country;

(d) be valid for 10 days;

(e) consist of a single sheet of paper;

(f) be made out for a single consignee.

2. The certificate referred to in paragraph 1 must comply with a model established in accordance with the procedure laid down in Article 26.

Article 22

Inspections shall be carried out on the spot by veterinary experts of the Member States and the Commission to verify whether the provisions of this Directive, and in particular Articles 19 and 20 thereof, are being applied in practice.

The experts from the Member States who are to be entrusted with the task of carrying out these inspections shall be appointed by the Commission, acting on proposals from the Member States.

Those inspections shall be made on behalf of the Community, which shall bear the expenditure incurred in this connection.

The frequency of and the procedures for these inspections shall be determined in accordance with the procedure laid down in Article 26.

Article 23

1. The general rules and principles applicable during inspections of aquaculture products imported from third countries shall be those laid down in Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (1).

2. The general rules and principles applicable during inspections of live aquaculture animals imported from third countries shall be those laid down by Article 7 of Directive 90/425/EEC.

Article 24

If an infectious or contagious disease of aquaculture animals, likely to endanger the health of livestock in a Member State, breaks out or spreads in a third country or if any other animal health reason so justifies, the rules, procedures and measures laid down in Article 17 of Directive 90/425/EEC shall apply.

CHAPTER 4

Final provisions

Article 25

Annexes C and E may be amended in accordance with the procedure laid down in Article 26.

(1) OJ No L 373, 31. 12. 1990, p. 1.

ANNEX A

LIST OF DISEASES AND SUSCEPTIBLE SPECIES

1	2
Disease	Susceptible species
LIST I	
Fish	
IHN (Infectious hematopoietic necrosis)	*Salmo gairdneri* *Oncorhynchus nerka* *Oncorhynchus tschawytscha* *Oncorhynchus rhodurus* *Salmo salar*
LIST II	
Fish	
VHS (Viral haemorrhagic septicaemia)	*Salmo gairdneri* *Salmo trutta* *Salmo salar* *Thymallus thymallus* *Coregonus* sp. *Esox lucius* (ley)
Molluscs	
Bonamia ostreae	*Ostrea edulis*
Marteilia sp.	*Ostrea edulis*
Haplosporidium sp.	*Ostrea edulis*
Perkinsus sp.	*Ruditapes decussatus*
LIST III	
Fish	
IPN (Infectious pancreatic necrosis) PN	*Salmo gairdneri* *Salmo trutta* *Salvelinus fontinalis* *Oncorhynchus* (two species)
SVC (Spring viremia of carp)	*Cyprinus carpio* *Ctenopharyngodon idella* *Hypophthalmichtys* sp.
BKD (Bacterial kidney disease)	All salmonids and *Oncorhynchus* in particular
Furunculosis in Atlantic salmon	*Salmo salar* and all other salmonidae
ERM (Enteric red mouth disease)	Salmonidae, *Anguilla anguilla*, *Psetta maxima* (turbot) *Notropis atherinoides* (bait minnow)
Gyrodactylosis *(Gyrodactylus salaris)*	*Salmo salar*
Myxobolosis (Myxosomiasis) (Whirling disease)	*Salmo gairdneri* *Salmo trutta* *Salmo salar* *Salvelinus fontinalis*
Crustaceans	
Aphanomycosis *Astacus* sp. (crayfish plague)	*Astacus* sp. *Austropotamobius pallipes* *Pacifastacus Leniusculus Dana*

ANNEX B

APPROVED ZONES

I. Continental zones for fish (column 2 of lists I and II in Annex A)

A. *Definition of continental zones*

A continental zone consists of

— a part of the territory comprising an entire catchment area from the sources of the waterways to the estuary, or more than one catchment area, in which fish is reared, kept or caught, or

— a part of a catchment area from the sources of the waterways to a natural or artificial barrier preventing fish migrating from downstream of that barrier.

The size and the geographical situation of a continental zone must be such that possibilities for recontamination, e.g. by migrating fish, are reduced to a minimum. That may require the establishment of a buffer-zone in which a monitoring programme is carried out without obtaining the status of approved zone.

B. *Grant of appeal*

In order to obtain approved status, a continental zone must meet the following requirements:

1. all fish are free for at least four years from any clinical or other sign of one or more of the diseases referred to in Annex A, column 1 of lists I and II;

2. all farms in the continental zone are placed under the supervision of the official services. Two health inspections per year for four years must have been carried out.

The health inspection must have been made at the times of year when the water temperature favours the development of these diseases.

The health inspection must consist at least of:

— an inspection of fish showing abnormalities,

— the taking of samples which are to be sent as quickly as possible to the approved laboratory to be tested for the pathogens in question.

However, zones having a historical record of absence of the diseases referred to in Annex A, column 1 of lists I and II, may obtain approved status if:

(a) their geographical situation does not permit easy introduction of diseases;

(b) an official disease control system has been in place for an extended period of time of at least 10 years during which:

— there has been regular monitoring of all farms,

— a disease notification system has been applied,

— no case of disease has been reported,

— no live fish from infected zones has been introduced;

3. if there is no farm in a continental zone to be approved, the official services must have subjected fish from the lower part of the catchment area to a health inspection twice a year for four years, in accordance with paragraph 2;

4. the laboratory examinations of fish taken during health inspections have produced negative results as regards the pathogens in question.

C. *Maintenance of approval*

Maintenance of approval is subject to the following requirements:

1. fish introduced into the zone must come from another approved zone or from an approved farm;

2. each farm must undergo two health inspections annually in accordance with point B 2; however, samples will be taken by rotation in 50 % of the fish farms in the continental zone each year;

3. the results of the laboratory examinations on the fish sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Annex A, column 1 of lists I and II;

4. a register must be kept by the farmers or the persons responsible for the introducing of fish, containing all the information necessary to enable the state of health of the fish to be monitored constantly.

D. *Suspension, re-establishment and withdrawal of approval*

1. Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst fish of a disease referred to in Annex A, column 1 of lists I and II must be notified as quickly as possible to the official service. The latter shall immediately suspend the approval of the zone.

2. A sample of at least 10 sick fish must be sent to the approved laboratory in order to be tested for the pathogens in question. The results of the tests must be communicated immediately to the official service.

3. Where the results are negative for the pathogens in question but positive for another cause, the official service shall restore approval.

4. However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first sampling and a sufficient number of sick fish must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question.

If the results are again negative or if there are no more sick fish, the official service will restore the approval.

5. Where the results are positive, approval must be withdrawn by the official service.

6. Restoration of the approval of a zone is subject to the following requirements:

(a) when an outbreak occurs:

— all fish in the infected farms must have been slaughtered, and infected or contaminated fish must have been destroyed,

— facilities and equipment must have been disinfected in accordance with a procedure approved by the official services;

(b) after elimination of the outbreak, the requirements set up in point B must be again complied with.

7. The central competent authority shall inform the Commission and the other Member States regarding suspension, restoration and withdrawal of the approval of zones.

II. Coastal zones for fish (column 2 of lists I and II of Annex A)

A. A coastal zone consists of a part of the coast or sea water or an estuary with a precise geographical delimitation which consists of a homogeneous hydrological system.

B. *Grant of approval*

In order to obtain approved status, a coastal zone for fish must meet the requirements laid down for continental zones referred to in point I B.

C. *Maintenance of status*

Maintenance of the approval for a coastal zone is subject to the requirements set out in point I C.

D. *Suspension, restoration and withdrawal of approval*

The rules are identical to those set out to in point I D.

III. Coastal zones for molluscs (column 2 of lists I and II of Annex A)

A. A coastal zone must comply with the definition laid down in point II A.

B. *Grant of approval*

In order to be approved, a coastal zone must meet the following requirements:

1. all molluscs have for at least two years shown no clinical or other sign of one or more of the diseases referred to in Annex A, column 1 of lists I and II;

2. all farms in the coastal zone are placed under the supervision of the official services. Health inspections are carried out at intervals adapted to the development of the pathogens in question.

During these inspections samples are taken and sent without delay to the approved laboratory to be tested for the pathogens in question;

3. if there is no farm in the continental zone, the official service must have submitted molluscs to a health inspection in accordan — with point 2, at intervals adapted to the development of the pathogens in question. However, if detailed investigations of farms show that the zone does not contain any

molluscs belonging to vector, carrier or susceptible species, the official service may approve the zone before any molluscs are introduced;

4. laboratory examinations of molluscs taken during health inspections by the official services have produced negative results as regards the pathogens in question.

For zones having a historical record of absence of the diseases referred to in Annex A, column 1 of lists I and II, this information may be taken into account for the grant of approval.

C. *Maintenance of approval*

Maintenance of approval is subject to the following requirements:

1. molluscs introduced into the coastal zone must come from other approved coastal zones or from approved farms in non-approved coastal zones;

2. each farm must undergo a health inspection in accordance with point B 2 at intervals adapted to the development of the pathogens in question;

3. the results of the laboratory examinations on the molluscs sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Annex A, column 1 of lists I and II;

4. a register must be kept by the farmers or the persons responsible for the introduction of molluscs, containing all information necessary to enable the state of health of the molluscs to be monitored constantly.

D. *Suspension, restoration and withdrawal of approval*

1. Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst molluscs of a disease, referred to in Annex A, column 1 of list II, must be notified as quickly as possible to the official service. The latter shall immediately suspend approval of the zone.

2. A sample of sick molluscs must be sent to the approved laboratory in order to be tested for the pathogens in question.

The results of the tests must be communicated immediately to the official service.

3. Where the results are negative for the pathogens in question, but positive for another cause, approval shall be restored.

4. However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first taking of samples and a sufficient number of sick molluscs must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question. If the results are again negative or if there are no longer any sick molluscs, the official service will restore approval.

5. Where the results are positive, approval must be withdrawn by the official service.

6. Restoration of approval of a zone is subject to the following requirements:

(a) when an outbreak occurs:

— infected or contaminated molluscs must have been destroyed,

— facilities and equipment must have been disinfected in accordance with a procedure approved by the official service;

(b) after elimination of the outbreak, the requirements set out in point B must again be complied with.

7. The central competent authority shall inform the Commission and the other Member States regarding suspension, restoration and withdrawal of the approval of zones.

ANNEX C

APPROVED FARMS IN A NON-APPROVED ZONE

I. Continental farms for fish (Column 2 of lists I and II of Annex A)

A. *Grant of approval*

In order to be approved, a farm must meet the following requirements:

1. Water must be supplied by a well or a borehole.
2. There must be a natural or artificial barrier for anadromic fish situated downstream.
3. It must comply with the relevant requirements set out in Annex B I B.

B. *Maintenance of approval*

Maintenance of approval shall be subject to the requirements set out in Annex B I C. However, sampling must be carried out once a year.

C. *Suspension, restoration and withdrawal of approval*

The requirements set out in Annex B I D shall apply.

II. Coastal farms for fish (Column 2 of lists I and II of Annex A)

A. *Grant of approval*

In order to be approved, a farm must meet the following requirements:

1. It must be supplied with water by means of a system which allows the destruction of the agents of the diseases referred to in Annex A, column 1 of lists I and II.
2. It must comply, *mutatis mutandis*, with the requirements laid down in Annex B II B.

B. *Maintenance of approval*

Maintenance of approval shall, *mutatis mutandis*, be subject to the requirements laid down in Annex B II C.

C. *Suspension, restoration and withdrawal of approval*

The requirements laid down in Annex B II D shall apply *mutatis mutandis*.

III. Coastal farms for molluscs (Column 2 of lists I and II of Annex A)

A. *Grant of approval*

In order to be approved, a farm must meet the following requirements:

1. It must be supplied with water by means of a system which allows the destruction of the agents of diseases referred to in Annex A, column 1 of list I and II.
2. It must comply, *mutatis mutandis*, with the requirements as set out in Annex B III B, points 1, 2 and 4.

B. *Maintenance of approval*

Maintenance of approval shall, *mutatis mutandis*, be subject to the guarantees laid down in Annex B III C, points 1 to 4.

C. *Suspension, restoration and withdrawal of approval*

The requirements set out in Annex B III D shall apply *mutatis mutandis*.

ANNEX D

RENEWAL OF WATER

Renewal of water during the transportation of aquaculture animals shall be carried out in facilities which are approved by the Member States and meet the following requirements:

1. The hygienic properties of the water available for changing must be such as not to alter the health situation of the species transported with regard to the agents of the diseases referred to in Annex A, column 1 of lists I and II.

2. These facilities shall contain devices designed to prevent any contamination of the host environment:

   — either by facilitating disinfection of the water, or

   — by ensuring that release of this water does not under any circumstances entail direct discharge into the open sea or free-flowing waterways.

ANNEX E

Models of movement documents

CHAPTER 1

MOVEMENT DOCUMENT FOR LIVE FISH, EGGS AND GAMETES FROM AN APPROVED ZONE

I. Country of origin: .....

Approved zone: .....

II. Farm of origin (name and address): .....

.....

III. Animals or products: .....

	Live fish	Eggs	Gametes
Family (common name and scientific name)			
Species (common name and scientific name)			
Quantity Number Total weight Average weight			

IV. Destination

Country of destination: .....

Consignee (name and address): .....

.....

V. Means of transport (nature and identification): .....

.....

VI. Health attestation

I, the undersigned, hereby certify that the animals or goods forming the present consignment originate from an approved zone and that they satisfy the requirements of Directive 90/677/EEC.

Done at ....., on .....

Name of official service:

Stamp of official service

.....
Name (in capitals)

.....
Function of signing officer

.....
Signature

CHAPTER 2

MOVEMENT DOCUMENT FOR LIVE FISH, EGGS OR GAMETES FROM AN APPROVED FARM

I. Country of origin: .....

II. Farm of origin (name and address): .....

.....

III. Animals or products: .....

	Live fish	Eggs	Gametes
Family (common name and scientific name) Species (common name and scientific name)			
Quantity Number Total weight Average weight			

IV. Destination

Country of destination: .....

Consignee (name and address): .....

.....

V. Means of transport (nature and identification): .....

.....

VI. Health attestation

I, the undersigned, hereby certify that the animals or products forming the present consignment originate from an approved farm and that they satisfy the requirements of Directive 91/67/EEC.

Done at ..... on .....

Name of official service

Stamp of official service

.....
Name (in capitals)

.....
Function of signing officer

.....
Signature

CHAPTER 3

MOVEMENT DOCUMENT FOR MOLLUSCS FROM AN APPROVED COASTAL ZONE

I. Country of origin: .....

Approved zone: .....

II. Farm of origin (name and address): .....

.....

III. Animals: .....

	Molluscs
Family (common name and scientific name)	
Species (common name and scientific name)	
Quantity Number Total weight Average weight	

IV. Destination

Country of destination: .....

Consignee (name and address): .....

.....

V. Means of transport (nature and identification): .....

.....

VI. Health certification

I, the undersigned, hereby certify that the animals forming the present consignment originate from an approved coastal zone and that they satisfy the requirements of Directive 91/67/EEC.

Done at ....., on .....

Name of official service:

.....

Name (in capitals)

Stamp of official service

.....

Function of signing officer

.....

Signature

CHAPTER 4

MOVEMENT DOCUMENT FOR MOLLUSCS FROM AN APPROVED FARM

I. Country of origin: .....

II. Farm of origin (name and address): .....

.....

III. Animals: .....

	Molluscs
Family (common name and scientific name) Species (common name and scientific name)	
Quantity Number Total weight Average weight	

IV. Destination

Country of origin: .....

Consignee (name and address): .....

.....

V. Means of transport (nature and identification): .....

.....

VI. Health certification

I, the undersigned, hereby certify that the animals forming the present consignment originate from an approved farm and that they satisfy the requirements of Directive 91/67/EEC.

Done at ....., on .....

Name of official service:

.....
Name (in capitals)

Stamp of official service

.....
Function of signing officer

.....
Signature

ภาคผนวก ฑ

COUNCIL DIRETTIVE

of 22 July 1991

laying down the health conditions for the production and the placing on the market of fishery products

(91/493/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

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

Having regard to the opinions of the European Parliament (2),

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

Whereas, with a view to achieving the internal market and more especially to ensuring the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 (4), as last amended by Regulation (EEC) No 2886/89 (5), it is essential that the marketing of fish and fish products should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms, whilst ensuring quality products for the consumer;

Whereas the European Parliament in its legislative resolution of 17 March 1989 (6) requested the Commission to come forward with comprehensive proposals on the hygienic production and placing on the market of fishery products, including solutions for the problem of nematodes;

Whereas fishery products freshly caught are in principle free of contamination with micro-organisms; whereas however contamination and subsequent decomposition may occur when handled and treated unhygienically;

Whereas therefore the essential requirements should be laid down for the correct hygienic handling of fresh and processed fishery products at all stages of production and during storage and transport;

Whereas it is appropriate to apply by analogy certain marketing standards which are laid down pursuant to Article 2 of Regulation (EEC) No 3796/81, in order to fix the health quality of these products;

Whereas it is the responsibility primarily of the fisheries industry to ensure that fishery products meet the health requirements laid down in this Directive;

Whereas the competent authorities of the Member States must, by carrying out checks and inspections, ensure that producers and manufacturers comply with the said requirements;

Whereas Community control measures should be introduced to guarantee the uniform application in all Member States of the standards laid down in this Directive;

Whereas, in order to ensure the smooth operation of the internal market, the measures should apply in an identical manner to trade within the Member States and to trade between the Member States;

Whereas in the context of intra-Community trade, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (7) as amended by Directive 90/675/EEC (8) apply to fishery products;

Whereas fishery products from third countries intended to be placed on the market of the Community must not qualify for more favourable arrangements than those applied in the Community; whereas provision should therefore be made for a Community procedure for the inspection in third countries of the conditions of production and placing on the market in order to permit the application of a common import system based on conditions of equivalence;

Whereas the products in question are subject to the rules concerning checks and to safeguard measures covered by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries;

Whereas, so that account may be taken of particular circumstances, derogations should be granted to some establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

(1) OJ No C 66, 11. 3. 1988, p. 2; OJ No C 282, 8. 11. 1989, p. 7 and OJ No C 84, 2. 4. 1990, p. 56.
(2) OJ No C 96, 17. 4. 1989, p. 29 and OJ No C 183, 15. 7. 1991.
(3) OJ No C 134, 24. 5. 1988, p. 31 and OJ No C 332, 31. 12. 1990, p. 59.
(4) OJ No L 379, 31. 12. 1981, p. 1.
(5) OJ No L 282, 2. 10. 1989, p. 1.
(6) OJ No C 96, 17. 4. 1989, p. 199.
(7) OJ No L 395, 30. 12. 1989, p. 13.
(8) OJ No L 373, 31. 12. 1990, p. 1.

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas the essential requirements laid down in this Directive may need further specification,

HAS ADOPTED THIS DIRECTIVE

CHAPTER I

General provisions

Article 1

This Directive lays down the health conditions for the production and the placing on the market of fishery products for human consumption.

Article 2

For the purposes of this Directive, the following definitions shall apply:

1. *'fishery products'* means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts;

2. *'aquaculture products'* means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;

3. *'chilling'* means the process of cooling fishery products to a temperature approaching that of melting ice;

4. *'fresh products'* means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

5. *'prepared products'* means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;

6. *'processed products'* means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;

7. *'preserve'* means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

8. *'frozen products'* means any fishery product which has undergone a freezing process to reach a core temperature of −18 °C or lower after temperature stabilization;

9. *'packaging'* means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;

10. *'batch'* means the quantity of fishery products obtained under practically identical circumstances;

11. *'consignment'* means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;

12. *'means of transport'* means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;

13. *'competent authority'* means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;

14. *'establishment'* means any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments;

15. *'placing on the market'* means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers, which must be subject to the health checks laid down by national rules for checking the retail trade;

16. *'importation'* means the introduction into the territory of the Community of fishery products from third countries;

17. *'clean seawater'* means seawater or briny water which is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in this Directive;

18. *'factory vessel'* means any vessel on which fishery products undergo one or more of the following operations followed by packaging: filleting, slicing, skinning, mincing, freezing or processing.

The following are not deemed to be 'factory vessels':

— fishing vessels in which only shrimps and molluscs are cooked on board;

— fishing vessels on board which only freezing is carried out.

Article 3

1. The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:

(a) they must have:

(i) been caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board vessels in accordance with hygiene rules to be established by the Council acting by a qualified majority on a proposal from the Commission. The Commission shall submit proposals to that effect before 1 October 1992;

(ii) where appropriate, been handled in factory vessels approved in accordance with Article 7, and in accordance with the requirements of Chapter I of the Annex.

The cooking of shrimps and molluscs on board must comply with the provisions of Chapter III, section I(5), or Chapter IV, section IV(7), of the Annex. Such vessels shall be specifically registered by the competent authorities;

(b) during and after landing they must have been handled in accordance with Chapter II of the Annex;

(c) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments approved in accordance with Article 7, in compliance with the requirements of Chapters III and IV of the Annex.

The competent authority may, notwithstanding Chapter II, section 2 of the Annex, authorize the transfer of fishery products *ex quay* into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there;

(d) they must have undergone a health check in accordance with Chapter V of the Annex;

(e) they must have been appropriately packaged in accordance with Chapter VI of the Annex;

(f) they must have been given an identification mark in accordance with Chapter VII of the Annex;

(g) they must have been stored and transported under satisfactory conditions of hygiene, in accordance with Chapter VIII of the Annex.

2. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed.

3. The placing on the market of aquaculture products shall be subject to the following conditions:

(a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime or faeces. If not processed immediately after having been slaughtered, they must be kept chilled;

(b) they must, in addition, comply with the requirements laid down under 1 (c) to (g).

4. (a) The placing on the market of live bivalve molluscs shall be subject to the requirements laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (1).

(b) When processed, bivalve molluscs must, in addition to the requirements in point (a), satisfy those of paragraph 1 (c) to (g).

Article 4

Fishery products to be placed on the market alive shall at all times be kept under the most suitable survival conditions.

Article 5

The placing on the market of the following products shall be forbidden:

— poisonous fish of the following families: *Tetraodontidae, Molidae, Diodontidae, Canthigasteridae,*

— fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins.

Detailed requirements concerning the species covered by this Article and concerning methods of analysis shall be laid down in accordance with the procedure prescribed in Article 15.

(1) See page 1 of this Official Journal.

Article 6

1. Member States shall ensure that persons responsible for establishment take all necessary measures, so that, at all stages of the production of fishery products, the specifications of this Directive are complied with.

To that end, the said persons responsible must carry out their own checks based on the following principles;

— identification of critical points in their establishment on the basis of the manufacturing processes used;

— establishment and implementation of methods for monitoring and checking such critical points;

— taking samples for analysis in an approved laboratory by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by this Directive;

— keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

2. If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3 (1) of Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

3. Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with the procedure laid down in Article 15.

Article 7

1. The competent authorities shall approve establishments once they have verified that these establishments meet the requirements of this Directive, with regard to the nature of the activities they carry out. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval.

The competent authorities shall take the necessary measures if the requirements cease to be met. To this end, they shall take particular account of the conclusions of any check carried out in accordance with Article 8.

The competent authority shall register those auction and wholesale markets which are not subject to approval after verifying that such installations comply with the provisions of this Directive.

2. However, subject to the express condition that products coming from factory-vessels and establishments, auction and wholesale markets meet the hygiene standards set by this Directive, Member States may, for the requirements relating to equipment and structures laid down in Chapters I to IV to the Annex, grant to factory-vessels and establishments, auction and wholesale markets a further period expiring on 31 December 1995 within which to comply with the conditions of approval set out in Chapter IX. Such derogations may be granted only to factory-vessels and establishments, auction and wholesale markets, already operating on 31 December 1991, which have, before 1 July 1992, submitted a duly justified application for derogation to the competent national authority. This application must be accompanied by a work plan and programme indicating the period within which it would be possible for them to comply with the requirements in question. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of this Directive can be accepted.

3. The competent authorities shall draw up a list of their approved establishments, each of which shall have an official number.

Each Member State shall notify the Commission of its list of approved establishments and of any subsequent amendment thereof. The Commission shall forward this information to the other Member States.

4. The inspection and monitoring of establishments shall be carried out regularly under the responsibility of the competent authority, which shall at all times have free access to all parts of establishments, in order to ensure compliance with the requirements of this Directive.

If such inspections and monitoring reveal that the requirements of this Directive are not being met, the competent authority shall take appropriate action.

5. Paragraphs 1, 3 and 4 shall also apply in respect of factory vessels.

6. Paragraphs 3 and 4 shall also apply to wholesale and auction markets.

Article 8

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks insofar as this is necessary to ensure the uniform application of this Directive. They may in particular verify whether establishments are in effect complying with the requirements of this Directive. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member States of the results of the investigations.

2. The arrangements for implementing paragraph 1 shall be adopted in accordance with the procedure laid down in Article 15.

Article 9

The rules laid down in Directive 89/662/EEC, as regards fishery products intended for human consumption, shall apply, in particular as regards the organization of and the action to be taken following the inspections to be carried out by the Member States of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC shall be amended as follows:

(a) in Annex A the following indent shall be added:

'— Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products (OJ No L 268, 24. 9. 1991, p. 15);'

(b) In Annex B the following indent shall be deleted:

'— fishery products intended for human consumption'.

CHAPTER II

Imports from third countries

Article 10

Provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country must undergo the checks laid down in Article 18 (3) of Directive 90/675/EEC.

Article 11

1. For each third country or group of third countries, fishery products must fulfil the specific import conditions fixed in accordance with the procedure laid down in Article 15, depending on the health situation in the third country concerned.

2. In order to allow the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, inspections may be carried out on the spot by experts from the Commission and the Member States.

The experts of the Member States who are to be entrusted with these inspections shall be appointed by the Commission acting on a proposal from the Member States.

These inspections shall be made on behalf of the Community, which shall bear any expenditure incurred.

The frequency of and procedure for these inspections shall be determined in accordance with the procedure laid down in Article 15.

3. When fixing the import conditions of fishery products referred to in paragraph 1, particular account shall be taken of:

(a) the legislation of the third country;

(b) the organization of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force;

(c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community;

(d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

4. The import conditions referred to in paragraph 1 shall include:

(a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;

(b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under (a);

(c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the Commission in accordance with the procedure laid down in Article 15;

For that purpose, one or more lists of such establishments shall draw up on the basis of a communication from the competent authorities of the third country to the Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

— compliance with requirements equivalent to those laid down in this Directive,

— monitoring by an official inspection service of the third country.

5. The conditions referred to in paragraph 4 (a) and (b) may be modified in accordance with the procedure laid down in Article 15.

The list referred to in paragraph 4 (c) may be amended by the Commission, in accordance with the rules established by Commission Decision 90/13/EEC (1).

6. To deal with specific situations and in accordance with the procedure laid down in Article 15, imports may be authorized direct from an establishment or factory vessel of a third country where the latter is unable to provide the guarantees laid down in paragraph 3, provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with paragraph (2). The authorization decision shall fix the specific import conditions to be followed for products coming from that establishment or factory vessel.

7. Pending the fixing of the import conditions referred to in paragraph 1, the Member States shall ensure that the conditions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Article 12

1. The rules and principles laid down by Directive 90/675/EEC shall apply, notably as regards the organization of and follow up to the inspections to be carried out by the Member States.

2. Without prejudice to compliance with the rules and principles referred to in paragraph 1 of this Article and pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 90/675/EEC, and in Article 11 of this Directive the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply.

CHAPTER III

Final provisions

Article 13

The Annexes shall be amended by the Council, acting by a qualified majority on a proposal from the Commission.

Article 14

The Commission, after consulting the Member States, shall by 1 July 1992 submit a report to the Council concerning the minimum structural and equipment requirements to be met by small establishments which distribute on the local market and are situated in regions subject to particular supply constraints, together with any proposals, on which the Council, acting under the voting procedure laid down in Article 43 of the Treaty, shall act before 31 December 1992.

Article 15

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Veterinary Committee set up by Decision 68/361/EEC (2) hereafter referred to as the Committee, either on his own initiative or at the request of a Member State.

2. 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.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) 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, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 16

In order to take into account the possible failure to take a decision on the detailed rules for applying this Directive by 1 January 1993, necessary transitional measures may be adopted in accordance with the procedure laid down in Article 15 for a period of two years.

Article 17

The provisions of this Directive shall be re-examined before 1 January 1998 by the Council, acting on proposals from the Commission, on the basis of experience gained.

(1) OJ No L 8, 11. 1. 1990, p. 70.

(2) OJ No L 255, 18. 10. 1968, p. 23.

Article 18

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall notify the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 19

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1991.

For the Council
The President
P. DANKERT

ANNEX

CHAPTER I

CONDITIONS APPLICABLE TO FACTORY VESSELS

I. Conditions concerning design and equipment

1. The minimum requirements for factory vessels are as follows:

(a) a reception area set aside for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. The reception area and its movable parts must be easy to clean. It must be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;

(b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;

(c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;

(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste processing unit operates on board, a separate hold must be designated for the storage of these by-products;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;

(g) equipment providing a supply of potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (1) or pressurized clean seawater. The seawater intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;

(h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash-basin taps must not be hand-operable.

2. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have:

(a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holds that are large enough not to be obstructed by fish waste and to allow water to drain freely;

(b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;

(c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products;

(d) adequate ventilation and, where necessary, proper vapour extraction;

(e) adequate lighting;

(f) appliances for cleaning and disinfecting tools, equipment and fittings;

(g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single use towels.

(1) OJ No L 229, 30. 9.1980, p. 11. Directive last amended by the 1985 Act of Accession (OJ No L 302, 15. 11. 1985, p. 218).

3. Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, etc., must be resistant to seawater corrosion, easy to clean and disinfect and well-maintained.

4. Factory vessels which freeze fishery products must have:

   (a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specifications of this Directive;

   (b) refrigeration plants sufficiently powerful to keep fishery products in the storage holds at a temperature that complies with the specifications of this Directive. The storage holds must be equipped with a temperature recording system placed so that it can easily be consulted.

II. Conditions of hygiene relating to on-board handling and storage of fishery products

1. A qualified person on board the factory vessel must be responsible for applying good fishery products manufacturing practices. That person shall have the authority to ensure that the provisions of this Directive are applied and shall make available to inspectors the programme for inspecting and checking critical points as applied on board, a register containing that person's comments and the temperature recordings that may be required.

2. The general conditions of hygiene applicable to areas and equipment shall be those laid down in Chapter III, section II (A), of this Annex.

3. The general conditions of hygiene applicable to staff shall be those laid down in Chapter III, section II (B), of this Annex.

4. Heading, gutting and filleting must be carried out under the conditions of hygiene laid down in Chapter IV, section I (2), (3) and (4) of this Annex.

5. On-board processing of fishery products must be carried out under the conditions of hygiene laid down in Chapter IV, sections III, IV and V of this Annex.

6. Fishery products must be wrapped and packaged under the conditions of hygiene laid down in Chapter VI of this Annex.

7. On-board storage of fishery products must be carried out under the conditions of hygiene laid down in Chapter VIII, points 1 and 2, of this Annex.

CHAPTER II

REQUIREMENTS DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.

2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:

   — unloading and landing operations proceed rapidly;

   — fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;

   — equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorized.

3. Parts of auction or wholesale markets where fishery products are displayed for sale must:

   (a) be covered and have walls which are easy to clean;

   (b) have waterproof flooring which is easy to wash and disinfect and laid in such a way as to facilitate the drainage of water and have a hygienic waste water disposal system;

(c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;

(d) be well lit to facilitate the inspection of fishery products provided for in Chapter V of this Annex;

(e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products not be admitted to markets; undesirable animals must not be admitted;

(f) be cleaned regularly and at least after each sale; crates must, after each sale, be cleaned and rinsed inside and outside with drinking water or clean seawater; where required, they must be disinfected;

(g) have displayed in a prominent position signs prohibiting smoking, spitting, eating and drinking;

(h) be closeable and be kept closed when the competent authority considers it necessary;

(i) have facilities to provide adequate water supplies satisfying the conditions laid down in Chapter III, section I, point 7 of this Annex;

(j) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption;

(k) insofar as they do not have their own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purposes of the competent authority, an adequately equipped lockable room and the equipment necessary for carrying out inspections.

4. After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditions laid down in Chapter VIII, of this Annex, to their place of destination.

5. However, if the conditions laid down in point 4 are not fulfilled, the markets in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in Chapter III, section I, point 3 of this Annex. In such cases, fishery products must be stored at a temperature approaching that of melting ice.

6. The general conditions of hygiene laid down in Chapter III, section II — with the exception of point B 1(a) — of this Annex shall apply *mutatis mutandis* to the markets in which fishery products are displayed for sale or stored.

7. The wholesale markets in which fishery products are displayed for sale or stored shall be subject to the same conditions as those laid down in points 3 and 5 of this Chapter and to those set out in points 4, 10 and 11 of Chapter III, section I of this Annex.

The general conditions of hygiene laid down in Chapter III, section II of this Annex shall apply *mutatis mutandis* to wholesale markets.

CHAPTER III

GENERAL CONDITIONS FOR ESTABLISHMENTS ON LAND

I. General conditions relating to premises and equipment

Establishment shall afford at least the following facilities:

1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building;

2. in areas where products are handled, prepared and processed:

(a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;

(b) walls which have smooth surfaces and are easy to clean, durable and impermeable;

(c) ceilings or roof linings which are easy to clean;

(d) doors in durable materials which are easy to clean;

(e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;

(f) adequate natural or artificial lighting;

(g) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand-operable. These facilities must be provided with single use hand towels;

(h) facilities for cleaning plant, equipment and utensils;

3. in cold rooms where fishery products are stored:

— the provisions set out under point 2 (a), (b), (c), (d) and (f);

— where necessary, a sufficiently powerful refrigeration plant to keep products at temperatures prescribed in this Directive;

4. appropriate facilities for protection against pests such as insects, rodents, birds, etc.;

5. instruments and working equipment such as cutting tables, containers, conveyor belts and knives made of corrosion-resistant materials, easy to clean and disinfect;

6. special watertight, corrosion-resistant containers for fishery products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;

7. facilities to provide adequate supplies of drinking water within the meaning of Directive 80/778/EEC, or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-drinking water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non-drinking-water pipes must be clearly distinguished from those used for drinking water or clean seawater;

8. hygienic waste water disposal system;

9 an adequate number of changing-rooms with smooth, water-proof, washable walls and floors, wash basins and flush lavatories. The latter may not open directly onto the work rooms. The wash basins must have materials for cleaning the hands and disposable towels; the wash basin taps must not be hand-operable;

10. if the volume of products treated requires regular or permanent presence an adequately equipped lockable room for the exclusive use of the inspection service;

11. adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorized by the competent authority;

12. establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals.

II. General conditions of hygiene

A. *General conditions of hygiene applicable to premises and equipment*

1. Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products.

2. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorization by the competent authority they may be used at the same time or other times for work on other foodstuffs.

4. Drinking water, within the meaning of Directive 80/778/EEC, or clean seawater must be used for all purposes. However, by way of an exception, non-drinking waster may be used for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.

5. Detergents, disinfectants and similar substances must be approved by the competent authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

B. *General conditions of hygiene applicable to staff*

1. The highest possible standard of cleanliness is required of staff. More specifically:

(a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fishery products;

(b) staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each time work is resumed; wounds to the hands must be covered by a waterproof dressing;

(c) smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk.

When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure set out in Article 15.

CHAPTER IV

SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE

I. Conditions for fresh products

1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing must be carried out as often as is necessary; the ice used, with or without salt, must be made from drinking water or clean seawater and be stored under hygienic conditions in receptacles provided for the purpose; such receptacles must be kept clean and in a good state of repair. Prepacked fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

2. If they are not carried out on board, operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with drinking water or clean seawater immediately after such operations.

3. Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on work tables any longer than is necessary for their preparation. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.

4. Guts and parts that may constitute a danger to public health must be separated from and removed from the vicinity of products intended for human consumption.

5. Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.

6. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leakproof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in Chapter III, section I, paragraph 6 of this Annex. The containers, receptacles and/or premises set aside for waste must always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

II. Conditions for frozen products

1. Plants must have:

(a) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down to in this Directive can be obtained in the product;

(b) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in this Directive, whatever the ambient temperature may be.

However, for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in this Directive are acceptable although they may not exceed −9 °C.

2. Fresh products to be frozen or quick-frozen must comply with the requirements of section I of this Chapter.

3. Storage rooms must have a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

Temperature charts must be available for inspection by the supervisory authorities at least during the period in which the products are stored.

III Conditions for thawing products

Establishments that carry out thawing operations must comply with the following requirements:

1. fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced.

During thawing, the temperature of the products must not increase excessively;

2. after thawing, fishery products must be handled in accordance with the requirements of this Directive. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish must be clearly marked on the packaging in accordance with Article 5 (3) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (1).

IV. Conditions for processed products

1. Fresh, frozen and thawed products used for processing must comply with the requirements of sections I or II of this Chapter.

2. Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment must be scientifically recognized by the law in force, or in the case of a treatment of products referred to in Chapter I Section 1 (b) and (c) of Directive 91/492/EEC which have not been relayed or purified, such treatment must be approved, in accordance with the procedure laid down in Article 15 of this Directive, within four months of receipt of a request from a Member State.

The person responsible for an establishment must keep a register of the processing carried out. Depending on the type of process employed, heating time and temperature, salt content, pH, water content, etc., must be monitored and controlled. Records must be kept at least for the expected storage life of the products and be available to the competent authority.

(1) OJ No L 33, 8. 2. 1979, p. 1. Directive last amended by Directive 91/72/EEC (OJ No L 42, 16. 1. 1991, p. 22).

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinading, the appropriate conditions for storage must be clearly marked on the packaging, in accordance with Directive 79/112/EEC.

In addition, the following conditions shall be complied with.

4. *Canning*

In the case of fishery products which have been subjected to sterilization in hermetically sealed containers:

(a) the water used for the preparation of cans must be drinking water;

(b) the process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which must be kept; the heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;

(c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, viz.:

— incubation tests: incubation must be carried out at 37 °C for seven days or at 35 °C for ten days, or at any other equivalent combination;

— microbiological examination of contents and containers in the establishment's laboratory or in another approved laboratory;

(d) samples must be taken of production each day at predetermined intervals, to ensure the efficacy of sealing. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can-seams;

(e) checks are carried out in order to ensure that containers are not damaged;

(f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark, in accordance with Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (1).

5. *Smoking*

Smoking must be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored.

(a) Materials used to produce smoke for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate the products.

(b) Materials used to produce smoke by burning wood that has been painted, varnished, glued or has undergone any chemical preservation treatment must be prohibited.

(c) After smoking, products must be cooled rapidly to the temperature required for their preservation before being packaged.

6. *Salting*

(a) Salting operations must take place in different premises and sufficiently removed from the premises where the other operations are carried out.

(b) Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used.

(c) Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process.

(d) Containers or areas used for salting or brining must be cleaned before use.

(1) OJ No L 186, 30. 6. 1989, p. 21.

7. *Cooked crustacean and molluscan shellfish products*

Crustaceans and molluscan shellfish must be cooked as follows:

(a) any cooking must be followed by rapid cooling. Water used for this purpose must be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;

(b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day.

After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature which will preclude the growth of pathogens, and be stored in appropriate premises;

(c) every manufacturer must carry out micro-biological checks on his production at regular intervals, complying with the standards to be fixed in accordance with Chapter V, Section 4 of this Annex.

8. *Mechanically recovered fish flesh*

The mechanical recovery of fish flesh must be carried out under the following conditions:

(a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;

(b) the machinery must be cleaned at frequent intervals and at least every two hours;

(c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

V. Conditions concerning parasites

1. During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible.

Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

The detailed rules for this inspection shall be adopted in accordance with the procedure laid down in Article 15 of this Directive, on a proposal from the Commission to be submitted before 1 October 1992.

2. The fish and fish products referred to in point 3 which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than – 20 °C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.

3. Fish and products subject to the conditions in point 2:

(a) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';

(b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60 °C:

— herring,

— mackerel,

— sprat,

— (wild) Atlantic and Pacific salmon;

(c) marinated and/or salted herring where this process is insufficient to destroy the larvae of nematodes.

This list may be amended, in the light of scientific data, in accordance with the procedure laid down in Article 15 of this Directive. In accordance with the same procedure, criteria will be laid down which must enable the processes which are deemed sufficient or insufficient to destroy nematodes to be defined.

4. Manufacturers must ensure that fish and fish products listed in point 3 or the raw materials for use in their manufacture are subjected to the treatment described in point 2, prior to their release for consumption.

5. The fishery products listed in point 3 must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

CHAPTER V

HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

I. General monitoring

Arrangements for checking and monitoring must be made by the competent authorities in order to establish whether the requirements laid down in this Directive are complied with.

Such arrangements will include, in particular:

1. a check on the fishing vessels, on the understanding that such a check may be carried out during the stay in port;

2. a check on the conditions of landing and first sale;

3. an inspection at regular intervals of establishments to check, in particular:

   (a) whether the conditions for approval are still fulfilled;

   (b) whether the fishery products are handled correctly;

   (c) the cleanliness of the premises, facilities and instruments and staff hygiene;

   (d) whether identification marks are put on correctly;

4. an inspection of the wholesale and auction markets;

5. a check on storage and transport conditions.

II. Special checks

1. *Organoleptic checks*

Without prejudice to the derogations provided for by Council Regulation (EEC) No 103/76 of 19 January 1976 laying down common marketing standards for certain fresh or chilled fish (1), each batch of fishery products must be submitted for inspection by the competent authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.

Fishery products complying, as far as the freshness criteria are concerned, with the common marketing standards already laid down pursuant to Article 2 of Regulation (EEC) No 3796/81 are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of this Directive.

The Commission may, where necessary, in accordance with the procedure referred to in Article 15 of this Directive, lay down specific organoleptic requirements for fishery products not harmonized under Regulation (EEC) No 3796/81.

The organoleptic examination must be repeated after the first sale of fishery products, if it is found that the requirements of this Directive have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements of the aforementioned Regulation.

If the organoleptic examination reveals that the fishery products are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of chemical checks or microbiological analyses.

2. *Parasite checks*

Before they are released for human consumption, fish and fish products must be subject to a visual inspection, by way of sample, for the purpose of detecting any parasites that are visible.

(1) OJ No L 20, 28. 1. 1976, p. 29. Regulation last amended by Regulation (EEC) No 33/89 (OJ No L 5, 7. 1. 1989, p. 18).

Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

The detailed rules for this inspection shall be established in accordance with the procedure laid down in Article 15.

3. *Chemicals checks*

A. Samples must be taken and subjected to laboratory analysis for the control of the following parameters:

(a) TVB-N (Total Volatile Basic Nitrogen) and TMA-N (Trimethylamine-Nitrogen)

The levels of these parameters must be specified for each category of species in accordance with the procedure laid down in Article 15 of this Directive.

(b) Histamine

Nine samples must be taken from each batch. These must fulfil the following requirements:

— the mean value must not exceed 100 ppm;

— two samples may have a value of more than 100 ppm but less than 200 ppm;

— no sample may have a value exceeding 200 ppm.

These limits apply only to fish species of the following families: Scombridae and Clupeidae. However, fish belonging to these families which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as high-performance liquid chromatography (HPLC).

B. Contaminants present in the aquatic environment

Without prejudice to the Community rules concerning water protection and management, and in particular those concerning pollution of the aquatic environment, fishery products must not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organochlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

A monitoring system must be established by the Member States to check the level of contamination of fishery products.

C. In accordance with the procedure laid down in Article 15 of this Directive, the following shall be decided on by not later than 31 December 1992:

(a) the methods of analysis to be used to check the chemical parameters, as well as the sampling plans;

(b) the acceptable levels for the chemical parameters.

4. *Microbiological analyses*

In accordance with the procedure laid down in Article 15 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health. The Commission will to this end submit appropriate proposals for measures by 1 October 1993.

CHAPTER VI

PACKAGING

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.

2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular:

— they must not be such as to impair the organoleptic characteristics of the fishery products;

— they must not be capable of transmitting to the fishery products substances harmful to human health;

— they must be strong enough to protect the fishery products adequately.

3. With the exception of certain containers made of impervious, smooth and corrosion-resistant material which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used. Packaging materials used for fresh products held under ice must provide adequate drainage for melt water.

4. Unused packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

CHAPTER VII

IDENTIFICATION MARKS

Without prejudice to the requirements laid down in Directive 79/112/EEC, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means of either labelling or the accompanying documents. For that purpose, the following information must appear on the packaging or in the accompanying documents:

— the country of dispatch;

— identification of the establishment by its official approval number or, in the case of separate registering of auction or wholesale markets as laid down in Article 7 (1), third subparagraph of this Directive, the registration number of the auction or wholesale market.

CHAPTER VIII

STORAGE AND TRANSPORT

1. Fishery products must, during storage and transport, be kept at the temperatures laid down in this Directive and in particular:

   — fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature of melting ice;

   — frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of − 18 °C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3 °C, during transport;

   — processed products must be kept at the temperatures specified by the manufacturer, when the circumstances so require, prescribed in accordance with the procedure laid down in Article 15 of this Directive.

2. Where frozen fishery products are transported from a cold-storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and where the distance to be covered is short, not exceeding 50 km or one hour's journey, the competent authority may grant a derogation from the conditions laid down in point 1, second indent.

3. Products may not be stored or transported with other products which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.

4. Vehicles used for the transport of fishery products must be constructed and equipped in such a way that the temperatures laid down in this Directive can be maintained throughout the period of transport. If ice is used to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fishery products. They must be smooth and easy to clean and disinfect.

5. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

6. Fishery products may not be transported in a vehicle or container which is not clean or which should have been disinfected.

7. The transport conditions of fishery products to be placed on the market alive must not adversely affect the products.

CHAPTER IX

POINTS OF ANNEX I WHICH MAY BE SUBJECT TO DEROGATIONS AND POSSIBLE CONDITIONS APPLICABLE IN THE CASE OF DEROGATIONS

Re Chapter I Part I of the Annex

1. *Point 1 (a)*

provided products are sheltered from the sun and the elements and from any source of dirt or contamination.

2. *Point 1 (c)*

provided any contamination of the products is prevented.

3. *Point 1 (d), first sentence*

provided the finished products are stored on board at the required temperature.

4. *Point 1 (g), last sentence*

provided products cannot be contaminated by waste water, waste or engine coolant.

5. *Point 1 (h)*

provided staff handling fishery products can wash their hands after using the toilet.

6. *Point 2 (a)*

provided floors are properly cleaned and disinfected.

7. *Point 2 (b), (c) and (d)*

8. *Point 2 (g) on taps and towels*

9. *Point 3*

provided equipment and tools are well maintained.

Re Chapter II of the Annex

10. *Point 3 (a)*

provided the walls are kept clean.

11. *Point 3 (b)*

provided the flooring is kept clean after every sale.

12. *Point 3 (c), first sentence*

13. *Point 3 (e): vehicles emitting exhaust fumes*

provided products contaminated by exhaust fumes are withdrawn from the market.

14. *Point 3 (j)*

provided that products which are not fit for human consumption cannot contaminate or be mixed with fishery products.

15. *Point 3 (k)*

16. *Point 7*

insofar as it refers to point 3 of the same Chapter and point 10 of Chapter III, section I.

Re Chapter III Part I of the Annex

17. *Point 1*

provided finished products cannot be contaminated by raw materials or waste.

18. *Point 2 (a)*

provided the flooring is cleaned and disinfected accordingly.

19. *Point 2 (b)*

provided the walls are kept clean.

20. *Point 2 (c)*

provided the ceiling is not a source of contamination.

21 *Point 2 (d)*

22. *Point 2 (e)*

provided products cannot be spoilt or contaminated by the steam.

23. *Point 2 (g)*

provided there are facilities available for staff to wash their hands.

24. *Point 3*

25. *Point 5*

insofar as it relates to corrosion-resistant materials provided instruments and working equipment are kept clean.

26. *Point 6*

provided products cannot be contaminated by waste or leakage therefrom.

27. *Point 10*

Re Chapter IV of the Annex

28. *Part I, point 1*

in respect of the requirement for products being held over to be put in the establishment's cold room provided the products are re-iced as often as necessary during a period not in excess of 12 hours or that a nearby cold room not belonging to the establishment can be used.

29. *Part I, point 6*

in respect of the requirement for waste to be put in leakproof covered containers provided products cannot be contaminated by waste or leakage therefrom.

30. *Part IV, point 5, first paragraph*

provided that every precaution is taken to prevent fishery products that are being prepared or stored from being affected by the smoke.

31. *Part IV, point 6 (a)*

provided fishery products that are being prepared or stored are not affected by salting operations.

ภาคผนวก ๒

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/48/EEC

of 16 June 1992

laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3 (1) (a) (i) of Directive 91/493/EEC

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products (1), and in particular Article 3 (1) (a) (i) thereof,

Having regard to the proposal from the Commission,

Whereas in accordance with Article 3 (1) (a) (i) of Directive 91/493/EEC it is essential that hygiene rules be laid down for fishery products caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board certain vessels;

Whereas general hygiene conditions applicable to fishing vessels should be laid down;

Whereas it is important to lay down additional hygiene conditions applicable to fishing vessels on board which catches are kept for more than twenty-four hours;

Whereas provisions should be made for the possibility of taking into consideration certain specific characteristics of certain fishing vessels;

Whereas it is appropriate to point out that the inspections and controls carried out pursuant to Directive 91/493/EEC apply equally to the vessels referred to in this Directive,

(1) OJ No L 268, 24. 9. 1991, p. 15.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The general hygiene conditions laid down in Annex I shall apply to fishery products handled on board fishing vessels.

2. The additional hygiene conditions laid down in Annex II shall apply to fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty-four hours, other than those equipped for keeping fish, shellfish and molluscs alive without other means of conservation on board.

3. If necessary, and in accordance with the procedure laid down in Article 2, derogations from or conditions additional to the provisions of Annex I may be laid down in order to take account of the specific characteristics, if any, of certain fishing vessels.

Article 2

The Annexes to this Directive may be amended in accordance with the procedure laid down in Article 15 of Directive 91/493/EEC.

Article 3

Member States may, provided that the products coming from fishing vessels expressly comply with the hygiene standards set by Directive 91/493/EEC, grant a further period to fishing vessels, expiring on 31 December 1995, within which to comply with the said requirements laid down in points 8 (b) and (c) of Annex II.

Such derogations may only be obtained by fishing vessels which, carrying out fishing activities on 30 June 1992, have submitted to the competent national authorities, before 31 December 1992, a duly justified application to that effect.

This application must set out details of the periods within which the fishing vessels can comply with the said requirements.

In the event that financial aid is solicited from the Community, only those projects that comply with the requirements of this Directive may be accepted.

Article 4

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall inform the Commissin thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 16 June 1992.

For the Council

The President

Arlindo MARQUES CUNHA

ANNEX I

General hygiene conditions applicable to fishery products on board fishing vessels

1. The sections of vessels or the containers reserved for the storage of fishery products must not contain objects or products liable to transmit harmful properties or abnormal characteristics to the foodstuffs. These sections or containers must be so designed as to allow them to be cleaned easily and to ensure that melt water cannot remain in contact with the fishery products.

2. When used, the sections of vessels or the containers reserved for the storage of fishery products must be completely clean and, in particular, must not be capable of being contaminated by the fuel used for the propulsion of the vessel or by bilge water.

3. As soon as they are taken on board, the fishery products must be protected firm contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either fresh water complying with the parameters set out in Annexes D and E of Directive 80/778/EEC (1) or clean seawater, so as not to impair their quality or wholesomeness.

4. The fishery products shall be handled and stored in such a way as to prevent bruising. The use of spiked instruments shall be tolerated for the moving of large fish or fish which might injure the handler, provided the flesh of these products is not damaged.

5. Fishery products other than those kept alive must undergo cold treatment as soon as possible after loading. However, in the case of fishing vessels where cooling is not possible from a practicable point of view, the fishery products must not be kept on board for more than eight hours.

6. Ice used for the chilling of products must be made from drinking water or clean seawater. Before use, it must be stored under conditions which prevent its contamination.

7. After the fishery products have been unloaded, the containers, equipment and sections of vessels which are directly in contact with the fishery products must be cleaned with drinking water or clean seawater.

8. Where fish is headed and/or gutted on board, such operations must be carried out hygienically and the products must be washed immediately and thoroughly with drinking water or clean seawater. The viscera and parts which may pose a threat to public health must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or frozen.

9. Equipment used for gutting, heading and the removal of fins, and containers and equipment in contact with the fishery products, must be made of or coated with a material which is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean.

10. Staff assigned to the handling of fishery products shall be required to maintain a high standard of cleanliness for themselves and their clothes.

(1) OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/377/EEC (OJ No L 377, 31. 12. 1991, p. 48).

ANNEX II

Additional hygiene conditions applicable to the fishing vessels referred to in Article 1 (2)

1. Fishing vessels must be equippped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperature laid down by Directive 91/493/EEC. These holds shall be separated from the machinery space and the quarters reserved for the crew by partitions which are sufficiently impervious to prevent any contamination of the stored fishery products.

2. The inside surface of the holds, tanks or containers shall be waterproof and easy to wash and disinfect. It shall consist of a smooth material or, failing that, smooth paint maintained in good condition, not being capable of transmitting to the fishery products substances harmful to human health.

3. The holds shall be designed to ensure that melt water cannot remain in contact with the fishery products.

4. Containers used for the storage of products must ensure their preservation under satisfactory conditions of hygiene and, in particular, allow drainage of melt water. When used they must be completely clean.

5. The working decks, the equipment and the holds, tanks and containers shall be cleaned each time they are used. Drinking water or clean seawater shall be used for this purpose. Disinfection, the removal of insects or rat extermination shall be carried out whenever necessary.

6. Cleaning products, disinfectants, insecticides and all potentially toxic substances shall be stored in locked premises or cupboards. Their use must not present any risk of contamination of the fishery products.

7. If fishery products are frozen on board, this operation must be carried out in accordance with the conditions laid down in Chapter IV (II) (1) and (3) of the Annex to Directive 91/493/EEC. Where freezing in brine is used, the brine shall not be a source of contamination for the fish.

8. Vessels equipped for chilling of fishery products in cooled seawater, either chilled by ice (CSW) or refrigerated by mechanical means (RSW), shall comply with the following requirements:

   (a) tanks must be equipped with adequate seawater filling and drainage installations and must incorporate devices for achieving uniform temperature throughout the tanks;

   (b) tanks must have a means of recording temperature connected to a temperature sensor positioned in the section of the tank where temperatures are highest;

   (c) the operation of the tank or container system must secure a chilling rate which ensures the mix of fish and seawater reaches 3° C at the most six hours after loading and 0° C at the most after sixteen hours;

   (d) after each unloading, the tanks, circulation systems and containers must be completely emptied and thoroughly cleaned using drinking water or clean seawater. They should only be filled with clean seawater;

   (e) the date and the number of the tank must be clearly indicated on the temperature recordings which must be kept available for the control authorities.

9. The competent authority shall keep up to date for control purposes a list of the vessels equipped in accordance with points 7 or 8, with the exception however of vessels equipped with removable containers which, without prejudice to point 5, second sentence of Annex I, are not engaged regularly in preserving fish in chilled seawater.

10. Shipowners or their representatives shall take all the measures necessary to prevent persons liable to contaminate fishery products from working on hand handling them, until there is evidence that such persons can do so without risk. The routine medical monitoring of such persons shall be governed by the national laws in force in the Member State concerned.

ประวัติผู้เขียน

นายทนงพันธ์ สัจจปาละ เกิดวันที่ 30 กรกฎาคม 2500 ที่กรุงเทพมหานคร สำเร็จการศึกษาชั้นมัธยมศึกษาตอนปลายจากโรงเรียนสวนกุหลาบวิทยาลัย สำเร็จการศึกษาวิทยาศาสตรบัณฑิต จากมหาวิทยาลัยเกษตรศาสตร์ พ.ศ. 2522 สำเร็จการศึกษานิติศาสตรบัณฑิต (เกียรตินิยมอันดับหนึ่ง) จากมหาวิทยาลัยสุโขทัยธรรมาธิราช พ.ศ. 2528 สำเร็จการศึกษาเนติบัณฑิต สมัยที่ 40 พ.ศ. 2530 และเข้าศึกษาต่อในหลักสูตรนิติศาสตรมหาบัณฑิต ที่จุฬาลงกรณ์มหาวิทยาลัย ในปีพ.ศ. 2532 ปัจจุบันรับราชการเป็นนักวิทยาศาสตร์การแพทย์ ระดับ 7 ที่กรมวิทยาศาสตร์การแพทย์ กระทรวงสาธารณสุข