

31989L0398**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***Official Journal L 186 , 30/06/1989 P. 0027 - 0032**Finnish special edition: Chapter 13 Volume 19 P. 0051**Swedish special edition: Chapter 13 Volume 19 P. 0051*

COUNCIL DIRECTIVE of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (89/398/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 Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (4), as last amended by Directive 85/7/EEC (5), has been amended on a number of occasions; whereas, on the occasion of new amendments, the said Directive should, for reasons of clarity, be redrafted;

Whereas the adoption of Directive 77/94/EEC was justified by the fact that the differences between national laws relating to foodstuffs for particular nutritional uses impeded their free movement, may have created unequal conditions of competition, and thus had a direct impact on the establishment and functioning of the common market;

Whereas the approximation of national laws presupposed, in an initial stage, the drawing-up of a common definition, the determination of measures enabling the consumer to be protected against fraud concerning the nature of these products and the adoption of rules to be complied with in labelling the products in question;

Whereas the products covered by this Directive are foodstuffs the composition and preparation of which must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended; whereas it may be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to achieve the specific nutritional objective;

Whereas, although foodstuffs intended for particular nutritional uses which are the subject of specific provisions can be efficiently monitored on the basis of the general rules for monitoring all types of foodstuffs, this is not always the case for those foodstuffs in respect of which no such specific provisions exist;

Whereas for the latter the usual means available to the monitoring bodies might not in certain cases enable them to check whether a foodstuff actually has the particular nutritional properties attributed to it; whereas it is necessary therefore to provide that, where necessary, the person responsible for placing that foodstuff on the market should assist the monitoring body in carrying out its activities;

Whereas the current state of development of Community rules on additives means that it is not possible, in the framework of this Directive, to adopt provisions on the use of additives in foodstuffs intended for particular nutritional uses if they do not belong to one of the groups mentioned in Annex I; whereas this question should therefore be re-examined in due course;

Whereas the drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature; whereas their adoption should be entrusted to the Commission in order to simplify and expedite the procedure;

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);

Whereas this Directive does not affect the time limits within which the Member States must comply with Directive 77/94/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

2. (a) Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

ii(i) of certain categories of persons whose digestive processes or metabolism are disturbed; or

i(ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or

(iii) of infants or young children in good health.

Article 2

1. The products referred to in Article 1 (2) (b) (i) and (ii) may be characterized as 'dietetic' or 'dietary'.

2. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the adjectives 'dietetic' or 'dietary' either alone or in conjunction with other words, to designate these foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1 is involved.

3. However, in accordance with provisions to be adopted according to the procedure provided for in Article 13, it shall be possible for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.

The aforesaid provisions may lay down the arrangements for indicating this suitability.

Article 3

1. The nature or composition of the products referred to in Article 1 must be such that the products are appropriate for the particular nutritional use intended.

2. The products referred to in Article 1 must also comply with any mandatory provisions applicable to foodstuffs for

normal consumption, save as regards changes made to them to ensure their conformity with the definitions given in Article 1.

Article 4

1. The specific provisions applicable to the groups of foods for particular nutritional uses appearing in Annex I shall be laid down by means of specific Directives.

Such specific Directives may cover in particular:

(a) essential requirements as to the nature or composition of the products;

(b) provisions regarding the quality of raw materials;

(c) hygiene requirements;

(d) permitted changes within the meaning of Article 3 (2);

(e) a list of additives;

(f)

provisions regarding labelling, presentation and advertising;

(g)

sampling procedures and methods of analysis necessary for checking compliance with the requirements of the specific Directives.

Such specific Directives shall be adopted:

- in the case of point (e), by the Council acting in accordance with the procedure laid down in Article 100a,

- in the case of the other points, in accordance with the procedure laid down in Article 13.

Provisions 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 (7).

2. A list of substances with specific nutritional purposes such as vitamins, mineral salts, amino acids and other substances intended to be added to foodstuffs intended for particular nutritional uses, together with the purity criteria applicable to them, and, where appropriate, the conditions under which they should be used, shall be adopted in accordance with the procedure laid down in Article 13.

Article 5

Conditions under which reference may be made in labelling, presentation and advertising to a diet or to a category of persons for which a product referred to in Article 1 is intended may be adopted in accordance with the procedure laid down in Article 13.

Article 6

1. The labelling and the labelling methods used, the presentation and the advertising of the products referred to in Article 1 must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties.

Derogations from the first subparagraph may be provided for in accordance with the procedure laid down in Article 13 in exceptional and clearly defined cases. Derogations may be continued until that procedure has been completed.

2. Paragraph 1 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

Article 7

1. 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 (8), as last amended by Directive 89/395/EEC (9), shall apply to the products referred to in Article 1, under the conditions set out below.

2. The designation under which a product is sold shall be accompanied by an indication of its particular nutritional characteristics; however, in the case of the products referred to in Article 1 (2) (b) (iii), this reference shall be replaced by a reference to the purpose for which they are intended.

3. The labelling of products for which no specific Directive has been adopted in accordance with Article 4 must also include:

(a) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics;

(b) the available energy value expressed in kilojoules and kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption.

If, however, the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product as marketed, these particulars may be replaced either by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 grams' or by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres'.

4. The particular labelling requirements for those products for which a specific Directive has been adopted shall be laid down in that Directive.

Article 8

1. The products referred to in Article 1 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the products.

2. Member States may, however, permit derogations from these provisions for purposes of the retail trade provided that the product is accompanied by the particulars provided for in Article 7 at the time when it is put on sale.

Article 9

To permit efficient official monitoring of foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in Annex I the following specific provisions shall apply:

1. When a product as referred to above is placed on the market for the first time the manufacturer or, where a product is manufactured in a third State, the importer, shall notify

the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.

2. Where the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer, shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification.

3. Where necessary, the competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product's compliance with Article 1 (2) together with the information provided for in Article 7 (3) (a). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

4. Member States shall communicate to the Commission the identity of the competent authorities within the meaning of this Article and any other useful information on them.

The Commission shall publish this information in the Official Journal of the European Communities.

Detailed rules for implementing this paragraph may be adopted in accordance with the procedure laid down in Article 13.

5. Four years after notification of this Directive, the Commission shall send the Council a report on the implementation of this Article, if necessary, together with appropriate proposals.

Article 10

1. Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and where appropriate, with Directives adopted in implementation of this Directive.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of Directives adopted in implementation of this Directive.

Article 11

1. Where a Member State has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in Annex I does not comply with Article 1 (2) or endangers human health, albeit freely circulating in one or more Member States, that Member State may temporarily suspend or restrict trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned, consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that the national measure must be dispensed with or modified, it shall initiate the procedure laid down in Article 13 for the adoption of appropriate measures.

Article 12

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 a foodstuff intended for particular nutritional uses 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 the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to this Directive or to the specific Directives 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 13 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 13

Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs, hereinafter referred to as 'the Committee', either on his own initiative or at the request of the 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 of three months from the date on which the matter was referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

Directive 77/94/EEC is hereby repealed.

References to the repealed Directive shall be construed as references to this Directive and are to be read in accordance with the correlation table set out in Annex II.

Article 15

1. Member States shall amend their laws, regulations and administrative provisions in such a way as:

- to permit trade in products complying with this Directive not later than 16 May 1990,
- to prohibit trade in products not complying with this Directive with effect from 16 May 1991.

They shall forthwith inform the Commission thereof.

2. Paragraph 1 shall not affect those national provisions which in the absence of the Directives referred to in Article 4 apply to certain groups of foodstuffs intended for particular nutritional uses.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES

(1) OJ No C 124, 23. 5. 1986, p. 7, and OJ No C 161, 19. 6. 1987, p. 12.

(2) OJ No C 99, 13. 4. 1987, p. 54, and OJ No C 120, 16. 5. 1989.

(3) OJ No C 328, 22. 12. 1986, p. 9.

(4) OJ No L 26, 31. 1. 1977, p. 55.

(5) OJ No L 2, 3. 1. 1985, p. 22.

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

(7) OJ No L 136, 20. 5. 1974, p. 1.

(8) OJ No L 33, 8. 2. 1979, p. 1.

(9) See page 17 of this Official Journal.

ANNEX I Groups of foods for particular nutritional uses for which specific provisions will be laid down by specific Directives ⁽¹⁾

1. Infant formulae

2. Follow-up milk and other follow-up foods

3. Baby foods

4. Low-energy and energy-reduced foods intended for weight control

5. Dietary foods for special medical purposes

6. Low-sodium foods, including low-sodium or sodium-free dietary salts

7. Gluten-free foods

8. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen

9. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes)

⁽¹⁾ It is understood that products already on the market when the Directive is adopted will not be affected by it.

ANNEX II CORRELATION TABLE

Directive 77/94/EEC

This Directive

Article 1 (1)

Article 1 (1)

Article 1 (2)

Article 2 (2)

Article 1 (3)

-

Article 2 (1)

Article 3 (1)

Article 2 (2) first subparagraph

Article 2 (1)

Article 2 (2) second subparagraph

-

Article 2 (3)

Article 2 (2)

Article 2 (4)

Article 2 (3)

Article 3

Article 3 (2)

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Article 4

Article 4 (1)

Article 6 (1)

Article 4 (2)

Article 5

Article 4 (3)

Article 6 (2)

Article 5 (1)

Article 7 (1)

Article 5 (2) point (a)

Article 7 (2)

Article 5 (2) points (b) and (c)

Article 7 (3) points (a) and (b)

Article 5 (2) point (d)

-

Article 5 (2) point (e)

Article 7 (4)

Article 5 (3)

-

Article 6

Article 8

-

Article 9

Article 7 (1)

Article 10 (1)

-

Article 10 (2)

Article 7 (2)

-

Article 8

-

-

Article 11

-

Article 12

Article 9

Article 13

Article 10

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Article 11

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Article 14

Article 12

Article 15

Article 13

Article 16

-

Annex I

31996L0084

Directive 96/84/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

Official Journal L 048 , 19/02/1997 P. 0020 - 0021

DIRECTIVE 96/84/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 December 1996 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

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

Whereas Article 4 of Council Directive 89/398/EEC (4) provides that specific provisions applicable to the groups of foodstuffs appearing in Annex I thereto must be laid down by means of specific Commission directives;

Whereas a modus vivendi was concluded on 20 December 1994 between the European Parliament, the Council and the Commission on the measures for implementing acts adopted in accordance with the procedure referred to in Article 189b of the Treaty (5);

Whereas the specific directives reflect the state of knowledge at the time of their adoption; whereas, therefore, any amendment to authorize innovations based on scientific and technical progress must, after consultation of the Scientific Committee for Food set up by Decision 95/273/EC (6), be approved in accordance with the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas a procedure must be laid down which allows the foodstuffs resulting from these technological innovations to be placed on the market on a temporary basis in order that proper benefit may be derived from the fruits of industry research pending the amendment of the specific directive concerned;

Whereas, however, on the grounds of consumer health protection, marketing authorization may be granted only after consultation of the Scientific Committee for Food;

Whereas authorization may be granted only if the product poses no danger to human health,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Article 4 of Directive 89/398/EEC, the following paragraph shall be added:

'1a. To enable foodstuff intended for particular nutritional uses and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after

consulting the Scientific Committee for Food and in accordance with the procedure laid down in Article 13, authorize for a two-year period the placing on the market of foodstuffs which do not comply with the rules as to composition laid down by the specific directives referred to in Annex I.

If necessary, the Commission may add in the authorization decision labelling rules relating to the change in composition.'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

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

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 19 December 1996.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President

S. BARRETT

(1) OJ No C 389, 31. 12. 1994, p. 21 and OJ No C 41, 13. 2. 1996, p. 13.

(2) OJ No C 256, 2. 10. 1995, p. 1.

(3) Opinion delivered on 11 October 1995 (OJ No C 287, 30. 10. 1995, p. 108). Council Common Position of 18 June 1996 (OJ No C 315, 24. 10. 1996, p. 1) and Decision of the European Parliament of 23 October 1996 (OJ No C 347, 18. 11. 1996). Council Decision of 9 December 1996.

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

(5) OJ No C 102, 4. 4. 1996, p. 1.

(6) OJ No L 167, 18. 7. 1995, p. 22.

31999L0041

Directive 1999/41/EC of the European Parliament and of the Council of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

Official Journal L 172 , 08/07/1999 P. 0038 - 0039

DIRECTIVE 1999/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 June 1999

amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

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

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty(3), in the light of the joint text approved by the Conciliation Committee on 18 March 1999,

(1) Whereas Article 4 of Directive 89/398/EEC(4) provides that specific provisions applicable to the groups of foods appearing in Annex I thereto are to be laid down by means of specific Directives;

(2) Whereas to date specific Directives have been adopted for infant formulae and follow-on formulae(5), for processed cereal-based foods and baby foods intended for infants and young children(6) and for foods intended for use in energy-restricted diets for weight reduction(7); whereas there are reasons relating to public health for adopting specific provisions, in accordance with Article 4 of Directive 89/398/EEC, for dietary foods for special medical purposes and foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, as referred to in Annex I to that Directive;

(3) Whereas, in the case of the groups of low-sodium foods, including low-sodium or sodium-free dietary salts, and gluten-free foods, such products can be satisfactorily placed on the market and be efficiently monitored officially under the general provisions of Directive 89/398/EEC, provided that the conditions for the use of certain terms used to indicate the particular nutritional properties of products are defined;

(4) Whereas the deletion of those categories from Annex I to Directive 89/398/EEC would be in line with the efforts being made to avoid unnecessarily detailed legislation;

(5) Whereas it is not clear whether an adequate basis exists for specific provisions to be adopted for the group mentioned in point 9 of Annex I to Directive 89/398/EEC, namely the group of foods intended for persons suffering from carbohydrate-metabolism disorders (diabetes);

(6) Whereas therefore advice should be obtained from, inter alia, the Scientific Committee for Food before a final decision is taken on the question;

(7) Whereas it is still possible to harmonize at Community level rules applicable to other groups of foodstuffs for particular nutritional uses, in the interest of consumer protection and the free movement of such foodstuffs,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 89/398/EEC is hereby amended as follows:

1. The following Articles shall be inserted: "Article 4a

Rules for the use of terms concerning

- the reduction or absence of sodium or salt (sodium chloride, table salt) content,
- the absence of gluten,

which may be used to describe the products referred to in Article 1, shall be adopted in accordance with the procedure laid down in Article 13.

Article 4b

Before 8 July 2002, the Commission shall, after consulting the Scientific Committee for Food, present to the European Parliament and to the Council a report on the desirability of special provisions for foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

In the light of the conclusions of this report, the Commission shall either, in accordance with the procedure laid down in Article 13, proceed with the preparation of the special provisions concerned or shall present, in accordance with the procedure laid down in Article 95 of the Treaty, any appropriate proposals for amendments to this Directive."

2. Article 9(5) shall be replaced by the following: "5. Before 8 July 2002 and every three years thereafter, the Commission shall send the European Parliament and the Council a report on the implementation of this Article."

3. Annex I shall be replaced by the following:

"ANNEX I

- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives:(1)

1. Infant formulae and follow-on formulae
 2. Processed cereal-based foods and baby foods for infants and young children
 3. Food intended for use in energy-restricted diets for weight reduction
 4. Dietary foods for special medical purposes
 5. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen;
- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by a specific Directive(2), dependant on the outcome of the procedure described in Article 4b:

6. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

(1) It is understood that products already on the market when Directive is adopted will not be affected by it.

(2) It is understood that products already on the market when Directive is adopted will not be affected by it."

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive not later than 8 July 1999. They shall forthwith inform the Commission thereof.

These measures shall be applied in such a way as to:

- permit trade in products complying with this Directive by 8 July 2000;
- prohibit trade in products not complying with this Directive by 8 January 2001

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 7 June 1999.

For the European Parliament

The President

J.M. GIL-ROBLES

For the Council

The President

E. BULMAHN

(1) OJ C 108, 16.4.1994, p. 17 and OJ C 35, 8.2.1996, p. 17.

(2) OJ C 388, 31.12.1994, p. 1.

(3) Opinion of the European Parliament of 11 October 1995 (OJ C 287, 30.10.1995, p. 104), Council Common Position of 22 July 1997 (OJ C 297, 29.9.1997, p. 1) and Decision of the European Parliament of 18 December 1997 (OJ C 14, 19.1.98, p. 123). Decision of the European Parliament of 5 May 1999 and Council Decision of 11 May 1999.

(4) OJ No L 186, 30.6.1989, p. 27. Directive as amended by Directive 96/84/EC (OJ No L 48, 19.2.1997, p.20).

(5) Commission Directive 91/321/EEC of May 1991 on infant formulae and follow-on formulae (OJ No L 175, 4.7.1991, p. 35). Directive as amended by Directive 96/4/EC (OJ No L 49, 28.2.1996, p. 12).

(6) Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ No L 49, 28.2.1996, p. 17).

(7) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ No L 55, 6.3.1996, p. 22)

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(Acts whose publication is obligatory)

**REGULATION (EC) No 1882/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 29 September 2003**

adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 40, 47, 55, 71, 80, 95, 137, 150, 152, 153, 155, 156, 175(1), 179, 285 and 300(3) thereof,

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

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

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

(1) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁴⁾ replaced Decision 87/373/EEC ⁽⁵⁾.

(2) In accordance with the statement of the Council and of the Commission ⁽⁶⁾ on Decision 1999/468/EC, the provisions relating to committees which assist the Commission in the exercise of its implementing powers, provided for in application of Decision 87/373/EEC, should be adapted in order to bring them into line with the provisions of Articles 3, 4 and 5 of Decision 1999/468/EC.

(3) The aforesaid statement indicates the methods for adapting the committee procedures, a process which is automatic provided that this does not affect the nature of the committee provided for in the basic act.

(4) The time limits set in the provisions to be adapted should remain in force. Wherever there is no specific time limit laid down for adopting the implementing measures, the time limit should be set at three months.

(5) The provisions of the instruments providing for recourse to the type I committee procedure established by Decision 87/373/EEC should therefore be replaced by provisions referring to the advisory procedure laid down in Article 3 of Decision 1999/468/EC.

(6) The provisions of the instruments providing for recourse to type IIa and IIb committee procedures established by Decision 87/373/EEC should be replaced by provisions referring to the management procedure provided for in Article 4 of Decision 1999/468/EC.

(7) The provisions of the instruments providing for recourse to type IIIa and IIIb committee procedures established by Decision 87/373/EEC should be replaced by provisions referring to the regulatory procedure provided for in Article 5 of Decision 1999/468/EC.

(8) This Regulation concerns solely the alignment of committee procedures. The names of the committees connected with such procedures have, where appropriate, been amended,

HAVE ADOPTED THIS REGULATION:

Article 1

The instruments listed in Annex I and subject to the advisory procedure shall be adapted, in accordance with that Annex, to the corresponding provisions of Decision 1999/468/EC.

⁽¹⁾ OJ C 75 E, 26.3.2002, p. 385.

⁽²⁾ OJ C 241, 7.10.2002, p. 128.

⁽³⁾ Opinion of the European Parliament of 2 September 2003 and Council Decision of 14 April 2003 (OJ C 153 E, 1.7.2003, p. 1).

⁽⁴⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁵⁾ OJ L 197, 18.7.1987, p. 33.

⁽⁶⁾ OJ C 203, 17.7.1999, p. 1.

Article 2

The instruments listed in Annex II and subject to the management procedure shall be adapted, in accordance with that Annex, to the corresponding provisions of Decision 1999/468/EC.

Article 3

The instruments listed in Annex III and subject to the regulatory procedure shall be adapted, in accordance with that Annex, to the corresponding provisions of Decision 1999/468/EC.

Article 4

References to provisions of the instruments in Annexes I, II and III are understood to be references to those provisions as adapted by this Regulation.

References in this Regulation to the former names of committees are understood to be references to the new names.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 29 September 2003.

For the European Parliament

The President

P. COX

For the Council

The President

G. ALEMANNO

ANNEX I

ADVISORY PROCEDURE

List of instruments subject to the advisory procedure and adapted to the corresponding provisions of Decision 1999/468/EC in accordance with the amendments below:

- 1) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment ⁽¹⁾.

Article 6(2) is replaced by the following:

‘2. The Commission shall be assisted by the Standing Committee, set up by Article 6(2) of Directive 98/37/EC (*), hereinafter referred to as “the Committee”.

It may be appraised, in accordance with the procedure referred to in this paragraph, of any matter to which the implementation and practical application of this Directive give rise.

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

(*) OJ L 207, 23.7.1998, p. 1. Directive as amended by Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 2) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ⁽²⁾.

Article 6(2) is replaced by the following:

‘2. The Commission shall be assisted by a standing committee (hereinafter referred to as “the Committee”).

The Committee may be appraised, in accordance with the procedure referred to in this paragraph, of any matter to which the implementation and practical application of this Directive give rise.

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 3) Council Directive 90/377/EEC of 29 June 1990 concerning a Community procedure to improve the transparency of gas and electricity prices charged to industrial end-users ⁽³⁾.

Article 7 is replaced by the following:

‘Article 7

1. For the adoption of the amendments referred to in Article 6, the Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 399, 30.12.1989, p. 18. Directive as last amended by European Parliament and Council Directive 96/58/EC (OJ L 236, 18.9.1996, p. 44).

⁽²⁾ OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

⁽³⁾ OJ L 185, 17.7.1990, p. 16. Directive as last amended by the 1994 Act of Accession.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 4) Council Regulation (EEC) No 3880/91 of 17 December 1991 on the submission of nominal catch statistics by Member States fishing in the north-east Atlantic ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 5) Council Regulation (EEC) No 2408/92 of 23 July 1992 on access for Community air carriers to intra-Community air routes ⁽²⁾.

Article 11 is replaced by the following:

'Article 11

1. The Commission shall be assisted by a committee.

2. The Committee shall advise the Commission on the application of Articles 9 and 10.

3. The Committee may furthermore be consulted by the Commission on any other matter concerning the application of this Regulation.

4. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

5. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 6) Council Directive 93/42/EEC of 14 June 1993 on medical devices ⁽³⁾.

Article 6 is replaced by the following:

'Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the Committee set up by Article 5 of Directive 83/189/EEC, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 365, 31.12.1991, p. 1. Directive as amended by Commission Regulation (EC) No 1637/2001 (OJ L 222, 17.8.2001, p. 20).

⁽²⁾ OJ L 240, 24.8.1992, p. 8. Regulation as last amended by the 1994 Act of Accession.

⁽³⁾ OJ L 169, 12.7.1993, p. 1. Directive as last amended by European Parliament and Council Directive 2001/104/EC (OJ L 6, 10.1.2002, p. 50).

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

7) Council Decision 93/704/EC of 30 November 1993 on the creation of a Community database on road accidents ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Statistical Programme Committee, set up by Council Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

8) Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres ⁽²⁾.

Article 6(3) is replaced by the following:

'3. The Commission shall be assisted by a standing committee (hereinafter referred to as "the Committee").

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

9) Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft ⁽³⁾.

Article 6(3) is replaced by the following:

'3. The Commission shall be assisted by a standing committee (hereinafter referred to as "the Committee").

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 329, 30.12.1993, p. 63.

⁽²⁾ OJ L 100, 19.4.1994, p. 1.

⁽³⁾ OJ L 164, 30.6.1994, p. 15.

- 10) Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts ⁽¹⁾.

Article 6(3) is replaced by the following:

‘3. The Commission shall be assisted by a standing committee (hereinafter referred to as “the Committee”).

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 11) Council Directive 96/67/EC of 15 October 1996 on access to the groundhandling market at Community airports ⁽²⁾.

Article 10 is replaced by the following:

‘Article 10

Advisory Committee

1. The Commission shall be assisted by a committee.
2. The Committee shall advise the Commission on the application of Article 9.
3. The Committee may furthermore be consulted on any other matter concerning the application of this Directive.
4. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
5. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 12) Council Directive 96/75/EC of 19 November 1996 on the systems of chartering and pricing in national and international inland waterway transport in the Community ⁽³⁾.

Article 8 is replaced by the following:

‘Article 8

1. The Commission shall be assisted by the Committee established by Directive 91/672/EEC (hereinafter referred to as “the Committee”).
2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

⁽¹⁾ OJ L 213, 7.9.1995, p. 1.

⁽²⁾ OJ L 272, 25.10.1996, p. 36.

⁽³⁾ OJ L 304, 27.11.1996, p. 12.

- 13) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment ⁽¹⁾.

Article 7(2) and (3) are replaced by the following:

‘2. The Commission shall be assisted by a standing committee (hereinafter referred to as “the Committee”).

The Committee shall draw up its rules of procedure.

3. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 14) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ⁽²⁾.

Article 6 is replaced by the following:

‘Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the Committee set up by Article 5 of Directive 98/34/EC (hereinafter referred to as “the Committee”).

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 15) Decision No 283/1999/EC of the European Parliament and of the Council of 25 January 1999 establishing a general framework for Community activities in favour of consumers ⁽³⁾.

Article 9 is replaced by the following:

‘Article 9

1. In defining the criteria for the selection of activities and projects referred to in Article 2(b) and (c) and in selecting these activities and projects, the Commission shall be assisted by a committee.

2. Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

3. In addition, at the beginning of each year, the Commission shall provide the Committee with information about the activities financed under Article 2(a).

4. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

⁽¹⁾ OJ L 181, 9.7.1997, p. 1.

⁽²⁾ OJ L 331, 7.12.1998, p. 1.

⁽³⁾ OJ L 34, 9.2.1999, p. 1. Decision as last amended by Commission Decision 2002/219/EC (OJ L 72, 14.3.2002, p. 27).

- 16) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ⁽¹⁾.

Articles 13 and 14 are replaced by the following:

'Article 13

Constitution of the Committee

1. The Commission shall be assisted by the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), hereinafter referred to as "the Committee".
2. The Committee shall adopt its rules of procedure.

Article 14

Advisory committee procedure

1. The Committee shall be consulted on the matters covered by Articles 5, 6(2), 7(4), 9(4) and Annex VII(5).
2. The Commission shall consult the Committee periodically on the surveillance tasks relating to the application of this Directive, and, where appropriate, issue guidelines on this matter.
3. Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
4. The Commission shall periodically consult the representatives of the telecommunications networks providers, the consumers and the manufacturers. It shall keep the Committee regularly informed of the outcome of such consultations.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 17) Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations ⁽²⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 18) Council Decision 1999/382/EC of 26 April 1999 establishing the second phase of the Community vocational training action programme 'Leonardo da Vinci' ⁽³⁾.

Article 7(5) and (6) are replaced by the following:

- '5. The representative of the Commission shall consult the Committee on all other appropriate matters concerning implementation of this programme. In such a case, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
6. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 91, 7.4.1999, p. 10.

⁽²⁾ OJ L 85, 23.3.1999, p. 1.

⁽³⁾ OJ L 146, 11.6.1999, p. 33.

- 19) Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels and amending Directive 93/12/EEC ⁽¹⁾.

Article 9 is replaced by the following:

'Article 9

Advisory committee

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.
3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 121, 11.5.1999, p. 13.

ANNEX II

MANAGEMENT PROCEDURE

List of instruments subject to the management procedure and adapted to the corresponding provisions of Decision 1999/468/EC in accordance with the amendments below:

- 1) Council Regulation (EEC) No 571/88 of 29 February 1988 on the organisation of Community surveys on the structure of agricultural holdings between 1988 and 1997 ⁽¹⁾.

Article 15 is replaced by the following:

'Article 15

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 2) Council Directive 89/130/EEC, Euratom of 13 February 1989 on the harmonisation of the compilation of gross national product at market prices ⁽²⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 3) Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks ⁽³⁾.

Articles 13 and 14 are replaced by the following:

'Article 13

1. An Implementation Committee for Spirit Drinks, hereinafter referred to as "the Committee", is hereby set up.
2. The Committee shall adopt its rules of procedure.

⁽¹⁾ OJ L 56, 2.3.1988, p. 1. Regulation as last amended by Commission Regulation (EC) No 143/2002 (OJ L 24, 26.1.2002, p. 16).

⁽²⁾ OJ L 49, 21.2.1989, p. 26.

⁽³⁾ OJ L 160, 12.6.1989, p. 1. Regulation as last amended by European Parliament and Council Regulation (EC) No 3378/94 (OJ L 366, 31.12.1994, p. 1).

Article 14

1. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 4) Council Regulation (Euratom, EEC) No 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities ⁽¹⁾.

Article 7 is replaced by the following:

'Article 7

1. A Committee on Statistical Confidentiality, hereinafter referred to as "the Committee", is hereby set up.
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 5) Council Regulation (EEC) No 3037/90 of 9 October 1990 on the statistical classification of economic activities in the European Community ⁽²⁾.

Article 9 is replaced by the following:

'Article 9

1. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 6) Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails ⁽³⁾.

Articles 12 and 13 are replaced by the following:

'Article 12

1. An implementation committee for the drinks referred to in this Regulation (hereinafter referred to as "the Committee") is hereby set up.

⁽¹⁾ OJ L 151, 15.6.1990, p. 1. Regulation as amended by Regulation (EC) No 322/97 (OJ L 52, 22.2.1997, p. 1).

⁽²⁾ OJ L 293, 24.10.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 29/2002 (OJ L 6, 10.1.2002, p. 3).

⁽³⁾ OJ L 149, 14.6.1991, p. 1. Regulation as last amended by European Parliament and Council Regulation (EC) No 2061/96 (OJ L 277, 30.10.1996, p. 1).

2. The Committee shall adopt its rules of procedure.

Article 13

Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 4(3) of Decision 1999/468/EC shall be one month.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 7) Council Regulation (EEC) No 3330/91 of 7 November 1991 on the statistics relating to the trading of goods between Member States ⁽¹⁾.

Article 30 is replaced by the following:

'Article 30

1. The Commission shall be assisted by the Committee on the statistics relating to the trading of goods between Member States, hereinafter referred to as "the Committee".
2. The provisions required for the implementation of this Regulation shall be adopted according to the procedure laid down in paragraph 3.
3. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 8) Council Regulation (EEC) No 3924/91 of 19 December 1991 on the establishment of a Community survey of industrial production ⁽²⁾.

Articles 9 and 10 are replaced by the following:

'Article 9

Committee

1. The Commission shall be assisted by the Statistical Programme Committee set up by Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".
2. The procedures for implementing this Regulation, including the measures for adjustment to technical progress concerning collection of data and the processing of the results, shall be laid down by the Commission in accordance with the procedure laid down in Article 10.
3. The Committee shall adopt its rules of procedure.

Article 10

Procedure

Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 316, 16.11.1991, p. 1. Regulation as last amended by European Parliament and Council Regulation (EC) No 1624/2000 (OJ L 187, 26.7.2000, p. 1).

⁽²⁾ OJ L 374, 31.12.1991, p. 1. Regulation as amended by the 1994 Act of Accession.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 9) Council Directive 91/692/EEC of 23 December 1991 standardising and rationalising reports on the implementation of certain Directives relating to the environment ⁽¹⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 10) Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC ⁽²⁾.

Article 15 is replaced by the following:

'Article 15

1. The lists of education and training courses set out in Annexes C and D may be amended on the basis of a reasoned request from any Member State concerned to the Commission. All appropriate information and in particular the text of the relevant provisions of national law shall accompany the request. The Member State making the request shall also inform the other Member States.

2. The Commission shall examine the education and training course in question and those required in the other Member States. It shall verify in particular whether the qualification resulting from the course in question confers on the holder:

— a level of professional education or training of a comparably high level to that of the post-secondary course referred to in point (i) of the second indent of the first subparagraph of Article 1(a), and

— a similar level of responsibility and activity.

3. The Commission shall be assisted by a committee.

The Committee shall adopt its rules of procedure.

4. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

⁽¹⁾ OJ L 377, 31.12.1991, p. 48.

⁽²⁾ OJ L 209, 24.7.1992, p. 25. Directive as last amended by European Parliament and Council Directive 2001/19/EC (OJ L 206, 31.7.2001, p. 1).

5. The Commission shall inform the Member State concerned of the decision and shall, where appropriate, publish the amended list in the *Official Journal of the European Union*.

6. The amendments made to the lists of education and training courses in Annexes C and D on the basis of the procedure laid down above shall be immediately applicable on the date set by the Commission.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 11) Council Directive 92/109/EEC of 14 December 1992 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances ⁽¹⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by the Committee set up by Article 10 of Regulation (EEC) No 3677/90 (hereinafter referred to as "the Committee").

The Committee shall examine any matter concerning the application of this Directive.

The Committee shall adopt its rules of procedure.

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The procedure laid down in paragraph 2 shall be followed in particular for:

- (a) the determination, where appropriate, of the conditions relating to the documentation and labelling of mixtures and preparations of substances in category 2 of Annex I as provided for in Article 2;
- (b) the amendment of the Annexes to this Directive, in cases where the tables of the Annex to the United Nations Convention are amended;
- (c) the amendment of the thresholds specified in Annex II.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 12) Council Regulation (EEC) No 696/93 of 15 March 1993 on the statistical units for the observation and analysis of the production system in the Community ⁽²⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Statistical Programme Committee set up by Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 370, 19.12.1992, p. 76. Directive as last amended by Commission Directive 2001/8/EC (OJ L 39, 9.2.2001, p. 31).

⁽²⁾ OJ L 76, 30.3.1993, p. 1. Regulation as last amended by the 1994 Act of Accession.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 13) Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses ⁽¹⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by a committee.

The committee shall examine any matter concerning the application of this Directive.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

4. The procedure laid down in paragraph 2 shall be followed in particular to take account of any future amendments to the United Nations recommendations.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 14) Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications ⁽²⁾.

Article 44a(3) is replaced by the following:

'3. Articles 4 and 7 of Decision 1999/468/EC () shall apply, having regard to the provisions of Article 8 of that Decision.*

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

4. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 15) Council Regulation (EEC) No 2186/93 of 22 July 1993 on Community coordination in drawing up business registers for statistical purposes ⁽³⁾.

Article 9 is replaced by the following:

'Article 9

Procedure

1. The Commission shall be assisted by the Statistical Programme Committee, set up by Council Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".

⁽¹⁾ OJ L 121, 15.5.1993, p. 20.

⁽²⁾ OJ L 165, 7.7.1993, p. 1. Directive as last amended by Directive 2001/19/EC.

⁽³⁾ OJ L 196, 5.8.1993, p. 1. Regulation as amended by the 1994 Act of Accession.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 16) Council Regulation (EEC) No 3696/93 of 29 October 1993 on the statistical classification of products by activity (CPA) in the European Economic Community ⁽¹⁾.

Article 6 is replaced by the following:

'Article 6

1. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 17) Council Regulation (EC) No 1172/95 of 22 May 1995 on the statistics relating to the trading of goods by the Community and its Member States with non-member countries ⁽²⁾.

Article 21 is replaced by the following:

'Article 21

1. The measures necessary for the implementation of this Regulation shall be adopted in accordance with the procedure laid down in paragraph 2.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 18) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽³⁾.

Article 31 is replaced by the following:

'Article 31

1. The Commission shall be assisted by a committee.

⁽¹⁾ OJ L 342, 31.12.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 204/2002 (OJ L 36, 6.2.2002, p. 1).

⁽²⁾ OJ L 118, 25.5.1995, p. 10. Regulation as last amended by Regulation (EC) No 374/98 (OJ L 48, 19.2.1999, p. 6).

⁽³⁾ OJ L 281, 23.11.1995, p. 31.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 19) Council Directive 95/57/EC of 23 November 1995 on the collection of statistical information in the field of tourism ⁽¹⁾.

Article 12 is replaced by the following:

'Article 12

1. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 20) Council Directive 95/64/EC of 8 December 1995 on statistical returns in respect of carriage of goods and passengers by sea ⁽²⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by the Statistical Programme Committee, set up by Council Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 21) Council Directive 96/50/EC of 23 July 1996 on the harmonisation of the conditions for obtaining national boat-masters' certificates for the carriage of goods and passengers by inland waterway in the Community ⁽³⁾.

⁽¹⁾ OJ L 291, 6.12.1995, p. 32.

⁽²⁾ OJ L 320, 30.12.1995, p. 25. Directive as last amended by Commission Decision 2000/363/EC (OJ L 132, 5.6.2000, p. 1).

⁽³⁾ OJ L 235, 17.9.1996, p. 31.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted in the application of Article 11 by the Committee set up by Article 7 of Directive 91/672/EEC (hereinafter referred to as "the Committee").

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 22) Council Regulation (EC) No 788/96 of 22 April 1996 on the submission by Member States of statistics on aquaculture production ⁽¹⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 23) Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid ⁽²⁾.

Article 17(3) is replaced by the following:

'3. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 24) Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security ⁽³⁾.

Article 27 is replaced by the following:

'Article 27

Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 108, 1.5.1996, p. 1.

⁽²⁾ OJ L 163, 2.7.1996, p. 1.

⁽³⁾ OJ L 166, 5.7.1996, p. 1. Regulation as last amended by European Parliament and Council Regulation (EC) No 1726/2001 (OJ L 234, 1.9.2001, p. 10).

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 25) Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ⁽¹⁾.

Article 20(2) and (3) are replaced by the following:

‘2. Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 26) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽²⁾.

Article 28(1) and (2) are replaced by the following:

‘1. The Commission shall be assisted by a Standing Committee on Biocidal Products (hereinafter referred to as “the Committee”).

The Standing Committee shall adopt its rules of procedure.

2. For matters referred to the Standing Committee by virtue of Articles 4, 11(3), 15, 17, 18, 19, 27(1)(b), 29 and 33 and for the compilation of specific data by product type referred to in Annex V, to be drawn from Annexes III A and III B and, as appropriate, from Annexes IV A and IV B, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 27) Council Regulation (EC) No 1172/98 of 25 May 1998 on statistical returns in respect of the carriage of goods by road ⁽³⁾.

Article 10 is replaced by the following:

‘Article 10

1. The Commission shall be assisted by the Statistical Programme Committee (hereinafter referred to as “the Committee”).

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 52, 22.2.1997, p. 1.

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

⁽³⁾ OJ L 163, 6.6.1998, p. 1. Regulation as amended by Commission Regulation (EC) No 2691/1999 (OJ L 326, 18.12.1999, p. 39).

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

28) Council Regulation (EC) No 1658/98 of 17 July 1998 on co-financing operations with European non-governmental development organisations (NGOs) in fields of interest to the developing countries ⁽¹⁾.

(a) Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

(b) Articles 9 and 10 are deleted and references to those Articles should be read as references to Article 8.

29) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽²⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

30) Council Regulation (EC) No 2836/98 of 22 December 1998 on integrating of gender issues in development cooperation ⁽³⁾.

⁽¹⁾ OJ L 213, 30.7.1998, p. 1.

⁽²⁾ OJ L 330, 5.12.1998, p. 32.

⁽³⁾ OJ L 354, 30.12.1998, p. 5.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by the geographically-determined committee competent for development (hereinafter referred to as "the Committee").
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 31) Council Decision 1999/382/EC of 26 April 1999 establishing the second phase of the Community vocational training action programme 'Leonardo da Vinci' ⁽¹⁾.

Article 7(1) and (3) are replaced by the following:

1. The Commission shall be assisted by a committee.
3. As regards the points referred to in paragraph 2, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.'

- 32) Council Decision 1999/297/EC of 26 April 1999 establishing a Community statistical information infrastructure relating to the industry and markets of the audiovisual and related sectors ⁽²⁾.

Article 4 is replaced by the following:

'Article 4

1. The Commission shall be assisted by the Statistical Programme Committee (hereinafter referred to as "the Committee").
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 146, 11.6.1999, p. 33.

⁽²⁾ OJ L 117, 5.5.1999, p. 39.

ANNEX III

REGULATORY PROCEDURE

List of instruments subject to the regulatory procedure and adapted to the corresponding provisions of Decision 1999/468/EC in accordance with the amendments below:

- 1) Council Directive 75/442/EEC of 15 July 1975 on waste ⁽¹⁾.

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 2) First Council Directive 79/267/EEC of 5 March 1979 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct life assurance ⁽²⁾.

Article 32b(6) is replaced by the following:

'6. The Commission shall be assisted by a committee.

Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 3) Council Regulation (EEC) No 357/79 of 5 February 1979 on statistical surveys of areas under vines ⁽³⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by the Standing Committee for Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).

⁽²⁾ OJ L 63, 13.3.1979, p. 1. Directive as last amended by European Parliament and Council Directive 2002/12/EC (OJ L 77, 20.3.2002, p. 11).

⁽³⁾ OJ L 54, 5.3.1979, p. 124. Regulation as last amended by Regulation (EC) No 2329/98 (OJ L 291, 30.10.1998, p. 2).

- 4) Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters ⁽¹⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 ^(*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ^(**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

^(*) OJ L 31, 1.2.2002, p. 1.

^(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 5) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽²⁾.

Articles 13 and 14 are replaced by the following:

'Article 13

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 ^(*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ^(**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 14

Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

^(*) OJ L 31, 1.2.2002, p. 1.

^(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 6) Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption ⁽³⁾.

Article 4 is replaced by the following:

'Article 4

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 ^(*), hereinafter referred to as "the Committee".

⁽¹⁾ OJ L 229, 30.8.1980, p. 1. Directive as last amended by European Parliament and Council Directive 96/70/EC (OJ L 299, 23.11.1996, p. 26).

⁽²⁾ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

⁽³⁾ OJ L 372, 31.12.1985, p. 50.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

7) Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ⁽¹⁾.

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

8) Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP) ⁽²⁾.

Article 8 is replaced by the following:

'Article 8

1. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

9) Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients ⁽³⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

⁽¹⁾ OJ L 370, 31.12.1985, p. 8. Regulation as last amended by Commission Regulation (EC) No 1360/2002 (OJ L 207, 5.8.2002, p. 1).

⁽²⁾ OJ L 145, 11.6.1988, p. 35. Directive as last amended by Commission Directive 1999/12/EC (OJ L 77, 23.3.1999, p. 22).

⁽³⁾ OJ L 157, 24.6.1988, p. 28. Directive as last amended by European Parliament and Council Directive 97/60/EC (OJ L 331, 3.12.1997, p. 7).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 10) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ⁽¹⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 11) Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products ⁽²⁾.

Article 20(3) and (4) are replaced by the following:

'3. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽³⁾.

⁽¹⁾ OJ L 184, 15.7.1988, p. 61. Directive as last amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

⁽²⁾ OJ L 40, 11.2.1989, p. 12. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

⁽³⁾ OJ L 40, 11.2.1989, p. 27. Directive as amended by European Parliament and Council Directive 94/34/EC (OJ L 237, 10.9.1994, p. 1).

Article 11 is replaced by the following:

'Article 11

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 13) Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption ⁽¹⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 14) Council Directive 89/109/EEC 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 ⁽²⁾.

Article 9 is replaced by the following:

'Article 9

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 40, 11.2.1989, p. 34. Directive as amended by the 1994 Act of Accession.

⁽²⁾ OJ L 40, 11.2.1989, p. 38.

- 15) 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⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 16) Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks ⁽²⁾.

Article 15 is replaced by the following:

'Article 15

Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.'

- 17) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽³⁾.

Article 17 is replaced by the following:

'Article 17

1. For the purely technical adjustments to the individual Directives provided for in Article 16(1) to take account of:

— the adoption of Directives in the field of technical harmonisation and standardisation, and/or

— technical progress, changes in international regulations or specifications, and new findings,

the Commission shall be assisted by a committee.

2. Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by European Parliament and Council Directive 1999/41/EC (OJ L 172, 8.7.1999, p. 38).

⁽²⁾ OJ L 160, 12.6.1989, p. 1. Directive as last amended by European Parliament and Council Regulation (EC) No 3378/94 (OJ L 366, 31.12.1994, p. 1).

⁽³⁾ OJ L 183, 29.6.1989, p. 1.

- 18) Council Regulation (EEC) No 837/90 of 26 March 1990 concerning statistical information to be supplied by the Member States on cereals production ⁽¹⁾.

Article 11 is replaced by the following:

'Article 11

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 19) Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms ⁽²⁾.

Article 21 is replaced by the following:

'Article 21

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 20) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs ⁽³⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 88, 3.4.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 2197/95 (OJ L 221, 19.9.1995, p. 2).

⁽²⁾ OJ L 117, 8.5.1990, p. 1. Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32).

⁽³⁾ OJ L 276, 6.10.1990, p. 40.

- 21) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment ⁽¹⁾.

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 22) Council Regulation (EEC) No 1382/91 of 21 May 1991 on the submission of data on the landings of fishery products in Member States ⁽²⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 23) Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails ⁽³⁾.

Article 14 is replaced by the following:

'Article 14

Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 135, 30.5.1991, p. 40. Directive as amended by Commission Directive 98/15/EC (OJ L 67, 7.3.1998, p. 29).

⁽²⁾ OJ L 133, 28.5.1991, p. 1. Regulation as amended by Regulation (EEC) No 2104/93 (OJ L 191, 31.7.1993, p. 1).

⁽³⁾ OJ L 149, 14.6.1991, p. 1. Regulation as last amended by European Parliament and Council Regulation (EC) No 2061/96 (OJ L 277, 30.10.1996, p. 1).

- 24) Council Directive 91/439/EEC of 29 July 1991 on driving licences ⁽¹⁾.

Article 7b is replaced by the following:

'Article 7b

1. The Commission shall be assisted by a committee on driving licences, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 25) Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources ⁽²⁾.

Article 9 is replaced by the following:

'Article 9

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 26) Council Directive 91/672/EEC of 16 December 1991 on the reciprocal recognition of national boatmasters' certificates for the carriage of goods and passengers by inland waterway ⁽³⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 237, 24.8.1991, p. 1. Directive as last amended by Commission Directive 2000/56/EC (OJ L 237, 21.9.2000, p. 45).

⁽²⁾ OJ L 375, 31.12.1991, p. 1.

⁽³⁾ OJ L 373, 31.12.1991, p. 29. Directive as amended by the 1994 Act of Accession.

- 27) Council Directive 91/675/EEC of 19 December 1991 setting up an insurance committee ⁽¹⁾.

Articles 1 and 2 are replaced by the following:

'Article 1

The Commission shall be assisted by the Insurance Committee, hereinafter referred to as "the Committee".

Article 2

1. Where the Council, in the acts which it adopts in the field of direct non-life insurance and direct life assurance, confers on the Commission powers for the implementation of the rules which it lays down, the procedure set out in paragraph 2 shall apply.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 28) Council Regulation (EEC) No 3925/91 of 19 December 1991 concerning the elimination of controls and formalities applicable to the cabin and hold baggage of persons taking an intra-Community flight and the baggage of persons making an intra-Community sea crossing ⁽²⁾.

(a) Article 6(2) is deleted.

(b) Article 8 is replaced by the following:

'Article 8

1. The provisions necessary for the application of this Regulation shall be adopted in accordance with the procedure laid down in paragraph 2.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 29) Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels ⁽³⁾.

Article 8 is replaced by the following:

'Article 8

Committee

1. The Commission shall be assisted by a committee with a view to the strictly technical adaptation of the Annexes to this Directive in the light of technical progress or changes in international regulations or specifications and new findings in this field.

2. Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 374, 31.12.1991, p. 32.

⁽²⁾ OJ L 374, 31.12.1991, p. 4.

⁽³⁾ OJ L 113, 30.4.1992, p. 19.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

30) Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora ⁽¹⁾.

Articles 20 and 21 are replaced by the following:

'Article 20

The Commission shall be assisted by a committee.

Article 21

1. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

31) Council Directive 92/59/EEC of 29 June 1992 on general product safety ⁽²⁾.

Article 11 is replaced by the following:

'Article 11

1. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

2. The Committee shall adopt its rules of procedure.

3. Any measure adopted under this procedure shall be valid for no longer than three months. That period may be prolonged under the same procedure.

4. Member States shall take all necessary measures to implement the decisions adopted under this procedure within less than 10 days.

5. The competent authorities of the Member States responsible for carrying out measures adopted under the procedure referred to in paragraph 1 shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 206, 22.7.1992, p. 7. Directive as last amended by Directive 97/62/EC (OJ L 305, 8.11.1997, p. 42).

⁽²⁾ OJ L 228, 11.8.1992, p. 24.

- 32) Council Directive 92/75/EEC of 22 September 1992 on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances ⁽¹⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 33) Council Decision 92/578/EEC of 30 November 1992 concerning the conclusion of the Agreement between the European Economic Community and the Swiss Confederation on the carriage of goods by road and rail ⁽²⁾.

Article 4 is replaced by the following:

'Article 4

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at four weeks.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 34) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽³⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 297, 13.10.1992, p. 16.

⁽²⁾ OJ L 373, 21.12.1992, p. 26.

⁽³⁾ OJ L 37, 13.2.1993, p. 1.

- 35) Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 36) Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽²⁾.

Article 15 is replaced by the following:

'Article 15

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at two months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 37) Council Regulation (EEC) No 959/93 of 5 April 1993 concerning statistical information to be supplied by Member States on crop products other than cereals ⁽³⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 52, 4.3.1993, p. 18.

⁽²⁾ OJ L 84, 5.4.1993, p. 1.

⁽³⁾ OJ L 98, 24.4.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 2197/95 (OJ L 221, 19.9.1995, p. 2).

- 38) Council Directive 93/23/EEC of 1 June 1993 on the statistical surveys to be carried out on pig production ⁽¹⁾.

Article 17 is replaced by the following:

'Article 17

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 39) Council Directive 93/24/EEC of 1 June 1993 on the statistical surveys to be carried out on bovine animal production ⁽²⁾.

Article 17 is replaced by the following:

'Article 17

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 40) Council Directive 93/25/EEC of 1 June 1993 on the statistical surveys to be carried out on sheep and goat stocks ⁽³⁾.

Article 20 is replaced by the following:

'Article 20

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 149, 21.6.1993, p. 1. Directive as last amended by Directive 97/77/EC (OJ L 10, 16.1.1998, p. 28).

⁽²⁾ OJ L 149, 21.6.1993, p. 5. Directive as last amended by Directive 97/77/EC.

⁽³⁾ OJ L 149, 21.6.1993, p. 10. Directive as last amended by Directive 97/77/EC.

- 41) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

4. The Committee may examine any question connected with implementation of this Directive.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 42) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs ⁽²⁾.

Article 14 is replaced by the following:

'Article 14

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 43) Council Decision 93/389/EEC of 24 June 1993 for a monitoring mechanism of Community CO₂ and other greenhouse gas emissions ⁽³⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 169, 12.7.1993, p. 1. Directive as last amended by European Parliament and Council Directive 2001/104/EC (OJ L 6, 10.1.2002, p. 50).

⁽²⁾ OJ L 175, 19.7.1993, p. 1.

⁽³⁾ OJ L 167, 9.7.1993, p. 31. Decision as amended by Decision 1999/296/EC (OJ L 117, 5.5.1999, p. 35).

- 44) Council Regulation (EEC) No 2018/93 of 30 June 1993 on the submission of catch and activity statistics by Member States fishing in the Northwest Atlantic ⁽¹⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 45) Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air traffic management equipment and systems ⁽²⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 46) Council Directive 93/77/EEC of 21 September 1993 on fruit juices and certain similar products ⁽³⁾.

Article 15 is replaced by the following:

'Article 15

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 186, 28.7.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 1636/2001 (OJ L 222, 17.8.2001, p. 1).

⁽²⁾ OJ L 187, 29.7.1993, p. 52. Directive as last amended by Commission Directive 97/15/EC (OJ L 95, 10.4.1997, p. 16).

⁽³⁾ OJ L 244, 30.9.1993, p. 23. Directive as amended by the 1994 Act of Accession.

- 47) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs ⁽¹⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 48) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽²⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 49) Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ⁽³⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 290, 24.11.1993, p. 14.

⁽²⁾ OJ L 237, 10.9.1994, p. 3. Directive as amended by European Parliament and Council Directive 96/83/EC (OJ L 48, 19.2.1997, p. 16).

⁽³⁾ OJ L 237, 10.9.1994, p. 13.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 50) Council Regulation (EC) No 1734/94 of 11 July 1994 on financial and technical cooperation with the West Bank and Gaza Strip ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the MED Committee set up pursuant to Article 11 of Regulation (EEC) No 1488/96 (*).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 189, 30.7.1996, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 51) Council Regulation (EC) No 2978/94 of 21 November 1994 on the implementation of IMO Resolution A.747(18) on the application of tonnage measurement of ballast spaces in segregated ballast oil tankers ⁽²⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by a committee. The committee shall meet at the invitation of the Commission whenever deemed necessary for the application of this Regulation.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 52) Council Directive 94/67/EEC of 16 December 1994 on the incineration of hazardous waste ⁽³⁾.

Article 16 is replaced by the following:

'Article 16

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 182, 16.7.1994, p. 4. Regulation as last amended by Regulation (EC) No 2840/98 (OJ L 354, 30.12.1998, p. 14).

⁽²⁾ OJ L 319, 12.12.1994, p. 1.

⁽³⁾ OJ L 365, 31.12.1994, p. 34.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 53) Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste ⁽¹⁾.

Article 21 is replaced by the following:

'Article 21

Committee procedure

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 54) Directive 94/63/EC of the European Parliament and of the Council of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations ⁽²⁾.

Article 8 is replaced by the following:

'Article 8

The committee

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 55) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽³⁾.

Article 6 is replaced by the following:

'Article 6

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".

⁽¹⁾ OJ L 365, 31.12.1994, p. 10.

⁽²⁾ OJ L 365, 31.12.1994, p. 24.

⁽³⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by European Parliament and Council Directive 2001/5/EC (OJ L 55, 24.2.2001, p. 59).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

56) Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices ⁽¹⁾.

Article 14 is replaced by the following:

'Article 14

Procedure

1. The Commission shall be assisted by the Statistical Programme Committee, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

57) Council Regulation (EC) No 2597/95 of 23 October 1995 on the submission of nominal catch statistics by Member States fishing in certain areas other than those of the North Atlantic ⁽²⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

58) Council Directive 96/16/EC of 19 March 1996 on statistical surveys of milk and milk products ⁽³⁾.

⁽¹⁾ OJ L 257, 27.10.1995, p. 1.

⁽²⁾ OJ L 270, 13.11.1995, p. 1. Regulation as amended by Commission Regulation (EC) No 1638/2001 (OJ L 222, 17.8.2001, p. 29).

⁽³⁾ OJ L 78, 28.3.1996, p. 27.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

59) Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid ⁽¹⁾.

Article 17(1) and (2) are replaced by the following:

'1. The Commission shall be assisted by a committee.

The Committee shall adopt its rules of procedure.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.'

60) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system ⁽²⁾.

Article 21 is replaced by the following:

'Article 21

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

4. The Committee may discuss any matter concerning the interoperability of the trans-European high-speed rail system.

5. Should it prove necessary, the Committee may set up working parties to aid it in carrying out its tasks, in particular with a view to coordinating the notified bodies.

6. The Committee shall be set up as soon as this Directive enters into force.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 163, 2.7.1996, p. 1.

⁽²⁾ OJ L 235, 17.9.1996, p. 6.

- 61) Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control ⁽¹⁾.

Article 19 is replaced by the following:

'Article 19

Committee procedure

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 62) Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management ⁽²⁾.

Article 12 is replaced by the following:

'Article 12

Committee and its functions

1. The amendments necessary to adapt the criteria and techniques referred to in Article 4(2) to scientific and technical progress, and the detailed arrangements for forwarding the information to be provided under Article 11, and other tasks specified in the provisions referred to in Article 4(3), shall be adopted in accordance with the procedure laid down in paragraph 2 of this Article. Such adaptation must not have the effect of modifying the limit values or the alert thresholds either directly or indirectly.
2. The Commission shall be assisted by a committee.
3. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 63) Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs ⁽³⁾.

(a) Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 257, 10.10.1996, p. 26.

⁽²⁾ OJ L 296, 21.11.1996, p. 55.

⁽³⁾ OJ L 299, 23.11.1996, p. 1.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

(b) Article 8 is repealed.

- 64) Council Regulation (EC) No 2258/96 of 22 November 1996 on rehabilitation and reconstruction operations in developing countries ⁽¹⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the relevant geographical committee, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 65) Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances ⁽²⁾.

Article 22 is replaced by the following:

'Article 22

Committee

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 66) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein ⁽³⁾.

⁽¹⁾ OJ L 306, 28.11.1996, p. 1.

⁽²⁾ OJ L 10, 14.1.1997, p. 13.

⁽³⁾ OJ L 61, 3.3.1997, p. 1. Regulation as last amended by Commission Regulation (EC) No 2476/2001 (OJ L 334, 18.12.2001, p. 3).

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months. As regards the Committee's tasks referred to in points 1 and 2 of Article 19, 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.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 67) Directive 96/73/EC of the European Parliament and of the Council of 16 December 1996 on certain methods for the quantitative analysis of binary textile fibre mixtures ⁽¹⁾.

Articles 5 and 6 are replaced by the following:

'Article 5

1. The Commission shall be assisted by a Committee for Directives relating to Textile Names and Labelling, hereinafter called "the Committee".
2. Adaptations to technical progress in the methods of quantitative analysis provided for in Annex II shall be made in accordance with the procedure laid down in Article 6.

Article 6

1. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 68) Council Directive 96/96/EC of 20 December 1996 on the approximation of the laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers ⁽²⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by a committee on the adaptation to technical progress of the Directive on roadworthiness tests for motor vehicles and their trailers, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 32, 3.2.1997, p. 1.

⁽²⁾ OJ L 46, 17.2.1997, p. 1. Directive as last amended by Commission Directive 2001/11/EC (OJ L 48, 17.2.2001, p. 20).

- 69) Council Regulation (EC, Euratom) No 58/97 of 20 December 1996 concerning structural business statistics ⁽¹⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by the Statistical Programme Committee set up by Decision 89/382/EEC, Euratom, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 70) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽²⁾.

Article 13 is replaced by the following:

'Article 13

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 71) Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ⁽³⁾.

Article 19 is replaced by the following:

'Article 19

1. In the case referred to in Article 3(2)(b), the Commission shall be assisted by the Statistical Programme Committee, hereinafter referred to as "the Committee".
2. In this instance, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 14, 17.1.1997, p. 7. Regulation as last amended by Commission Regulation (EC) No 1614/2002 (OJ L 244, 12.9.2002, p. 7).

⁽²⁾ OJ L 43, 14.2.1997, p. 1.

⁽³⁾ OJ L 52, 22.2.1997, p. 1.

- 72) Council Regulation (EC) No 550/97 of 24 March 1997 on HIV/AIDS-related operations in developing countries ⁽¹⁾.

Article 8 is replaced by the following:

'Article 8

1. The Commission shall be assisted by the geographically-determined committee competent for development, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 73) Council Regulation (EC) No 1484/97 of 22 July 1997 on aid for population policies and programmes in the developing countries ⁽²⁾.

Article 11 is replaced by the following:

'Article 11

1. The Commission shall be assisted by the committee competent for development, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.
4. An exchange of views shall take place once a year on the basis of a presentation by the representative of the Commission of the general guidelines for the operations to be carried out in the year ahead, in the framework of a joint meeting of the committees pursuant to paragraph 1.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 74) Council Regulation (EC) No 2046/97 of 13 October 1997 on north-south cooperation in the campaign against drugs and drug addiction ⁽³⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by the geographically-determined committee competent for development.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

⁽¹⁾ OJ L 85, 27.3.1997, p. 1.

⁽²⁾ OJ L 202, 30.7.1997, p. 1.

⁽³⁾ OJ L 287, 21.10.1997, p. 1.

4. An exchange of views shall take place once a year on the basis of a presentation by the representative of the Commission of the general guidelines for the operations to be carried out in the year ahead, in the framework of a joint meeting of the committees pursuant to paragraph 1.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 75) Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service ⁽¹⁾.

Article 21 is replaced by the following:

'Article 21

The Committee

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 76) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽²⁾.

Article 28(3) is replaced by the following:

'3. For matters referred to the Standing Committee by virtue of Articles 10, 11(4), 16, 27(1)(a) and (2), and 32, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.'

- 77) Council Regulation (EC) No 448/98 of 16 February 1998 completing and amending Regulation (EC) No 2223/96 with respect to the allocation of financial intermediation services indirectly measured (FISIM) within the European system of national and regional accounts (ESA) ⁽³⁾.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the Statistical Programme Committee, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 15, 21.1.1998, p. 14. Directive as amended by Directive 2002/39/EC (OJ L 176, 5.7.2002, p. 21).

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

⁽³⁾ OJ L 58, 27.2.1998, p. 1.

78) Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics ⁽¹⁾.

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by the Statistical Programme Committee, hereinafter referred to as "the Committee".

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

79) Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community ⁽²⁾.

Article 7 is replaced by the following:

'Article 7

1. For the purposes of implementing this Decision, the Commission shall be assisted by a committee.

2. Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

80) Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC ⁽³⁾.

Article 11 is replaced by the following:

'Article 11

Committee procedure

1. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

2. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

81) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ⁽⁴⁾.

⁽¹⁾ OJ L 162, 5.6.1998, p. 1.

⁽²⁾ OJ L 268, 3.10.1998, p. 1.

⁽³⁾ OJ L 350, 28.12.1998, p. 58. Directive as amended by Commission Directive 2000/71/EC (OJ L 287, 14.11.2000, p. 46).

⁽⁴⁾ OJ L 331, 7.12.1998, p. 1.

Article 7 is replaced by the following:

'Article 7

1. The Commission shall be assisted by the committee set up by Article 6(2) of Directive 90/385/EEC.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.
4. The Committee referred to in paragraph 1 may examine any question connected with the implementation of this Directive.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 82) Decision No 276/1999/EC of the European Parliament and of the Council of 25 January 1999 adopting a multi-annual Community action plan on promoting safer use of the Internet by combating illegal and harmful content on global networks ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 83) Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation ⁽²⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 33, 6.2.1999, p. 1.

⁽²⁾ OJ L 66, 13.3.1999, p. 16.

- 84) Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts ⁽¹⁾.

Article 5 is replaced by the following:

'Article 5

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 (*), hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 31, 1.2.2002, p. 1.

(**) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 85) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ⁽²⁾.

Article 15 is replaced by the following:

'Article 15

Regulatory committee procedure

1. The procedure laid down in paragraph 2 shall apply in respect of the matters covered by Articles 3(3) and 4(1).
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 86) Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs ⁽³⁾.

Article 12 is replaced by the following:

'Article 12

1. The Commission shall be assisted by the Statistical Programme Committee, hereinafter referred to as "the Committee".
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 66, 13.3.1999, p. 26.

⁽²⁾ OJ L 91, 7.4.1999, p. 10.

⁽³⁾ OJ L 63, 12.3.1999, p. 6.

- 87) Council Regulation (EC) No 856/1999 of 22 April 1999 establishing a special framework of assistance for traditional ACP suppliers of bananas ⁽¹⁾.

Articles 6 and 8 are replaced by the following:

‘Article 6

1. The Commission shall be assisted by the geographically-determined committee competent for development.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

Article 8

1. The Commission shall be assisted by the geographically-determined committee competent for development.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.’

- 88) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ⁽²⁾.

Article 17 is replaced by the following:

‘Article 17

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).’

- 89) Council Regulation (EC) No 975/1999 of 29 April 1999 laying down the requirements for the implementation of development cooperation operations which contribute to the general objective of developing and consolidating democracy and the rule of law and to that of respecting human rights and fundamental freedoms ⁽³⁾.

Article 13 is replaced by the following:

‘Article 13

1. The Commission shall be assisted by a Human Rights and Democracy Committee, hereinafter referred to as “the Committee”.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

⁽¹⁾ OJ L 108, 27.4.1999, p. 2.

⁽²⁾ OJ L 182, 16.7.1999, p. 1.

⁽³⁾ OJ L 120, 8.5.1999, p. 1.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 90) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾.

Article 20 is replaced by the following:

'Article 20

1. Amendments required to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 29(4)(a) of Directive 67/548/EEC.

2. The Commission shall be assisted by a committee.

3. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

- 91) Directive 1999/94/EC of the European Parliament and of the Council of 13 December 1999 relating to the availability of consumer information on fuel economy and CO₂ emissions in respect of the marketing of new passenger cars ⁽²⁾.

Article 10 is replaced by the following:

'Article 10

1. The Commission shall be assisted by a committee.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).'

⁽¹⁾ OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).

⁽²⁾ OJ L 12, 18.1.2000, p. 16.

31991L0321**Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae***Official Journal L 175 , 04/07/1991 P. 0035 - 0049**Finnish special edition: Chapter 15 Volume 10 P. 0107**Swedish special edition: Chapter 15 Volume 10 P. 0107*

COMMISSION DIRECTIVE of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (1), and in particular Article 4 thereof,

Whereas the essential composition of the products in question must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data;

Whereas on the basis of these data the essential composition of infant formulae and follow-on formulae manufactured from cows' milk proteins and soya proteins alone or in a mixture can already be defined; whereas the same is not true for preparations based wholly or partly on other sources of protein; whereas for this reason specific rules for such products, if necessary, will therefore have to be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification, to allow innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas because of the persons for which these products are intended it will be necessary to lay down microbiological criteria and maximum levels for contaminants; whereas given the complexity of the subject these will have to be adopted at a later stage;

Whereas infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first four to six months of life; whereas in order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae;

Whereas pursuant to Article 7 (1) of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by 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 (2), as last amended by Directive 89/395/EEC (3); whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate, in order to promote and protect breast-feeding;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain; whereas, on the other hand, the method of use must be specified in conformity with Article 3 (1) (8) and Article 10 (2) of Directive 79/112/EEC, in order to prevent inappropriate uses likely to be detrimental to the health of infants;

Whereas, pursuant to Article 2 (2) of Directive 79/112/EEC, and in order to supply objective and scientifically verified information, it is necessary to define the conditions under which claims about the particular composition of an infant formula are authorized;

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

Whereas given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast-feeding;

Whereas this Directive does not concern the conditions of sale of publications specializing in baby care and of scientific publications;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure;

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 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities.

2. For the purposes of this Directive,

(a) 'infants' means children under the age of 12 months;

(b) 'young children' means children aged between one and three years;

(c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the Community only if they conform to the definitions and rules laid down in this Directive. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.
2. Follow-on formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.
3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.
2. Follow-on formulae must comply with the compositional criteria specified in Annex II.
3. In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

Article 5

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

- mineral substances,
- vitamins,
- amino acids and other nitrogen compounds,
- other substances having a particular nutritional purpose.

The purity criteria for these substances shall be stipulated at a later stage.

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive. Article 6 1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants. Where necessary the maximum levels of any such substance shall be stipulated at a later date.

2. Microbiological criteria shall be established at a later date.

Article 7

1. The name under which the products covered by Article 1 (2) are sold shall be, respectively:

- in English:

'infant formula' and 'follow-on formula',

- in Danish:

'Modermælkserstatning' and 'Tilskudsblanding',

- in German:

'Säuglingsanfangsnahrung' and 'Folgenahrung',

- in Greek:

'Διαιτίαση αββήτων' and 'Διαιτίαση αββήτων αββήτων',

- in Spanish:

'Preparado para lactentes' and 'Preparado de continuación',

- in French:

'Préparation pour nourrissons' and 'Préparation de suite',

- in Italian:

'Alimento per lattanti' and 'Alimento di proseguimento',

- in Dutch:

'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

- in Portuguese:

'Fórmula para lactentes' and 'Fórmula de transição'.

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively:

- in English:

'Infant milk' and 'follow-on milk',

- in Danish:

'Modermælkserstatning udelukkende baseret paa mælk' and 'Tilskudsblanding udelukkende baseret paa mælk',

- in German:

'Säuglingsmilchnahrung' and 'Folgemilch',

- in Greek:

'ΆΥΕΈά άέά άñΥοεç » and 'ΆΥΕΈά αεαάγôaañçò άñααοεέêρò çέέêσσάò »,

- in Spanish:

'Leche para lactentes' and 'Leche de continuación',

- in French:

'Lait pour nourrissons' and 'Lait de suite',

- in Italian:

'Latte per lattanti' and 'Latte di proseguimento',

- in Dutch:

'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

- in Portuguese:

'Leite para lactentes' and 'Leite de transição'.

2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed;

(b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;

(c) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;

(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, per 100 ml of the product ready for use;

(f) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited. The term 'adapted' may only be used in conformity with paragraph 6 and Annex IV, point 1.

4. The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) a statement concerning the superiority of breast-feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care;

5. The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealize the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

6. The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in Annex IV and in accordance with the conditions laid down therein.

7. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 6 shall also apply to:

(a) the presentation of the products concerned, 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 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

Article 9

1. Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

- (a) the benefits and superiority of breast-feeding;
- (b) maternal nutrition and the preparation for and maintenance of breast-feeding;
- (c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
- (d) the difficulty of reversing the decision not to breast-feed;
- (e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

4. Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organizations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof. Those provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 December 1992,
- prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, 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 11

This Directive is addressed to the Member States. Done at Brussels, 14 May 1991. For the Commission

Martin BANGEMANN

Vice-President

(1) OJ No L 186, 30. 6. 1989, p. 27. (2) OJ No L 33, 8. 2. 1979, p. 1. (3) OJ No L 186, 30. 6. 1989, p. 17.

ANNEX I

ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: The values refer to the product ready for use

1. Energy Minimum Maximum 250 kJ 315 kJ (60 kcal/100 ml) (75 kcal/100 ml) 2. Proteins (Protein content = nitrogen content \times 6,38) for cows' milk proteins. (Protein content = nitrogen content \times 6,25) for soya protein isolates. 2.1. Formulae manufactured from unmodified cows' milk proteins Minimum Maximum 0,56 g/100 kJ 0,7 g/100 kJ (2,25 g/100 kcal) (3 g/100 kcal) The chemical index of the proteins present shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together. The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein. 2.2 Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio) Minimum Maximum 0,45 g/100 kJ 0,7 g/100 kJ (1,8 g/100 kcal) (3 g/100 kcal) For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). 2.3. Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins Minimum Maximum 0,56 g/100 kJ 0,7 g/100 kJ (2,56 g/100 kcal) (3 g/100 kcal) Only soya protein isolates must be used in manufacturing these formulae. The chemical index shall be equal to at least 80 % of that of the reference protein (breast milk, as defined in Annex VI). For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Annex V). The L-carnitine content shall be at least equal to 1,8 μ moles/100 kJ (7,5 μ moles/100 kcal). 2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose. 3. Lipids Minimum Maximum 0,8 g/100 kJ 1,5 g/100 kJ (3,3 g/100 kcal) (6,5 g/100 kcal) 3.1. The use of the following substances is prohibited: - sesame seed oil, - cotton seed oil, - fats containing more than 8 % trans isomers of fatty acids. 3.2. Lauric acid Minimum Maximum - 15 % of the total fat content 3.3. Myristic acid Minimum Maximum - 15 % of the total fat content 3.4. Linoleic acid (in the form of glycerides = linoleates) Minimum Maximum 70 mg/100 kJ 285 mg/100 kJ (300 mg/100 kcal) (1 200 mg/100 kcal) 4. Carbohydrates Minimum Maximum 1,7 g/100 kJ 3,4 g/100 kJ (7 g/100 kcal) (14 g/100 kcal) 4.1. Only the following carbohydrates may be used: - lactose, - maltose, - sucrose, - malto-dextrins, - glucose syrup or dried glucose syrup, - pre-cooked starch - gelatinized starch naturally free of gluten 4.2. Lactose Minimum Maximum 0,85 g/100 kJ - (3,5 g/100 kcal) - This provision does not apply to formulae in which soya proteins represent more than 50 % of the total protein content. 4.3. Sucrose Minimum Maximum - 20 % of the total carbohydrate content 4.4 Pre-cooked starch and/or gelatinized starch Minimum Maximum - 2 g/100 ml, and 30 % of the total carbohydrate content 5. Mineral substances 5.1. Formulae manufactured from cows' milk proteins Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Sodium (mg) 5 14 20 60 Potassium (mg) 15 35 60 145 Chloride (mg) 12 29 50 125 Calcium (mg) 12 - 50 - Phosphorus (mg) 6 22 25 90 Magnesium (mg) 1,2 3,6 5 15 Iron (mg) (1) 0,12 0,36 0,5 1,5 Zinc (mg) 0,12 0,36 0,5 1,5 Copper (μ g) 4,8 19 20 80 Iodine (μ g) 1,2 - 5 -

(1) Limit applicable to formulae with added iron.

The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0. 5.2. Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are as follows: Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Iron (mg) 0,25 0,5 1 2 Zinc (mg) 0,18 0,6 0,75 2,4 6. Vitamins Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Vitamin A (ìg-RE) (1) 14 43 60 180 Vitamin D (ìg) (2) 0,25 0,65 1 2,5 Thiamin (ìg) 10 - 40 - Riboflavin (ìg) 14 - 60 - Nicotinamide (ìg-EN) (3) 60 - 250 - Pantothenic acid (ìg) 70 - 300 - Vitamin B6 (ìg) 9 - 35 - Biotin (ìg) 0,4 - 1,5 - Folic acid (ìg) 1 - 4 - Vitamin B12 (ìg) 0,025 - 0,1 - Vitamin C (ìg) 1,9 - 8 - Vitamin K (ìg) 1 - 4 - Vitamin E (mg á-TE) (4) 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ - 0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal -

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10 ìg = 400 i.u. of vitamin D.

(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.

(4) á-TE = d-á-tocopherol equivalent.

ANNEX II

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: The values refer to the product ready for use

1. Energy Minimum Maximum 250 kJ/100 ml 335 KJ/100 ml (60 kcal/100 ml) (80 kcal/100 ml) 2. Proteins (Protein content = nitrogen content \times 6,38) for cows' milk proteins. (Protein content = nitrogen content \times 6,25) for soya protein isolates. Minimum Maximum 0,5 g/100 kJ 1 g/100 kJ (2,25 g/100 kcal) (4,5 g/100 kcal) The chemical index of the proteins present shall be at least equal to 80 % of that of the reference protein (casein as defined in Annex VI). The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein. For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used. Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose. 3. Lipids Minimum Maximum 0,8 g/100 kJ 1,5 g/100 kJ (3,3 g/100 kcal) (6,5 g/100 kcal) 3.1. The use of the following substances is prohibited: - sesame seed oil, - cotton seed oil, - fats containing more than 8 % trans isomers of fatty acids. 3.2. Lauric acid Minimum Maximum - 15 % of the total fat content 3.3. Myristic acid Minimum Maximum - 15 % of the total fat content 3.4. Linoleic acid (in the form of glycerides = linoleates) Minimum Maximum 70 mg/100 kJ - (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils 4. Carbohydrates Minimum Maximum 1,7 g/100 kJ 3,4 g/100 kJ (7 g/100 kcal) (14 g/100 kcal) 4.1. The use of ingredients containing gluten is prohibited. 4.2. Lactose Minimum Maximum 0,45 g/100 kJ - (1,8 g/100 kcal) This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content. 4.3. Sucrose, fructose, honey Minimum Maximum - separately or as a whole: 20 % of the total carbohydrate content 5. Mineral substances 5.1. Per 100 kJ Per 100 kcal Minimum Maximum Minimum Maximum Iron (mg) 0,25 0,5 1 2 Iodine (ìg) 1,2 - 5 - 5.2. Zinc 5.2.1. Follow-on formulae manufactured entirely from cows' milk Minimum Maximum 0,12 mg/100 kJ - (0,5 mg/100 kcal) 5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk Minimum Maximum 0,18 mg/100 kJ - (0,75 mg/100 kcal) 5.3. Other mineral substances: The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex VIII. 5.4. The calcium/phosphorus ratio shall not exceed 2,0. 6. Vitamins Per 100 kJ Per

100 kcal Minimum Maximum Minimum Maximum Vitamin A (ig-ER) (1) 14 43 60 180 Vitamin D (ig) (2) 0,25 0,75 1 3 Vitamin C (ig) 1,9 - 8 - Vitamin E (mg á-TE) (3) 0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ - 0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal -

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10 ig = 400 u.i. of vitamin D.

(3) á-TE = d-á-tocopherol equivalent.

ANNEX III

NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin Vitamin formulation Vitamin A Retinyl acetate Retinyl palmitate Beta-carotene Retinol Vitamin D Vitamin D2 (ergocalciferol) Vitamin D3 (cholecalciferol) Vitamin B1 Thalmin hydrochloride Thalmin mononitrate Vitamin B2 Riboflavin Riboflavin-5-phosphate, sodium Niacin Nicotinamide Nicotinic acid Vitamin B6 Pyridoxine hydrochloride Pyridoxine-5-phosphate Folate Folic acid Pantothenic acid D-pantothenate, calcium D-pantothenate, sodium Dexpantenol Vitamin B12 Cyanocobalamin Hydroxocobalamin Biotin D-biotin Vitamin C L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate Vitamin E D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate Vitamin K Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances Permitted salts Calcium (Ca) Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide Magnesium (Mg) Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid Iron (Fe) Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate) Copper (Cu) Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate Iodine (I) Potassium iodide Sodium iodide Potassium iodate Zinc (Zn) Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide Manganese (Mn) Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate Sodium (Na) Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide Potassium (K) Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide

3. Amino acids and other nitrogen compounds

L-arginine and its hydrochloride

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-cysteine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

Taurine

4. Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

Claim related to Conditions warranting the claim 1. Adapted protein The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0. 2. Low sodium The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal). 3. Sucrose free No sucrose is present. 4. Lactose only Lactose is the only carbohydrate present. 5. Lactose free No lactose is present (1). 6. Iron enriched Iron is added.

(1) When determined by a method the detection limits of which will be established at a later stage.

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

Per 100 kJ (1) Per 100 kcal Arginine 16 69 Cystine 6 24 Histidine 11 45 Isoleucine 17 72 Leucine 37 156 Lysine 29 122 Methionine 7 29 Phenylalanine 15 62 Threonine 19 80 Tryptophan 7 30 Tyrosine 14 59 Valine 19 80

(1) 1 kJ = 0,239 kcal.

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein:

(g/100 g of protein)

Casein (1) Breast milk (1) Arginine 3,7 3,8 Cystine 0,3 1,3 Histidine 2,9 2,5 Isoleucine 5,4 4,0
Leucine 9,5 8,5 Lysine 8,1 6,7 Methionine 2,8 1,6 Phenylalanine 5,2 3,4 Threonine 4,7 4,4
Tryptophan 1,6 1,7 Tyrosine 5,8 3,2 Valine 6,7 4,5

(1) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383.

ANNEX VII

The mineral elements in cows' milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following:

Per 100 g SNF (1) Per g of proteins Sodium (mg) 550 15 Potassium (mg) 1 680 43 Chloride (mg) 1 050 28 Calcium (mg) 1 350 35 Phosphorus (mg) 1 070 28 Magnesium (mg) 135 3,5 Copper (µg) 225 6 Iodine NS (2) NS

(1) SNF: 'solids-no fats'.

(2) NS: non-specified, varies widely according to season and stock farming conditions.

—

1.2,3 //

This provision does not apply to formulae in which soya proteins represent more than 50 % of the total protein content .

4.3 .

Sucrose

1.2.3 //

Minimum

Maximum //

—

20 % of the total carbohydrate content

1.2,34.4

Pre-cooked starch and/or gelatinised starch

1.2.3 //

Minimum

Maximum //

—

2 g/100 ml, and 30 % of the total carbohydrate content

1.2,35 .

Mineral substances

5.1 .

Formulae manufactured from cows' milk proteins

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Sodium (mg)

5

14

20

60

Potassium (mg)

15

35

60

145

Chloride (mg)

12

29

50

125

Calcium (mg)

12

—

50

—

Phosphorus (mg)

6

22

25

90

Magnesium (mg)

1,2

3,6

5

15

Iron (mg) (1)

0,12

0,36

0,5

1,5

Zinc (mg)

0,12

0,36

0,5

1,5

Copper (* g)

4,8

19

20

80

Iodine (* g)

1,2

—

5

_ // // // // //

(1) Limit applicable to formulae with added iron .

1.2The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0 .

5.2 .

Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins //

All requirements of paragraph 5.1 are applicables except those concerning iron and zinc, which are as follows :

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Iron (mg)

0,25

0,5

1

2

Zinc (mg)

0,18

0,6

0,75

2,4 // // // // //

1.26 .

Vitamins

1.2.3.4.5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // //

Vitamin A (* g-RE) (1)

14

43

60

180

Vitamin D (* g) (2)

0,25

0,65

1

2,5

Thiamin (* g)

10

—

40

—

Riboflavin (* g)

14

—

60

—

Nicotinamide (* g-EN) (3)

60

—

250

—

Pantothenic acid (* g)

70

—

300

—

Vitamin B6 (* g)

9

—

35

—

Biotin (* g)

0,4

—

1,5

—

Folic acid (* g)

1

—

4

—

Vitamin B12 (* g)

0,025

—

0,1

—

Vitamin C (* g)

1,9

—

8

—

Vitamin K (* g)

1

—

4

—

Vitamin E (mg *-TE) (4)

0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ

—

0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal

_ // // // // //

(1) RE = all trans retinol equivalent .

(2) In the form of cholecalciferol, of which 10 *g = 400 i.u . of vitamin D .

(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60 .

(4) *-TE = d-*-tocopherol equivalent .

ANNEX II

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB : The values refer to the product ready for use

1.2.31 .

Energy // //

Minimum

Maximum //

250 kJ/100 ml

335 KJ/100 ml //

(60 kcal/100 ml)

(80 kcal/100 ml)

1.2,32 .

Proteins //

(Protein content = nitrogen content x 6,38) for cows' milk proteins . //

(Protein content = nitrogen content x 6,25) for soya protein isolates .

1.2.3 //

Minimum

Maximum //

0,5 g/100 kJ

1 g/100 kJ //

(2,25 g/100 kcal)

(4,5 g/100 kcal)

1.2,3 //

The chemical index of the proteins present shall be at least equal to 80 % of that of the reference protein (casein as defined in Annex VI). //

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein . //

For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used . //

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose .

1.2.33 .

Lipids // //

Minimum

Maximum //

0,8 g/100 kJ

1,5 g/100 kJ //

(3,3 g/100 kcal)

(6,5 g/100 kcal)

1.2,33.1 .

The use of the following substances is prohibited : //

_ sesame seed oil, //

_ cotton seed oil, //

_ fats containing more than 8 % trans isomers of fatty acids .

1.2.33.2 .

Lauric acid // //

Minimum

Maximum //

—

15 % of the total fat content

3.3 .

Myristic acid // //

Minimum

Maximum //

—

15 % of the total fat content

1.2,33.4 .

Linoleic acid (in the form of glycerides = linoleates)

1.2.3 //

Minimum

Maximum //

70 mg/100 kJ

_ //

(300 mg/100 kcal): // //

this limit applies only to follow-on formulae containing vegetable oils //

4 .

Carbohydrates // //

Minimum

Maximum //

1,7 g/100 kJ

3,4 g/100 kJ //

(7 g/100 kcal)

(14 g/100 kcal)

1.2,34.1 .

The use of ingredients containing gluten is prohibited .

4.2 .

Lactose

1.2.3 //

Minimum

Maximum //

0,45 g/100 kJ

_ //

(1,8 g/100 kcal) //

1.2,3 //

This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content .

4.3 .

Sucrose, fructose, honey

1.2.3 //

Minimum

Maximum //

—

separately or as a whole : // //

20 % of the total carbohydrate content

1.2,35 .

Mineral substances

5.1 . //

1.2,3,4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // // // // // //

Iron (mg)

0,25

0,5

1

2

Iodine (* g)

1,2

—

5

_ // // // // //

1.2.35.2 .

Zinc //

1.2,35.2.1 .

Follow-on formulae manufactured entirely from cows' milk

1.2.3Minimum

Maximum //

0,12 mg/100 kJ

_ //

(0,5 mg/100 kcal) //

1.2,35.2.2 .

Follow-on formulae containing soya protein isolates, or mixed with cows' milk

1.2.3Minimum

Maximum //

0,18 mg/100 kJ

_ //

(0,75 mg/100 kcal) //

1.2,35.3 .

Other mineral substances : //

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk . The typical composition of cows' milk is given, for guidance, in Annex VIII .

5.4 .

The calcium/phosphorus ratio shall not exceed 2,0 .

6 .

Vitamins

1.2,3.4,5 // // // //

Per 100 kJ

Per 100 kcal

1.2.3.4.5Minimum

Maximum

Minimum

Maximum // // // // // // // // //

Vitamin A (* g-ER) (1)

14

43

60

180

Vitamin D (* g) (2)

0,25

0,75

1

3

Vitamin C (* g)

1,9

—

8

—

Vitamin E (mg *-TE) (3)

0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ

—

0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal

_// // // // //

(1) RE = all trans retinol equivalent .

(2) In the form of cholecalciferol, of which 10 *g = 400 u.i . of vitamin D .

(3) *-TE = d-*-tocopherol equivalent .

ANNEX III

NUTRITIONAL SUBSTANCES

1 . Vitamins

1.2Vitamin

Vitamin formulation

Vitamin A

Retinyl acetate //

Retinyl palmitate //

Beta-carotene //

Retinol

Vitamin D

Vitamin D2 (ergocalciferol) //

Vitamin D3 (cholecalciferol)

Vitamin B1

Thalmin hydrochloride //

Thalmin mononitrate

Vitamin B2

Riboflavin //

Riboflavin-5-phosphate, sodium

Niacin

Nicotinamide //

Nicotinic acid

Vitamin B6

Pyridoxine hydrochloride //

Pyridoxine-5-phosphate

Folate

Folic acid

Pantothenic acid

D-pantothenate, calcium //

D-pantothenate, sodium //

Dexpanthenol

Vitamin B12

Cyanocobalamin //

Hydroxocobalamin

Biotin

D-biotin

Vitamin C

L-ascorbic acid //

Sodium L-ascorbate //

Calcium L-ascorbate //

6-palmityl-L-ascorbic acid (ascorbyl palmitate) //

Potassium ascorbate

Vitamin E

D-alpha tocopherol //

DL-alpha tocopherol //

D-alpha tocopherol acetate //

DL-alpha tocopherol acetate

Vitamin K

Phylloquinone (Phytomenadione) // //

2 . Mineral substances

1.2Mineral substances

Permitted salts

Calcium (Ca)

Calcium carbonate //

Calcium chloride //

Calcium salts of citric acid //

Calcium gluconate //

Calcium glycerophosphate //

Calcium lactate //

Calcium salts of orthophosphoric acid //

Calcium hydroxide

Mineral substances

Permitted salts

Magnesium (Mg)

Magnesium carbonate //

Magnesium chloride //

Magnesium oxide //

Magnesium salts of orthophosphoric acid //

Magnesium sulphate //

Magnesium gluconate //

Magnesium hydroxide //

Magnesium salts of citric acid

Iron (Fe)

Ferrous citrate //

Ferrous gluconate //

Ferrous lactate //

Ferrous sulphate //

Ferric ammonium citrate //

Ferrous fumarate //

Ferric diphosphate (Ferric pyrophosphate)

Copper (Cu)

Cupric citrate //

Cupric gluconate //

Cupric sulphate //

Copper-lysine complex //

Cupric carbonate

Iodine (I)

Potassium iodide //

Sodium iodide //

Potassium iodate

Zinc (Zn)

Zinc acetate //

Zinc chloride //

Zinc lactate //

Zinc sulphate //

Zinc citrate //

Zinc gluconate //

Zinc oxide

Manganese (Mn)

Manganese carbonate //

Manganese chloride //

Manganese citrate //

Manganese sulphate //

Manganese gluconate

Sodium (Na)

Sodium bicarbonate //

Sodium chloride //

Sodium citrate //

Sodium gluconate //

Sodium carbonate //

Sodium lactate //

Sodium salts of orthophosphoric acid //

Sodium hydroxide

Potassium (K)

Potassium bicarbonate //

Potassium carbonate //

Potassium chloride //

Potassium salts of citric acid //

Potassium gluconate //

Potassium lactate //

Potassium salts of orthophosphoric acid //

Potassium hydroxide // //

3 . Amino acids and other nitrogen compounds

L-arginine and its hydrochloride

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-cysteine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

Taurine

4 . Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

ANNEX IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

1.2 Claim related to

Conditions warranting the claim

1 . Adapted protein

The protein content is lower than 0,6 g/100 kJ (2,5 g/100 kcal) and the whey protein/casein ratio is not less than 1,0 .

2 . Low sodium

The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).

3 . Sucrose free

No sucrose is present .

4 . Lactose only

Lactose is the only carbohydrate present .

5 . Lactose free

No lactose is present (1).

6 . Iron enriched

Iron is added . // //

(1) When determined by a method the detection limits of which will be established at a later stage .

ANNEX V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following :

1.2.3 Per 100 kJ (1)

Per 100 kcal // // //

Arginine

16

69

Cystine

6

24

Histidine

11

45

Isoleucine

17

72

Leucine

37

156

Lysine

29

122

Methionine

7

29

Phenylalanine

15

62

Threonine

19

80

Tryptophan

7

30

Tyrosine

14

59

Valine

19

80 // // //

(1) 1 kJ = 0,239 kcal .

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein :

(g/100 g of protein)

1.2.3Casein (1)

Breast milk (1) // // //

Arginine

3,7

3,8

Cystine

0,3

1,3

Histidine

2,9

2,5

Isoleucine

5,4

4,0

Leucine

9,5

8,5

Lysine

8,1

6,7

Methionine

2,8

1,6

Phenylalanine

5,2

3,4

Threonine

4,7

4,4

Tryptophan

1,6

1,7

Tyrosine

5,8

3,2

Valine

6,7

4,5 // // //

(1) Amino acid content of foods and biological data on protein . FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383 .

ANNEX VII

The mineral elements in cows' milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following :

1.2.3Per 100 g SNF (1)

Per g of proteins // // //

Sodium (mg)

550

15

Potassium (mg)

1 680

43

Chloride (mg)

1 050

28

Calcium (mg)

1 350

35

Phosphorus (mg)

1 070

28

Magnesium (mg)

135

3,5

Copper (* g)

225

6

Iodine

NS (2)

NS // // //

(1) SNF : "solids-no fats '.

(2) NS : non-specified, varies widely according to season and stock farming conditions .

11994NN01/11/C9**ACT concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, ANNEX I - List referred to in Article 29 of the Act of Accession - XI. INTERNAL MARKET AND FINANCIAL SERVICES - C. FREE MOVEMENT OF GOODS - IX. FOODSTUFFS***Official Journal C 241 , 29/08/1994 P. 0212***IX. FOODSTUFFS**

1. 376 L 0118: Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption (OJ No L 24, 30.1.1976, p. 49), as amended by:

- 378 L 0630: Council Directive 78/630/EEC of 19 June 1978 (OJ No L 206, 29.7.1978, p. 12),
- 179 H: Act concerning the conditions of accession and the adjustments to the Treaties - Accession of the Hellenic Republic (OJ No L 291, 19.11.1979, p. 17),
- 383 L 0635: Council Directive 83/635/EEC of 13 December 1983 (OJ No L 357, 21.12.1983, p. 37),
- 185 I: Act concerning the conditions of accession and the adjustments to the Treaties - Accession of the Kingdom of Spain and the Portuguese Republic (OJ No L 302, 15.11.1985, p. 23).

The following replaces Article 3 (2) (c):

'(c) "floedepulver" in Denmark, "Rahmpulver" and "Sahnepulver" in Germany and Austria, "graeddpulver" in Sweden, "kermajauhe/graeddpulver" in Finland and "floetepulver" in Norway to denote the product defined in point 2 (d) of the Annex.'

2. 379 L 0112: 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 (OJ No L 33, 8.2.1979, p. 1), as amended by:

- 179 H: Act concerning the conditions of accession and the adjustments to the Treaties - Accession of the Hellenic Republic (OJ No L 291, 19.11.1979, p. 17),
- 185 I: Act concerning the conditions of accession and the adjustments to the Treaties - Accession of the Kingdom of Spain and the Portuguese Republic (OJ No L 302, 15.11.1985, p. 23),
- 385 L 0007: Council Directive 85/7/EEC of 19 December 1984 (OJ No L 2, 3.1.1985, p. 22),
- 386 L 0197: Council Directive 86/197/EEC of 26 May 1986 (OJ No L 144, 29.5.1986, p. 38),
- 389 L 0395: Council Directive 89/395/EEC of 14 June 1989 (OJ No L 186, 30.6.1989, p. 17),
- 391 L 0072: Commission Directive 91/72/EEC of 16 January 1991 (OJ No L 42, 15.2.1991, p. 27).

(a) The following is added to Article 5 (3):

- ' - in Finnish "saateilytetty, kaesitelty ionisoivalla saateilyllae",
- in Norwegian "bestraalt, behandlet med ioniserende straaing",
- in Swedish "bestraalad, behandlad med joniserande straalning";`

(b) in Article 9 (6), the corresponding heading in the Harmonized System to CN codes 2206 00 91, 2206 00 93 and 2206 00 99 is 22.06;

(c) the following is added to Article 9a (2):

' - in Finnish "viimeinen kaeyttoejankohta",

- in Norwegian "siste forbruksdag",

- in Swedish "sista foerbrukningsdag";`

(d) in Article 10a, the corresponding heading in the Harmonized System to tariff headings Nos 22.04 and 22.05 is 22.04.

3. 380 L 0590: Commission Directive 80/590/EEC of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs (OJ No L 151, 19.6.1980, p. 21), as amended by:

- 185 I: Act concerning the conditions of accession and the adjustments to the Treaties - Accession of the Kingdom of Spain and the Portuguese Republic (OJ No L 302, 15.11.1985, p. 23).

(a) The following are added to the title of the Annex:

'LIITE`

'VEDLEGG`

'BILAGA` .

(b) the following is added to the text in the Annex:

'Tunnus` .

4. 389 L 0108: Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption (OJ No L 40, 11.2.1989, p. 34).

The following is added to Article 8 (1) (a):

'>TABLE>

`

5. 391 L 0321: Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (OJ No L 175, 4.7.1991, p. 35).

(a) In Article 7 (1), the following is added after the words 'Fórmula para lactentes` and 'Fórmula de transição` :

' - in Finnish:

"AEidinmaidonkorvike" and "Vierotus-valmiste",

- in Norwegian:

"Morsmelkerstatning" and "Tilskudds-blanding",

- in Swedish:

"Modersmjölksersaettning" and "Tillskotts-naering";`

(b) in Article 7 (1), the following is added after the words 'Leite para lactentes` and 'Leite de transição` :

' - in Finnish:

"Maitopohjainen aedinmaidonkorvike" and "Maitopohjainen vierotusvalmiste",

- in Norwegian:

"Morsmelkerstatning utelukkende basert paa melk" and "Tilskuddsblanding utelukkende basert paa melk",

- in Swedish:

"Modersmjölksersättning utslutande baserad paa mjölk" and "Tillskottsnaering utslutande baserad paa mjölk".`

6. 393 L 0077: Council Directive 93/77/EEC of 21 September 1993 relating to fruit juices and certain similar products (OJ No L 244, 30.9.1993, p. 23).

The following is added to Article 3 (2):

' (f) "must", together with the name (in Swedish) of the fruit used, for fruit juices; in Norway "eplemost" for apple juice with no added sugars;

(g) "taeysmehu", together with the name (in Finnish) of the fruit used, for juices with no added water, with no added sugars except those to correct sweetness (at the maximum rate of 15 g/kg) and no other ingredients;

(h) "tuoremehu", together with the name (in Finnish) of the fruit used, for juices with no added water, no added sugars or other ingredients and with no heat treatments;

(i) "mehu", together with the name (in Finnish) of the fruit used, for juices with added water or sugars and with a juice content of at least 35 % by weight.`.

31996L0004**Commission Directive 96/4/EC, Euratom of 16 February 1996 amending Directive 91/321/EEC on infant formulae and follow-on formulae (Text with EEA relevance)***Official Journal L 049 , 28/02/1996 P. 0012 - 0016*

COMMISSION DIRECTIVE 96/4/EC of 16 February 1996 amending Directive 91/321/EEC on infant formulae and follow-on formulae (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (1), and in particular Article 4 thereof,

Whereas given the nature of infant formulae and follow-on formulae the detailed rules as to nutrient declaration on the labelling need to be clarified in order to avoid any problems which may arise from the application of other relevant Community legislation;

Whereas new scientific data justify certain modifications to the mandatory essential composition of infant formulae and follow-on formulae specified in Annexes I and II to Commission Directive 91/321/EEC (2), as amended by the Act of Accession of Austria, Finland and Sweden;

Whereas nucleotides, being the natural constituents of human milk, have been used to supplement infant formulae and follow-on formulae for many years in Member States and third countries without any negative effects; whereas therefore there is no justification for prohibiting their use in the manufacture of these products;

Whereas technological progress has resulted in the production of infant formulae, based on protein partial hydrolysates, which due to their low levels of immunoreactive proteins may be useful; whereas for this reason a claim as to these particular characteristics should be permitted; whereas these products are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions, which are not covered by this Directive;

Whereas Directive 91/321/EEC should be amended accordingly;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/321/EEC is amended as follows:

1. Article 6 is replaced by the following:

'Article 6

Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels shall be established without delay.

Microbiological criteria shall also be established as necessary.`

2. Article 7 is amended as follows:

(a) Points (d) and (e) of paragraph 2 are replaced by the following:

'(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;`

(b) The following is inserted as paragraph 2a:

'2a. The labelling may bear:

(a) the average quantity of nutrients mentioned in Annex III when such declaration is not covered by the provisions of paragraph 2 (e) of this Article, expressed in numerical form, per 100 ml of the product ready for use;

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in Annex VIII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values;`

3. The Annexes are amended as shown in the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 March 1997. They shall forthwith inform the Commission thereof. Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products conforming to this Directive no later than 1 April 1997,
- prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, 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 shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 16 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

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

(2) OJ No L 175, 4. 7. 1991, p. 35.

ANNEX

The Annexes to Directive 91/321/EEC are amended as follows:

1. Annex I is amended as follows:

(a) The introductory wording of Section 2 and Sections 2.1 and 2.2 are replaced by the following:

'2. Protein

(Protein content = nitrogen content \times 6,38) for cows' milk proteins.

(Protein content = nitrogen content \times 6,25) for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.1. Formulae manufactured from cows' milk proteins

>TABLE>

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

2.2. Formulae manufactured from protein partial hydrolysates

>TABLE>

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilization (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 μ moles/100 kJ (42 μ moles/100 kcal) and the L-carnitine content shall be equal to at least 1,8 μ moles/100 kJ (7,5 μ moles/100 kcal).

(b) The minimum content for lipids in Section 3 is modified as follows:

'Minimum

1,05 g/100 kJ

(4,4 g/100 kcal)'

(c) The third indent of Section 3.1 is deleted.

(d) The following shall be added to Section 3.

'3.5. The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

3.6. The trans fatty acid content shall not exceed 4 % of the total fat content.

3.7. The erucic acid content shall not exceed 1 % of the total fat content.

3.8. Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

1 % of the total fat content for n-3 LCP and

2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid)

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.`

(e) The following shall be added in Section 5.1:

>TABLE>

(f) In Section 6 of Annex I, the reference to nicotinamide is replaced by the following:

>TABLE>

2. Annex II is amended as follows:

(a) In Section 2, first paragraph following the numerical values, add the words: '. . . or breast milk . . .` after the word 'casein` ,

and at the end of Section 2, add the following paragraph:

'For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Annex V.`

(b) The third indent of Section 3.1 is deleted.

(c) The following shall be inserted in Section 3:

'3.5. The trans fatty acid content shall not exceed 4 % of the total fat content.

3.6. The erucic acid content shall not exceed 1 % of the total fat content.`

3. The following is added as Section 7 to both Annex I and Annex II:

'7. The following nucleotides may be added:

>TABLE>

4. Annex III is amended as follows:

(a) The following shall be added to Section 2:

>TABLE>

(b) The following substances shall be added to Section 3:

'cytidine 5'-monophosphate and its sodium salt

uridine 5'-monophosphate and its sodium salt

adenosine 5'-monophosphate and its sodium salt

guanosine 5'-monophosphate and its sodium salt

inosine 5'-monophosphate and its sodium salt`.

5. The following shall be added to Annex IV:

>TABLE>

6. The following is added as Annex VIII:

'ANNEX VIII

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND
YOUNG CHILDREN

>TABLE>

31999L0050**Commission Directive 1999/50/EC of 25 May 1999 amending Directive 91/321/EEC on infant formulae and follow-on formulae (Text with EEA relevance)***Official Journal L 139 , 02/06/1999 P. 0029 - 0031*

COMMISSION DIRECTIVE 1999/50/EC

of 25 May 1999

amending Directive 91/321/EEC on infant formulae and follow-on formulae

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses(1), as amended by Directive 96/84/EC of the European Parliament and of the Council(2), and in particular Article 4(1) thereof,

After consulting the Scientific Committee for Food,

(1) Whereas Article 6 of Commission Directive 91/321/EEC(3), as last amended by Directive 96/4/EC(4), provides that infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children and that necessary maximum levels for such substances shall be established without delay;

(2) Whereas different regulations on the maximum levels of pesticide residues in such products cause trade barriers between certain Member States;

(3) Whereas maximum levels for pesticide residues stipulated in Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables(5), as last amended by Directive 97/41/EC(6), 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals(7), as last amended by Commission Directive 98/82/EC(8), 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin(9), as last amended by Directive 98/82/EC, and 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables(10), as last amended by Directive 98/82/EC, are without prejudice to specific provisions applicable to infant formulae and follow-on formulae;

(4) Whereas, taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time;

(5) Whereas on the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998 there are at present doubts as to the adequacy of existing acceptable daily intake values (ADI) for the protection of the health of infants and young children; whereas the doubts expressed concern not only pesticides and pesticide residues, but also dangerous chemical substances, and consequently the Commission will examine the

possibility of fixing, as soon as possible, maximum levels for heavy metals in foods intended for infants and young children;

(6) Whereas, therefore, as far as foods for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides;

(7) Whereas this very low common limit should be fixed at 0,01 mg/kg which is in practice the minimum detectable level;

(8) Whereas severe limitations on pesticide residues should be required; whereas, with careful selection of raw materials, and given that infant formulae and follow-on formulae undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues;

(9) Whereas, however, for a small number of pesticides even such low levels might allow the possibility that under worst-case intake conditions the ADI of these pesticides is exceeded; whereas, therefore, infant formulae and follow-on formulae should be free of those particular pesticides and should be produced without the use of such pesticides;

(10) Whereas this Directive reflects current knowledge about these substances; whereas any amendment, based on scientific or technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

(11) Whereas Directive 91/321/EEC should be amended accordingly;

(12) 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 91/321/EEC is hereby amended as follows:

1. the following point (e) is added to Article 1(2):

"(e) 'pesticide residue' means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Council Directive 91/414/EEC(11), including its metabolites and products resulting from its degradation or reaction;

2. Article 6 is replaced by the following:

"Article 6

1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels shall be established without delay.

2. Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

3. Those pesticides listed in Annex IX shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

4. Microbiological criteria shall be established as necessary.";

3. the following is added as Annex IX:

"ANNEX IX

Pesticides which shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae

Chemical name of the substance

..."

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 June 2000. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- (a) permit trade in products conforming to this Directive no later than 30 June 2000,
- (b) prohibit trade in products which do not comply with this Directive, with effect from 1 July 2002.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 May 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

- (1) OJ L 186, 30.6.1989, p. 27.
- (2) OJ L 48, 19.2.1997, p. 20.
- (3) OJ L 175, 4.7.1991, p. 35.
- (4) OJ L 49, 28.2.1996, p. 12.
- (5) OJ L 340, 9.12.1976, p. 26.
- (6) OJ L 184, 12.7.1997, p. 33.
- (7) OJ L 221, 7.8.1986, p. 37.
- (8) OJ L 290, 29.10.1998, p. 25.
- (9) OJ L 221, 7.8.1986, p. 43.
- (10) OJ L 350, 14.12.1990, p. 71.
- (11) OJ L 230, 19.8.1991, p. 1.

CORRIGENDA**Corrigendum to Commission Regulation (EC) No 2321/1999 of 29 October 1999 on the supply of milk products as food aid**

(Official Journal of the European Communities L 280 of 30 October 1999)

On page 75, in the Annex, point 22:

for: **'Export refunds'** ⁽⁴⁾: refund applicable on 25.10.1999, fixed by Commission Regulation (EC) No 2223/1999 (OJ L 271, 21.10.1999, p. 6)',

read: **'Export refunds'** ⁽⁴⁾: refund applicable on 25.10.1999, fixed by Commission Regulation (EC) No 2186/1999 (OJ L 267, 15.10.1999, p. 28').

COMMISSION DIRECTIVE 2003/14/EC
of 10 February 2003
amending Directive 91/321/EEC on infant formulae and follow-on formulae
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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⁾, as last amended by Directive 1999/41/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 4(1) thereof,

Having regard to the opinion of the Scientific Committee on Food,

Whereas:

- (1) Article 6 of Commission Directive 91/321/EEC ⁽³⁾, as last amended by Directive 1999/50/EC ⁽⁴⁾, stipulates that infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.
- (2) On the basis of opinions given by the Scientific Committee on Food on 19 September 1997 and 4 June 1998, Directive 91/321/EEC established a general maximum residue level of 0,01 mg/kg for any individual pesticide in infant formulae and follow-on formulae.
- (3) In the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0,01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the acceptable daily intake. This is the case for pesticides or metabolites of pesticides with an acceptable daily intake lower than 0,0005 mg/kg body weight.
- (4) Directive 91/321/EEC establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for infant formulae and follow-on formulae. The pesticides in question should be listed in Annex IX to Directive 91/321/EEC. However, this prohibition does not necessarily guarantee

that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.

- (5) The health of infants and young children can be better protected by applying additional requirements which can be enforced by analysis regardless of a product's origin.
- (6) Most of the pesticides which have acceptable daily intake values lower than 0,0005 mg/kg body weight are already prohibited in the Community or will be prohibited by July 2003. The prohibited pesticides should not be detectable in infant formulae and follow-on formulae by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in infant formulae and follow-on formulae even if they have not been used. For the purposes of control, a harmonised approach has to be followed.
- (7) Pending Commission decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽⁵⁾, as last amended by Commission Directive 2003/5/EC ⁽⁶⁾, the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in the present Directive. The latter should be set at levels ensuring that their respective acceptable daily intake values are not exceeded by infants and young children under worst-case intake conditions.
- (8) Directive 91/321/EEC should be amended accordingly.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 172, 8.7.1999, p. 38.

⁽³⁾ OJ L 175, 4.7.1991, p. 35.

⁽⁴⁾ OJ L 139, 2.6.1999, p. 29.

⁽⁵⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁶⁾ OJ L 8, 14.1.2003, p. 7.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/321/EEC is amended as follows:

1. Article 6 is amended as follows:

— Paragraph 1 is replaced by the following:

‘1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels for substances other than those referred to in paragraphs 2 and 3 shall be established without delay.’

— Paragraph 3 is replaced by the following:

‘3. (a) Those pesticides listed in Annex IX shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae. However, for the purpose of control:

(i) pesticides listed in Table 1 of Annex IX are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level which is considered to be the limit of quantification of the analytical methods shall be kept under regular review in the light of technical progress;

(ii) pesticides listed in Table 2 of Annex IX are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

(b) By derogation of paragraph 2, for the pesticides listed in Annex X, the maximum residue levels specified therein shall apply.

For pesticides listed in Annex X, where a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex IX and Annex X to this Directive shall be amended accordingly.

(c) The levels referred to in subparagraphs (a) and (b) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.’

2. Annex IX is replaced by Annex I to this Directive.

3. Annex II to this Directive is added as Annex X.

Article 2

1. The Member States shall authorise trade in products which comply with Article 6(3) of Directive 91/321/EEC by 6 March 2004 at the latest.

2. The Member States shall prohibit trade in products which do not comply with Article 6(3) of Directive 91/321/EEC by 6 March 2005.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 March 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 10 February 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

‘ANNEX IX

Pesticides which shall not be used in agricultural production intended for the production of infant formulae and follow-on formulae

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin'

ANNEX II

ANNEX X

Specific maximum residue levels of pesticides or metabolites of pesticides in infant formulae and follow-on formulae

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006'

31996L0005**Commission Directive 96/5/EC, Euratom of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance)***Official Journal L 049 , 28/02/1996 P. 0017 - 0028*

COMMISSION DIRECTIVE 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 in particular Article 4 thereof,

Whereas the Community measures envisaged by this Directive do not exceed what is necessary for the attainment of the objectives already provided for by Directive 89/398/EEC;

Whereas processed cereal-based foods and baby foods for infants and young children are used as part of a diversified diet and do not constitute the sole source of nourishment of infants and young children;

Whereas there is a great variety of the products in question reflecting the widely varied diet of infants being weaned and young children owing to social and cultural circumstances existing in the Community;

Whereas the essential composition of the products in question must be appropriate for the nutritional requirements of infants and young children in good health as established by generally accepted scientific data, account being taken of the abovementioned factors;

Whereas the essential nutritional requirements for the composition of the two broad categories of these products, namely processed cereal-based foods and baby foods should be laid down;

Whereas although, because of the nature of such products, a number of mandatory requirements and other restrictions as to the level of vitamins, minerals and other nutrients should be imposed, such nutrients may be added voluntarily by manufacturers provided that they use exclusively the substances listed in Annex IV to this Directive;

Whereas the use of the products to which such nutrients have been voluntarily added at levels currently observed in the Community do not appear to result in excessive intakes of those nutrients by infants and young children; whereas attention will be paid to any future developments of the situation, and if necessary, appropriate measures will be taken;

Whereas the provisions relating to the use of additives in the manufacture of processed cereal-based foods and baby foods will be laid down in a Council Directive;

Whereas the use of novel food ingredients will be dealt with horizontally for all foodstuffs in a separate measure;

Whereas this Directive reflects current knowledge about these products; whereas any amendment, to allow for innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas, in view of the persons for whom the products are intended, the necessary microbiological criteria and maximum levels for contaminants should be laid down without delay;

Whereas pursuant to Article 7 of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by 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 (2), as last amended by Commission Directive 93/102/EC (3);

Whereas in this Directive the additions and exceptions to those general rules are adopted and expanded upon, where appropriate;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling showing the energy value and principal nutrients they contain; whereas, on the other hand, the method of use should be specified in accordance with point 8 of Article 3 (1) and Article 10 of Directive 79/112/EEC, in order to prevent inappropriate uses liable to harm the health of infants;

Whereas, whilst claims not specifically prohibited may generally be made for the products in question in conformity with the rules applicable for all foodstuffs, such claims should, where appropriate, take into account the compositional criteria specified in this Directive;

Whereas the Scientific Committee for Food has, in accordance with Article 4 of Directive 89/398/EEC, 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 4 of Directive 89/398/EEC.

2. This Directive covers foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health in the Community and are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. They comprise:

(a) 'Processed cereal-based foods' which are divided into the following four categories:

(i) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;

(ii) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;

(iii) pastas which are to be used after cooking in boiling water or other appropriate liquids;

(iv) rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids.

(b) 'Baby foods' other than processed cereal-based foods.

3. This Directive does not apply to milks intended for young children.

4. For the purpose of this Directive:

- 'infants' shall mean children under the age of twelve months,

- 'young children' shall mean children aged between 1 and 3 years.

Article 2

Member States shall ensure that the products referred to in Article 1 are marketed within the Community only if they conform to the rules laid down in this Directive.

Article 3

Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data.

Article 4

1. Processed cereal-based foods shall comply with the compositional criteria specified in Annex I.
2. Baby foods which are described in Annex II shall comply with the compositional criteria specified therein.

Article 5

Only the nutritional substances listed in Annex IV may be added in the manufacture of processed cereal-based foods and baby foods. Within 12 months of the entry into force of this Directive maximum levels, in addition to those already stipulated, shall be laid down where necessary.

The purity criteria for those substances shall be laid down at a later stage.

Article 6

Processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels shall be established without delay.

Microbiological criteria shall also be established as necessary.

Article 7

1. The labelling of the products concerned shall bear in addition to the particulars provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(a) A statement as to the appropriate age from which the product may be used, regard being had to its composition, texture or other particular properties. The stated age shall not be less than four months for any product. Products recommended for use from the age of four months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise.

(b) Information as to the presence or absence of gluten if the indicated age from which the product may be used is below six months.

(c) The available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(d) The average quantity of each mineral substance and of each vitamin governed by a specific level in Annex I and Annex II respectively, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(e) Instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

2. The labelling may bear:

(a) the average quantity of the nutrients set out in Annex IV when such declaration is not covered by the provisions of point (d) of paragraph 1, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;

(b) in addition to numerical information, information on vitamins and minerals shown in Annex V, expressed as a percentage of the reference values given therein, per 100 g or 100 ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15 % of the reference values.

Article 8

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 October 1997,
- prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, 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 9

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

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 16 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

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

(2) OJ No L 33, 8. 2. 1979, p. 1.

(3) OJ No L 291, 25. 11. 1993, p. 14.

ANNEX I

ESSENTIAL COMPOSITION OF PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use marketed as such or reconstituted as instructed by the manufacturer.

1. Cereal content

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25 % of the final mixture on a dry weight for weight basis.

2. Protein

2.1. For products mentioned in points (a) (ii) and (a) (iv) of Article 1 (2), the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal).

2.2. For products mentioned in point (a) (ii) of Article 1 (2), the added protein shall not be less than 0,48 g/100 kJ (2 g/100 kcal).

2.3. For biscuits mentioned in point (a) (iv) of Article 1 (2), made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0,36 g/100 kJ (1,5/100 kcal).

2.4. The chemical index of the added protein shall be equal to at least 80 % of that of the reference protein (casein as defined in Annex III), or the protein energy ratio (PER) of the protein in the mixture shall be equal to at least 70 % of that of the reference protein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

3. Carbohydrates

3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in points (a) (i) and (a) (iv) of Article 1 (2):

- the amount of added carbohydrates from these sources shall not exceed 1,8 g/100 kJ (7,5 g/100 kcal),

- the amount of added fructose shall not exceed 0,9 g/100 kJ (3,75 g/100 kcal).

3.2. If sucrose, fructose, glucose syrups or honey are added to products mentioned in point (a) (ii) of Article 1 (2),

- the amount of added carbohydrates from these sources shall not exceed 1,2 g/100 kJ (5 g/100 kcal),

- the amount of added fructose shall not exceed 0,6 g/100 kJ (2,5 g/100 kcal).

4. Lipids

4.1. For products mentioned in points (a) (i) and (a) (iv) of Article 1 (2) the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

4.2. For products mentioned in point (a) (ii) of Article 1 (2), the lipid content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal). If the lipid content exceeds 0,8 g/100 kJ (3,3 g/100 kcal):

(a) the amount of lauric acid shall not exceed 15 % of the total lipid content;

(b) the amount of myristic acid shall not exceed 15 % of the total lipid content;

(c) the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1 200 mg/100 kcal).

5. Minerals

5.1. Sodium

- sodium salts may only be added to processed cereal-based foods for technological purposes,

- the sodium content of processed cereal-based foods shall not exceed 25 mg/100 kJ (100 mg/100 kcal).

5.2. Calcium

5.2.1. For products mentioned in point (a) (ii) of Article 1 (2), the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).

5.2.2. For products mentioned in point (a) (iv) of Article 1 (2), manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

6. Vitamins

6.1. For processed cereal-based foods the amount of thiamin shall not be less than 25 µg/100 kJ (100 µg/100 kcal).

6.2. For products mentioned in point (a) (ii) of Article 1 (2):

>TABLE>

These limits are also applicable if vitamins A and D are added to other processed cereal-based foods.

ANNEX II

ESSENTIAL COMPOSITION OF BABY FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Protein

1.1. If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the total protein from the named sources shall not be less than 1,7 g/100 kJ (7 g/100 kcal).

1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:

- the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 % by weight, of total named protein sources,
- the protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).

1.3. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8 % by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
- the protein from the named sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),

- the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

1.4. If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, then:

- the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100kcal).

1.5. The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

2. Carbohydrates

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

- 10 g/100 ml for vegetable juices and drinks based on them,
- 15 g/100 ml for fruit juices and nectars and drinks based on them,
- 20 g/100 g for fruit-only dishes,
- 25 g/100 g for desserts and puddings,
- 5 g/100 g for other non-milk-based drinks.

3. Fat

3.1. For products referred to in point 1.1 of this Annex:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, then:

- the total fat in the product from all sources should not exceed 1,4 g/100 kJ (6 g/100 kcal).

3.2. For all other products:

the total fat in the product from all sources should not exceed 1,1 g/100 kJ (4,5 g/100 kcal).

4. Sodium

4.1. The final sodium content in the product should be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. However if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product should not be more than 70 mg/100 kJ (300 mg/100 kcal).

4.2. Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

5. Vitamins

Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product should be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product should be not less than 25 ìg RE/100 kJ (100 ìg RE/100 kcal) (1).

Vitamin A shall not be added to other baby foods.

Vitamin D.

Vitamin D shall not be added to baby foods.

(1) RE = all trans retinol equivalents.

ANNEX III

AMINO ACID COMPOSITION OF CASEIN

>TABLE>

ANNEX IV

NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin A

Retinol

Retinyl acetate

Retinyl palmitate

beta carotene

Vitamin D

Vitamin D2 (= ergocalciferol)

Vitamin D3 (= cholecalciferol)

Vitamin B1

Thiamin hydrochloride

Thiamin mononitrate

Vitamin B2

Riboflavin

Riboflavin-5'-phosphate, sodium

Niacin

Nicotinamide

Nicotinic acid

Vitamin B6

Pyridoxine hydrochloride

Pyridoxine-5-phosphate

Pyridoxine dipalmitate

Pantothenic Acid

D-pantothenate, calcium

D-pantothenate, sodium

Dexpanthenol

Folate

Folic acid

Vitamin B12

Cyanocobalamin

Hydroxocobalamin

Biotin

D-biotin

Vitamin C

L-Ascorbic acid

Sodium L-ascorbate

Calcium L-ascorbate

6-Palmityl-L-ascorbic acid (ascorbyl palmitate)

potassium ascorbate

Vitamin K

Phylloquinone (Phytomenadione)

Vitamin E

D-alpha tocopherol

DL-alpha tocopherol

D-alpha tocopherol acetate

DL-alpha tocopherol acetate

2. Amino acids

>TABLE>

3. Others

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

L-Carnitine

L-carnitine hydrochloride

4. Salts of minerals and trace elements

Calcium

Calcium carbonate

Calcium chloride
Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium oxide
Calcium hydroxide
Calcium salts of orthophosphoric acid
Magnesium
Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium oxide
Magnesium hydroxide
Magnesium salts of orthophosphoric acid
Magnesium sulphate
Magnesium lactate
Magnesium glycerophosphate
Potassium
Potassium chloride
Potassium salts of citric acid
Potassium gluconate
Potassium lactate
Potassium glycerophosphate
Iron
Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous lactate
Ferrous sulphate
Ferrous fumarate
Ferric diphosphate (Ferric pyrophosphate)

Elemental iron (carbonyl + electrolytic + hydrogen-reduced)

Ferric saccharate

Sodium ferric diphosphate

Ferrous carbonate

Copper

Copper-lysine complex

Cupric carbonate

Cupric citrate

Cupric gluconate

Cupric sulphate

Zinc

Zinc acetate

Zinc acetate

Zinc citrate

Zinc lactate

Zinc sulphate

Zinc oxide

Zinc gluconate

Manganese

Manganese carbonate

Manganese chloride

Manganese citrate

Manganese gluconate

Manganese sulphate

Manganese glycerophosphate

Iodine

Sodium iodide

Potassium iodide

Potassium iodate

Sodium iodate.

ANNEX V

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

>TABLE>

31998L0036**Commission Directive 98/36/EC of 2 June 1998 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance)***Official Journal L 167 , 12/06/1998 P. 0023 - 0024*

COMMISSION DIRECTIVE 98/36/EC of 2 June 1998 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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), as amended by Directive 96/84/EC of the European Parliament and of the Council (2), and in particular Article 4(1) thereof,

After consulting the Scientific Committee for Food on the provisions liable to affect public health;

Whereas the essential compositional criteria for processed cereal-based foods and baby foods are specified in Annexes I and II respectively to Commission Directive 96/5/EC (3);

Whereas, because of the particular nutrient composition and chemical, physical and organoleptic properties of cheese, if products made of cheese and other ingredients were made to meet the protein requirements laid down in Annex II to Directive 96/5/EC, they would have too high a fat content and be unpalatable to infants and young children;

Whereas therefore the protein requirement for those products should be redefined;

Whereas the diverse culinary habits in the Community have resulted in the marketing of sauces used as accompaniment to a meal which are organoleptically important but not significant in nutrient contribution; whereas therefore these sauces should be exempt from the protein requirements in Annex II;

Whereas maximum levels for some substances added for nutritional purposes are laid down in the Annexes to Directive 96/5/EC; whereas Article 5 of Directive 96/5/EC provides that maximum levels, in addition to those already stipulated, should be laid down where necessary;

Whereas Directive 96/5/EC should be amended accordingly;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annexes to Directive 96/5/EC are amended as shown in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1998. They shall forthwith inform the Commission thereof. Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products conforming to this Directive no later than 1 January 1999,
- prohibit trade in products which do not comply with this Directive with effect from 1 January 2000.

When Member States adopt these provisions, they 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 shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 2 June 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 186, 30. 6. 1989, p. 27.

(2) OJ L 48, 19. 2. 1997, p. 20.

(3) OJ L 49, 28. 2. 1996, p. 17.

ANNEX

The Annexes to the Directive 96/5/EC are amended as follows:

1. In Annex II, section 1, the following shall be inserted:

'1.3a. If cheese is mentioned together with other ingredients in the name of a savoury product, whether or not the product is presented as a meal, then:

- the protein from the dairy sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),
- the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).'

'1.4a. Sauces presented as an accompaniment to a meal are exempt from the requirements of sections 1.1 to 1.4 inclusive.

1.4b. Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2,2 g dairy protein/100 kcal. All other sweet dishes are exempt from the requirements in 1.1 to 1.4.'

2. The following Annex VI is added:

'ANNEX VI

Maximum limits for vitamins, minerals and trace elements, if added, in processed cereal-based foods and baby foods intended for infants and young children

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer, except for potassium and calcium for which the requirements refer to the product as sold.

>TABLE>

31999L0039**Commission directive 1999/39/EC of 6 May 1999 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance)***Official Journal L 124 , 18/05/1999 P. 0008 - 0010*

COMMISSION DIRECTIVE 1999/39/EC

of 6 May 1999

amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses(1), as amended by Directive 96/84/EC of the European Parliament and of the Council(2), and in particular Article 4(1) thereof,

After consulting the Scientific Committee for Food,

(1) Whereas Article 6 of Commission Directive 96/5/EC(3), as amended by Directive 98/36/EC(4), provides that processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children and that necessary maximum levels for such substances shall be established without delay;

(2) Whereas different regulations on the maximum levels of pesticide residues in processed cereal-based foods and baby foods cause trade barriers between certain Member States;

(3) Whereas maximum levels for pesticide residues stipulated in Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables(5), as last amended by Directive 97/41/EC(6), in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals(7), as last amended by Directive 98/82/EC(8), in Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin(9), as last amended by Directive 98/82/EC, and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables(10), as last amended by Directive 98/82/EC, are without prejudice to specific provisions applicable to processed cereal-based foods and baby foods;

(4) Whereas, taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time;

(5) Whereas on the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998 there are at presents doubts as to the adequacy of existing acceptable daily intake values (ADI) for the protection of the health of infants and young children; whereas the doubts expressed concern not only pesticides and pesticide residues, but also dangerous chemical substances, and consequently the Commission will examine the

possibility of fixing, as soon as possible, maximum levels for heavy metals in foods intended for infants and young children;

(6) Whereas, therefore, as far as foods for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides pending case-by-case scientific screening and evaluation of substances;

(7) Whereas this very low common limit should be fixed at 0,01 mg/kg which is in practice the minimum detectable level;

(8) Whereas the Commission in cooperation with interested parties will endeavour to complete the review without delay and to fix the appropriate and scientifically justified levels to be incorporated in a new Annex VII;

(9) Whereas severe limitations on pesticide residues should be required; whereas, with careful selection of raw materials, and given that processed cereal-based foods and baby foods undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues;

(10) Whereas, however, for a small number of pesticides even such low levels might allow the possibility that under worst-case intake conditions the ADI of these pesticides is exceeded; whereas, therefore, processed cereal-based foods and baby foods should be free of those particular pesticides and should be produced without the use of such pesticides;

(11) Whereas, as and when ADI is derived from the scientific evaluation of pesticides carried out pursuant to Council Directive 91/414/EEC(11), as last amended by Commission Directive 1999/1/EC(12), this ADI will be used as the basis for the establishment of maximum residue limits for processed cereal-based foods and baby foods, using, where appropriate, the approach followed in the framework of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC;

(12) Whereas this Directive reflects current knowledge about these substances; whereas any amendment, based on scientific or technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

(13) Whereas Directive 96/5/EC should be amended accordingly;

(14) 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 96/5/EC is hereby amended as follows:

1. The following indent is added to Article 1(4): "- 'pesticide residue' shall mean the residue in processed cereal-based foods and baby foods of a plant protection product, as defined in point 1 of Article 2 of Council Directive 91/414/EEC(13), including its metabolites and products resulting from its degradation or reaction,"

2. Article 6 is replaced by the following: "Article 6

1. Processed cereals-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels shall be established without delay.

2. Processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg, except for those substances for which specific levels have been set in Annex VII, in which case these specific levels shall apply.

The above levels apply to processed cereal-based foods and baby foods as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

3. Those pesticides listed in Annex VIII shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods.

4. Microbiological criteria shall be established as necessary;"

3. the following Annexes VII and VIII are added:

"ANNEX VII

Specific maximum residue levels of pesticides in processed cereal-based foods and baby foods

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ANNEX VIII

Pesticides which shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods.

Chemical name of the substance"

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 June 2000. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

(a) permit trade in products conforming to this Directive no later than 30 June 2000;

(b) prohibit trade in products which do not comply with this Directive, with effect from 1 July 2002.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 May 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 186, 30.6.1989, p. 27.

(2) OJ L 48, 19.2.1997, p. 20.

(3) OJ L 49, 28.2.1996, p. 17.

(4) OJ L 167, 12.6.1998, p. 23.

- (5) OJ L 340, 9.12.1976, p. 26.
- (6) OJ L 184, 12.7.1997, p. 33.
- (7) OJ L 221, 7.8.1986, p. 37.
- (8) OJ L 290, 29.10.1998, p. 25.
- (9) OJ L 221, 7.8.1986, p. 43.
- (10) OJ L 350, 14.12.1990, p. 71.
- (11) OJ L 230, 19.8.1991, p. 1.
- (12) OJ L 21, 28.1.1999, p. 21.
- (13) OJ L 230, 19.8.1991, p. 1

COMMISSION DIRECTIVE 2003/13/EC
of 10 February 2003
amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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⁾, as last amended by Directive 1999/41/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 4(1) thereof,

Having regard to the opinion of the Scientific Committee on Food,

Whereas:

- (1) Article 6 of Commission 96/5/EC ⁽³⁾, as last amended by Directive 1999/39/EC ⁽⁴⁾, stipulates that processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children.
- (2) On the basis of opinions given by the Scientific Committee on Food on 19 September 1997 and 4 June 1998, Directive 96/5/EC established a general maximum residue level of 0,01 mg/kg for any individual pesticide in processed cereal-based foods and baby foods.
- (3) In the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0,01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the acceptable daily intake. This is the case for pesticides or metabolites of pesticides with an acceptable daily intake lower than 0,0005 mg/kg body weight.
- (4) Directive 96/5/EC establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for processed cereal-based foods and baby foods. The pesticides in question should be listed in Annex VIII to Directive 96/5/EC. However, this prohibition does not necessarily guarantee that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.
- (5) The health of infants and young children can be better protected by applying additional requirements which can be enforced by analysis regardless of a product's origin.

- (6) Most of the pesticides which have acceptable daily intake values lower than 0,0005 mg/kg body weight are already prohibited in the Community or will be prohibited by July 2003. The prohibited pesticides should not be detectable in processed cereal-based foods and baby foods by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in processed cereal-based foods and baby foods even if they have not been used. For the purposes of control, a harmonised approach has to be followed.
- (7) Pending Commission decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽⁵⁾, as last amended by Commission Directive 2003/5/EC ⁽⁶⁾, the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in the present Directive. The latter should be set at levels ensuring that their respective acceptable daily intake values are not exceeded by infants and young children under worst-case intake conditions.
- (8) Directive 96/5/EC should be amended accordingly.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/5/EC is amended as follows:

1. Article 6 is amended as follows:

— Paragraph 1 is replaced by the following:

‘1. Processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels for substances other than those referred to in paragraphs 2 and 3 shall be established without delay.’

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 172, 8.7.1999, p. 38.

⁽³⁾ OJ L 49, 28.2.1996, p. 17.

⁽⁴⁾ OJ L 124, 18.5.1999, p. 8.

⁽⁵⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁶⁾ OJ L 8, 14.1.2003, p. 7.

— Paragraph 3 is replaced by the following:

‘3. (a) Those pesticides listed in Annex VIII shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods. However, for the purpose of control:

(i) pesticides listed in Table 1 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level which is considered to be the limit of quantification of the analytical methods shall be kept under regular review in the light of technical progress;

(ii) pesticides listed in Table 2 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

The levels referred to in (i) and (ii) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

(b) For pesticides listed in Annex VII, where a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex VII and Annex VIII to this Directive shall be amended accordingly.’

2. Annex VII is replaced by Annex I to this Directive.

3. Annex VIII is replaced by Annex II to this Directive.

Article 2

1. The Member States shall authorise trade in products which comply with Article 6(3) of Directive 96/5/EC by 6 March 2004 at the latest.

2. The Member States shall prohibit trade in products which do not comply with Article 6(3) of Directive 96/5/EC by 6 March 2005.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 March 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 10 February 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

ANNEX VII

Specific maximum residue levels of pesticides or metabolites of pesticides in processed cereal-based foods and baby foods

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006'

ANNEX II

'ANNEX VIII

Pesticides which shall not be used in agricultural production intended for the production of processed cereal-based foods and baby foods

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin'

31996L0008**Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (Text with EEA relevance)***Official Journal L 055 , 06/03/1996 P. 0022 - 0026*

COMMISSION DIRECTIVE 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 in particular Article 4 thereof,

Whereas the Community measures envisaged by this Directive do not exceed what is necessary for the attainment of the objectives already provided for by Directive 89/398/EEC;

Whereas the products covered by this Directive are varied and are generally distinguished as those intended to replace the whole of the daily diet and those intended to replace part of the daily diet;

Whereas the composition of such products should be such as to fulfil the daily nutritional requirements for essential nutrients, such as to provide a significant part of those requirements, as the case may be, of the persons for whom they are intended;

Whereas a number of products have been recently developed to be used as a replacement for snacks and to supply certain quantities of selected essential macronutrients and micronutrients; whereas the essential composition of those products will be adopted at a later date;

Whereas, in addition, the energy provided by the products covered by this Directive must be restricted;

Whereas the energy content of some products intended to replace the whole of the daily diet is very low; whereas specific rules for these very low energy products will be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification to allow innovation based on scientific and technical progress will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas pursuant to Article 4 (2) of Directive 89/398/EEC, the provisions relating to the substances with specific nutritional purposes to be used in the manufacture of the products should be laid down in a separate Commission Directive;

Whereas the provisions relating to the use of additives in the manufacture of the products should be laid down in the relevant Council Directives;

Whereas pursuant to Article 7 of Directive 89/398/EEC, the products covered by this Directive are subject to the general rules laid down by 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 (2), as last amended by Commission Directive 93/102/EC (3); whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, 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 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for foods for particular nutritional uses intended for use in energy restricted diets for weight reduction and presented as such.

2. Foods for use in energy-restricted diets for weight reduction are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. They are divided in two categories:

(a) products presented as a replacement for the whole of the daily diet;

(b) products presented as a replacement for one or more meals of the daily diet.

Article 2

Member States shall ensure that the products referred to in Article 1 may be marketed within the Community only if they conform to the rules laid down in this Directive.

Article 3

Foods covered by this Directive shall comply with the compositional criteria specified in Annex 1.

Article 4

All individual components making up the products referred to in point (a) of Article 1 (2), as sold, shall be contained in the same package.

Article 5

1. The name under which the product is sold shall be:

(a) for products covered by point (a) of Article 1 (2),

'Total diet replacement for weight control';

(b) for products covered by point (b) of Article 1 (2),

'Meal replacement for weight control'.

2. The labelling of the products concerned shall bear, in addition to those provided for in Article 3 of Council Directive 79/112/EEC, the following mandatory particulars:

(a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

(b) the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of Annex 1, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption. In addition, for products mentioned in point (b) of Article 1 (2), information on vitamins and minerals listed in the Table of point 5 of Annex I shall also be expressed as a percentage of the values as defined in the Annex to Council Directive 90/496/EEC (4);

(c) instructions for appropriate preparation, when necessary and a statement as to the importance of following those instructions;

(d) if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, there shall be a statement to the effect that the food may have a laxative effect;

(e) a statement on the importance of maintaining an adequate daily fluid intake;

(f) for products mentioned in point (a) of Article 1 (2):

(i) a statement that the product provides adequate amounts of all essential nutrients for the day;

(ii) a statement that the product should not be used for more than three weeks without medical advice;

(g) for products mentioned in point (b) of Article 1 (2), a statement to the effect that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.

3. The labelling, advertising and presentation of the products concerned shall not make any reference to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety.

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 October 1997,
- prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, 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 7

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 26 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

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

(2) OJ No L 33, 8. 2. 1979, p. 1.

(3) OJ No L 291, 29. 11. 1993, p. 14.

(4) OJ No L 276, 6. 10. 1990, p. 40.

ANNEX I

ESSENTIAL COMPOSITION OF FOODS FOR ENERGY RESTRICTED DIETS

The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

1.1. The energy provided by a product mentioned in Article 1 (2) (a) shall not be less than 3 360 kJ (800 kcal) and shall not exceed 5 040 kJ (1 200 kcal) for the total daily ration.

1.2. The energy provided by a product mentioned in Article 1 (2) (b) shall not be less than 840 kJ (200 kcal) and shall not exceed 1 680 kJ (400 kcal) per meal.

2. Protein

2.1. The protein contained in products mentioned in Article 1 (2) (a) and (b) shall provide not less than 25 % and not more than 50 % of the total energy of the product. In any case the amount of protein of products mentioned in Article 1 (2) (a) shall not exceed 125 g.

2.2. The abovementioned provisions on protein refer to a protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein given in Annex 2. If the chemical index is lower than 100 % of the reference protein, the minimum protein levels shall be correspondingly increased. In any case the chemical index of the protein shall at least be equal to 80 % of that of the reference protein.

2.3. The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.

2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. Fat

3.1. The energy derived from fat shall not exceed 30 % of the total available energy of the product.

3.2. For products mentioned in Article 1 (2) (a), the linoleic acid (in the form of glycerides) shall not be less than 4,5 g.

3.3. For products mentioned in Article 1 (2) (b), the linoleic acid (in the form of glycerides) shall not be less than 1 g.

4. Dietary fibre

The dietary fibre content of products mentioned in Article 1 (2) (a) shall not be less than 10 g and shall not exceed 30 g for the daily ration.

5. Vitamins and minerals

5.1. The products mentioned in Article 1 (2) (a) shall provide for the whole of the daily diet at least:

100 % of the amounts of vitamins and minerals specified in Table 1.

5.2. The products mentioned in Article 1 (2) (b) shall provide at least 30 % of the amounts of vitamins and minerals specified in the Table per meal; however, the amount of potassium per meal provided by these products shall be at least 500 mg.

>TABLE>

ANNEX II

>TABLE>

31992L0052**Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries***Official Journal L 179 , 01/07/1992 P. 0129 - 0130**Finnish special edition: Chapter 11 Volume 19 P. 0216**Swedish special edition: Chapter 11 Volume 19 P. 0216*

COUNCIL DIRECTIVE 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 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 Community rules concerning infant formulae and follow-on formulae are laid down by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (4) in Commission Directive 91/321/EEC (5);

Whereas given the nature of the products in question it is desirable that Community rules or international standards relating to their composition are made applicable to such products intended for export to third countries;

Whereas in order to prevent inappropriate use of these products which could prejudice the health of infants it is also desirable to extend the application of the Community rules on labelling of infant formulae and follow-on formulae to those products intended for export to third countries;

Whereas the products complying with Directive 91/321/EEC may be marketed in the Community as from 1 December 1992; whereas no legislation prohibits the export of such products to third countries,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns infant formulae and follow-on formulae, as defined by Article 1 (2) (c) and (d) of Directive 91/321/EEC, intended for export to third countries.

Article 2

Member States shall ensure that the products referred to in Article 1 may be exported from the Community only if they comply with this Directive.

Article 3

1. No product other than infant formulae may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

2. In addition the products referred to in Article 1 must comply:

(a) with Articles 3, 4, 5 and 6 of Directive 91/321/EEC or with relevant applicable world standards established by Codex Alimentarius;

(b) with Article 7 (2) to (6) of Directive 91/321/EEC;

(c) with the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (6),

unless otherwise requested or stipulated by provisions established by the importing country.

3. These products shall be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae.

4. The stipulations, prohibitions and restrictions laid down in Article 7 (2) to (6) of Directive 91/321/EEC shall also apply to the presentation of the products concerned and in particular their form, aspect or packaging and the packaging materials used.

Article 4

Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to prohibit exports of products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time 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, 18 June 1992.

For the Council

The President

Vitor MARTINS

(1) OJ No C 124, 16. 5. 1992, p. 14 and OJ No C 155, 20. 6. 1992, p. 18.

(2) OJ No C 125, 18. 5. 1992.

(3) OJ No C 106, 27. 4. 1992, p. 4.

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

(5) OJ No L 175, 4. 7. 1991, p. 35.

(6) OJ No L 186, 30. 6. 1989, p. 21. As last amended by Directive 91/238/EEC (OJ No L 107, 27. 4. 1991, p. 50).

31999L0021**Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (Text with EEA relevance)***Official Journal L 091 , 07/04/1999 P. 0029 - 0036*

COMMISSION DIRECTIVE 1999/21/EC

of 25 March 1999

on dietary foods for special medical purposes

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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), as amended by Directive 96/84/EC of the European Parliament and of the Council(2), and in particular Article 4(1) thereof,

After consulting the Scientific Committee for food,

(1) Whereas dietary foods for special medical purposes are intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition; whereas for this reason they must be used under medical supervision which may be applied with the assistance of other competent health professionals;

(2) Whereas such foods are numerous and their composition may differ substantially depending on the specific disease, disorder or medical condition of the patients for whom they are intended, the age of the patients and the place in which they receive health care support, on whether the foods are intended to be used as the sole source of nourishment or not, and possibly on other factors;

(3) Whereas, because of the wide diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules;

(4) Whereas, however, some basic rules concerning vitamin and mineral substances content can be laid down for products considered to be nutritionally complete for covering the particular nutritional requirements of the intended user; whereas such rules for nutritionally incomplete foods can be laid down only for the maximum levels of these substances as appropriate;

(5) Whereas this Directive reflects current knowledge about those products; whereas any modification to allow for innovation based on scientific and technical progress will be decided in accordance with the procedure laid down in Article 13 of Directive 89/398/EEC;

(6) Whereas pursuant to Article 4(2) of Directive 89/398/EEC, the provisions relating to the substances with specific nutritional purposes to be used in the manufacture of foods for special medical purposes should be laid down in a separate Commission directive;

(7) Whereas pursuant to Article 7 of Directive 89/398/EEC, the products covered by that Directive are subject to the general rules laid down by 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(3), as last amended by Commission Directive 1999/10/EC(4); whereas the present Directive adopts and expands upon the additions and exceptions to those general rules, where appropriate;

(8) Whereas, in particular, in view of the nature and destination of dietary foods for special medical purposes, it is necessary to provide information concerning the energy value and principal nutrients contained in such foods;

(9) Whereas, given the particular nature of dietary foods for special medical purposes, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products;

(10) Whereas, in accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of approximating the laws of the Member States relating to foodstuffs intended for particular nutritional uses to lay down rules on foods for special medical purposes; whereas this Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 3b of the Treaty;

(11) 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 4(1) of Directive 89/398/EEC and lays down compositional and labelling requirements for dietary foods for special medical purposes as defined in paragraph 2 and presented as such.

2. For the purposes of this Directive:

(a) "infants" means children under the age of 12 months;

(b) "dietary foods for special medical purposes" means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

3. Dietary foods for special medical purposes are classified in the following three categories:

(a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(b) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.

The foods referred to in points (b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.

Article 2

Member States shall ensure that dietary foods for special medical purposes may be marketed within the Community only if they comply with the rules laid down in this Directive.

Article 3

The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

They must comply with the compositional criteria specified in the Annex.

Article 4

1. The name under which dietary foods for special medical purposes are sold shall be respectively:

- in Spanish:

"Alimento dietético para usos médicos especiales"

- in Danish:

"Levnedsmiddel/Levnedsmidler til særlige medicinske formål"

- in German:

"Diätetisches/Diätetische Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diäten)"

- in Greek:

"Διαιτητικά τρόφιμα για ειδικούς ιατρικούς σκοπούς"

- in English:

"Food(s) for special medical purposes"

- in French:

"Aliment(s) diététique(s) destiné(s) a des fins médicales spéciales"

- in Italian:

"Alimento dietetico destinato a fini medici speciali"

- in Dutch:

"Dieetvoeding voor medisch gebruik"

- in Portuguese:

"Produto dietético de use clínico"

- in Finnish:

"Kliininen ravintovalmiste/kliinisiä ravintovalmisteita"

- in Swedish:

"Livsmedel för speciella medicinska ändamål".

2. The labelling shall bear, in addition to the particulars provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(b) the average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(c) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(d) information on the osmolality or the osmolarity of the product where appropriate;

(e) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

3. The labelling shall in addition bear the following mandatory particulars, preceded by the words "important notice" or their equivalent:

(a) a statement that the product must be used under medical supervision;

(b) a statement whether the product is suitable for use as the sole source of nourishment;

(c) a statement that the product is intended for a specific age group, as appropriate;

(d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

4. The labelling shall also include:

(a) the statement "For the dietary management of..." where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;

(b) where appropriate a statement concerning adequate precautions and contra-indications;

(c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

(d) where appropriate a warning that the product is not for parenteral use.

5. The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

Article 5

1. To facilitate efficient official monitoring of dietary foods for special medical purposes, when a product is placed on the market, the manufacturer, or where a product is manufactured in a third country, the importer, shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product. Member

States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation.

2. The competent authorities within the meaning of this Article are those referred to in Article 9(4) of Directive 89/398/EEC.

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2000 at the latest. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive with effect from 1 May 2000,
- prohibit trade in products which do not comply with this Directive with effect from 1 November 2001.

When Member States adopt these provisions, 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 7

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 25 March 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 186, 30.6.1989, p. 27.

(2) OJ L 48, 19.2.1997, p. 20.

(3) OJ L 33, 8.2.1979, p. 1.

(4) OJ L 69, 16.3.1999, p. 22.

ANNEX

ESSENTIAL COMPOSITION OF FOODS FOR SPECIAL MEDICAL PURPOSES

The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Products referred to in Article 1(3)(a) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Article 1(3)(b) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) intended specifically for infants shall not exceed those specified in Table 1, without

prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

4. Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to other nutrients applicable to infant formulae and follow-on formulae, as the case may be, laid down in Directive 91/321/EEC and its subsequent modifications.

5. Products referred to in Article 1(3)(a), other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2.

6. Products referred to in Article 1(3)(b) other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2 without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

7. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) other than those intended specifically for infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 1

Values for vitamins, mineral and trace elements in nutritionally complete foods intended for use by infants

Vitamins:

>TABLE>

Minerals:

>TABLE>

TABLE 2

Values for vitamins, minerals and trace elements in nutritionally complete foods other than those intended for use by infants

Vitamins:

>TABLE>

Minerals:

>TABLE>

Corrigendum to the Commission Directive 1999/21/EC on dietary foods for special medical purposes

(Official Journal of the European Communities L 91 of 7 April 1999)

On page 30, in Article 1(3), final paragraph:

For: 'The foods referred to in points (b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.'

Read: 'The foods referred to in points (a) and (b) may also be used as a partial replacement or as a supplement to the patient's diet.'

On page 33, in the Annex, in Table 1, Vitamins:

For: 'Vitamin A (μg ER)',

Read: 'Vitamin A (μg RE)'.

On page 34, in the Annex, in Table 1, Minerals:

For: 'Copper Cuivre (μg)',

Read: 'Copper (μg)'.

On page 35, in the Annex, in Table 2, Vitamins:

For: 'Niacin (mg EN)',

Read: 'Niacin (mg NE)'.

COMMISSION DIRECTIVE 2001/15/EC
of 15 February 2001
on substances that may be added for specific nutritional purposes in foods for particular nutritional uses
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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⁾, as last amended by European Parliament and Council Directive 1999/41/EC ⁽²⁾, and in particular Article 4(2) thereof,

After consulting the Scientific Committee for Food,

Whereas:

- (1) A number of nutritional substances such as vitamins, minerals, amino acids and others may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom those foods are intended are fulfilled and/or in order to satisfy legal requirements laid down in specific directives adopted pursuant to Article 4(1) of Directive 89/398/EEC.
- (2) It is not possible to define nutritional substances as a distinct group for the purpose of this Directive nor to draw up at this stage an exhaustive list of all categories of nutritional substances that may be added in foods for particular nutritional uses.
- (3) The range of foods for particular nutritional uses is very wide and diversified and the technological processes used for their manufacture are varied. For this reason, the widest possible choice of substances that can be safely used in the manufacture of foods for particular nutritional uses should be available for the categories of nutritional substances to be listed in this Directive.
- (4) The choice of substances should be based primarily on their safety and subsequently on their availability for use by humans and their organoleptic and technological properties. The inclusion of substances in the list of those that may be used in the manufacture of foods for particular nutritional uses does not mean that their addition to those foods is necessary or desirable.
- (5) Where the addition of a nutritional substance has been judged necessary, this has been stipulated by specific rules in the relevant specific directives together with the appropriate quantitative conditions, as the case may be.

- (6) In the absence of any specific rules or in the case of foods for particular nutritional uses not covered by specific directives, nutritional substances should be used in order to manufacture products that are in conformity with the definition of such products and fulfil the particular nutritional requirements of the persons for whom they are intended. The products in question must also be safe when used as instructed by the manufacturer.
- (7) The provisions concerning the list of the nutritional substances that may be used in the manufacture of infant formulae and follow-on formulae and of processed cereal-based foods and baby foods for infants and young children are laid down in Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae ⁽³⁾, as last amended by Directive 1999/50/EC ⁽⁴⁾, and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children ⁽⁵⁾, as last amended by Directive 1999/39/EC ⁽⁶⁾. Therefore those provisions need not be repeated in this Directive.
- (8) A number of the nutritional substances may also be used in foodstuffs as food additives. In this context purity criteria have been or are to be adopted for them at Community level in accordance with Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽⁷⁾, as amended by European Parliament and Council Directive 94/34/EC ⁽⁸⁾. Those purity criteria should be applicable for those substances whatever the purpose of their use in foodstuffs.
- (9) Pending the adoption of purity criteria for the rest of the substances at Community level, and in order to ensure a high level of protection for public health, generally acceptable purity criteria recommended by international organisations or agencies including but not limited to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), EUP (European Pharmacopoeia) should apply. Member States should be permitted to maintain national rules setting stricter purity criteria, without prejudice to the rules set out in the Treaty.

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 172, 8.7.1999, p. 38.

⁽³⁾ OJ L 175, 4.7.1991, p. 35.

⁽⁴⁾ OJ L 139, 2.6.1999, p. 29.

⁽⁵⁾ OJ L 49, 28.2.1996, p. 17.

⁽⁶⁾ OJ L 124, 18.5.1999, p. 8.

⁽⁷⁾ OJ L 40, 11.2.1989, p. 27.

⁽⁸⁾ OJ L 237, 10.9.1994, p. 1.

- (10) Some specific nutrients or their derivatives have been identified as specifically necessary for the manufacture of some foods belonging to the group of foods for special medical purposes and their potential use should be reserved to the manufacture of these products.
- (11) The measures provided in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. For the categories of substances added for specific nutritional purposes in foods for particular nutritional uses listed in the Annex to this Directive only the chemical substances mentioned under each category may be used in the manufacture of foodstuffs for particular nutritional uses covered by Directive 89/398/EEC.

The use of those substances shall be in conformity with any specific provisions concerning those substances that may be laid down in specific directives provided for in Article 4(1) of Directive 89/398/EEC.

2. Without prejudice to European Parliament and Council Regulation (EC) No 258/97 ⁽¹⁾, other substances added for specific nutritional purposes, not belonging to one of the categories listed in the Annex to this Directive, may be used in the manufacture of foods for particular nutritional uses.

3. The use of nutritional substances in foods for particular nutritional uses shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended as established by generally accepted scientific data.

4. The competent authorities of Member States, referred to in Article 9 of Directive 89/398/EEC, shall be empowered to require the manufacturer or, where appropriate, the importer to produce the scientific work and the data establishing the use of substances added for specific nutritional purposes in compliance with paragraph 3. If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

Article 2

1. Purity criteria for substances listed in the Annex, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.

2. For those substances listed in the Annex for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply. National rules setting stricter purity criteria may be maintained.

Article 3

Member States shall adopt and publish the provisions necessary to comply with this Directive by 31 March 2002 at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions in such a way as to:

- (a) permit trade in products complying with this Directive with effect from 1 April 2002;
- (b) prohibit trade in products which do not comply with this Directive with effect from 1 April 2004.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 15 February 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

ANNEX

SUBSTANCES THAT MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN FOODS FOR PARTICULAR NUTRITIONAL USES

For the purpose of this table:

- 'FSMP' means foods for particular nutritional uses intended for special medical purposes,
- 'All FPNU' means dietary foods for particular nutritional uses including FSMPs but excluding infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children.

Substance	Condition of use	
	All FPNU	FSMP
Category 1. Vitamins		
VITAMIN A		
— retinol	x	
— retinyl acetate	x	
— retinyl palmitate	x	
— beta-carotene	x	
VITAMIN D		
— cholecalciferol	x	
— ergocalciferol	x	
VITAMIN E		
— D-alpha-tocopherol	x	
— DL-alpha-tocopherol	x	
— D-alpha-tocopheryl acetate	x	
— DL-alpha-tocopheryl acetate	x	
— D-alpha-tocopheryl acid succinate	x	
VITAMIN K		
— phyloquinone (phytomenadione)	x	
VITAMIN B1		
— thiamin hydrochloride	x	
— thiamin mononitrate	x	
VITAMIN B2		
— riboflavin	x	
— riboflavin 5'-phosphate, sodium	x	
NIACIN		
— nicotinic acid	x	
— nicotinamide	x	
PANTOTHENIC ACID		
— D-pantothenate, calcium	x	
— D-pantothenate, sodium	x	
— dexpanthenol	x	
VITAMIN B6		
— pyridoxine hydrochloride	x	
— pyridoxine 5'-phosphate	x	
— pyridoxine dipalmitate	x	

Substance	Condition of use	
	All FPNU	FSMP
FOLIC ACID		
— pteroylmonoglutamic acid	x	
VITAMIN B12		
— cyanocobalamin	x	
— hydroxocobalamin	x	
BIOTIN		
— D-biotin	x	
VITAMIN C		
— L-ascorbic acid	x	
— sodium-L-ascorbate	x	
— calcium-L-ascorbate	x	
— potassium-L-ascorbate	x	
— L-ascorbyl 6-palmitate	x	
Category 2. Minerals		
CALCIUM		
— carbonate	x	
— chloride	x	
— salts of citric acid	x	
— gluconate	x	
— glycerophosphate	x	
— lactate	x	
— salts of orthophosphoric acid	x	
— hydroxide	x	
— oxide	x	
MAGNESIUM		
— acetate	x	
— carbonate	x	
— chloride	x	
— salts of citric acid	x	
— gluconate	x	
— glycerophosphate	x	
— salts of orthophosphoric acid	x	
— lactate	x	
— hydroxide	x	
— oxide	x	
— sulphate	x	
IRON		
— ferrous carbonate	x	
— ferrous citrate	x	
— ferric ammonium citrate	x	
— ferrous gluconate	x	
— ferrous fumarate	x	

Substance	Condition of use	
	All FPNU	FSMP
— ferric sodium diphosphate	x	
— ferrous lactate	x	
— ferrous sulphate	x	
— ferric diphosphate (ferric pyrophosphate)	x	
— ferric saccharate	x	
— elemental iron (carbonyl + electrolytic + hydrogen reduced)	x	
COPPER		
— cupric carbonate	x	
— cupric citrate	x	
— cupric gluconate	x	
— cupric sulphate	x	
— copper lysine complex	x	
IODINE		
— potassium iodide	x	
— potassium iodate	x	
— sodium iodide	x	
— sodium iodate	x	
ZINC		
— acetate	x	
— chloride	x	
— citrate	x	
— gluconate	x	
— lactate	x	
— oxide	x	
— carbonate	x	
— sulphate	x	
MANGANESE		
— carbonate	x	
— chloride	x	
— citrate	x	
— gluconate	x	
— glycerophosphate	x	
— sulphate	x	
SODIUM		
— bicarbonate	x	
— carbonate	x	
— chloride	x	
— citrate	x	
— gluconate	x	
— lactate	x	
— hydroxide	x	
— salts of orthophosphoric acid	x	

Substance	Condition of use	
	All FPNU	FSMP
POTASSIUM		
— bicarbonate	x	
— carbonate	x	
— chloride	x	
— citrate	x	
— gluconate	x	
— glycerophosphate	x	
— lactate	x	
— hydroxide	x	
— salts of orthophosphoric acid	x	
SELENIUM		
— sodium selenate	x	
— sodium hydrogen selenite	x	
— sodium selenite	x	
CHROMIUM (III) and their hexahydrates		
— chloride	x	
— sulphate	x	
MOLYBDENUM (VI)		
— ammonium molybdate	x	
— sodium molybdate	x	
FLUORINE		
— potassium fluoride	x	
— sodium fluoride	x	
Category 3. Amino acids		
— L-alanine	x	
— L-arginine	x	
— L-aspartic acid		x
— L-citrulline		x
— L-cysteine	x	
— Cystine	x	
— L-histidine	x	
— L-glutamic acid	x	
— L-glutamine	x	
— glycine	x	
— L-isoleucine		x
— L-leucine	x	
— L-lysine	x	
— L-lysine acetate	x	
— L-methionine	x	
— L-ornithine	x	
— L-phenylalanine	x	
— L-proline		x

Substance	Condition of use	
	All FPNU	FSMP
— L-threonine	x	
— L-tryptophan	x	
— L-tyrosine	x	
— L-valine	x	
For amino acids, as far as applicable, also the sodium, potassium calcium and magnesium salts as well as their hydrochlorides may be used		
Category 4. Carnitine and taurine		
— L-carnitine	x	
— L-carnitine hydrochloride	x	
— taurine	x	
Category 5. Nucleotides		
— adenosine 5'-phosphoric acid (AMP)	x	
— sodium salts of AMP	x	
— cytidine 5'-monophosphoric acid (CMP)	x	
— sodium salts of CMP	x	
— guanosine 5'-phosphoric acid (GMP)	x	
— sodium salts of GMP	x	
— inosine 5'-phosphoric acid (IMP)	x	
— sodium salts of IMP	x	
— uridine 5'-phosphoric acid (UMP)	x	
— sodium salts of UMP	x	
Category 6. Choline and inositol		
— choline	x	
— choline chloride	x	
— choline bitartrate	x	
— choline citrate	x	
— inositol	x	

COMMISSION DIRECTIVE 2004/5/EC
of 20 January 2004
amending Directive 2001/15/EC to include certain substances in the Annex
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 in particular Article 4(2) thereof,

After consulting the Scientific Committee on Food or the European Food Safety Authority,

Whereas:

- (1) Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses ⁽²⁾ specifies certain categories of substances and mentions for each of them the chemical substances that may be used in the manufacture of foodstuffs for particular nutritional uses. It provides that Member States are to prohibit trade in products not complying with the Directive with effect from 1 April 2004.
- (2) At the time of the adoption of Directive 2001/15/EC a number of chemical substances added for specific nutritional purposes in some foods for particular nutritional uses, which are marketed in some Member States, could not be included in the Annex to that Directive because they had not been evaluated by the Scientific Committee on Food (SCF).
- (3) Those chemical substances that have since been evaluated by the Scientific Committee on Food or by the European Food Safety Authority and have received a favourable scientific evaluation should be included in the Annex to Directive 2001/15/EC.
- (4) Since products containing those substances are on the market in certain Member States, it is necessary that this Directive be transposed before 1 April 2004, in order to avoid that the prohibition provided for in Directive 2001/15/EC becomes applicable to those substances for a limited period of time, which would cause an undue disruption of the market.
- (5) Directive 2001/15/EC should be amended accordingly.

- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 2001/15/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2004 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 January 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 186, 30.6.1989, p.27, Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 52, 22.2.2001, p. 19.

ANNEX

The Annex to Directive 2001/15/EC is amended as follows:

1. In the Section concerning Category 2. Minerals, the following line is added under the heading CALCIUM:

Substance	Conditions of use	
	All FPNU	FSMP
— sulphate	x	

2. In the Section concerning Category 3. Amino acids, the following lines are added:

Substance	Conditions of use	
	All FPNU	FSMP
— L-serine		x
— L-arginine-L-aspartate		x
— L-lysine-L-aspartate		x
— L-lysine-L-glutamate		x
— N-acetyl-L-cysteine		x
— N-acetyl-L-methionine		x in products intended for persons over 1 year of age

3. In the Section concerning Category 4. Carnitine and taurine, the following line is added:

Substance	Conditions of use	
	All FPNU	FSMP
— L-carnitine-L-tartrate	x	

COMMISSION DIRECTIVE 2004/6/EC
of 20 January 2004
derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to
certain products
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Community,

Article 1

Having regard to 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 in particular Article 4(2) thereof,

By way of derogation from point (b) of the second subparagraph of Article 3 of Directive 2001/15/EC in so far as the requirements of the first subparagraph of Article 1(1) of the Directive apply and until 31 December 2006 Member States may continue to allow in their territory trade in products containing the substances listed in the Annex to this Directive provided that:

Whereas:

- (1) Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses ⁽²⁾ specifies certain categories of substances and mentions for each of them the chemical substances that may be used in the manufacture of foodstuffs for particular nutritional uses. It provides that Member States are to prohibit trade in products not complying with the Directive with effect from 1 April 2004.
- (2) At the time of the adoption of Directive 2001/15/EC a number of substances added for specific nutritional purposes to some foods for particular nutritional uses, which are marketed in some Member States, could not be included in the Annex to that Directive because they had not been evaluated by the Scientific Committee on Food (SCF).
- (3) While the evaluation of those substances is being completed by the European Food Safety Authority their use should continue to be permitted in the manufacture of products marketed before the entry into force of this Directive.
- (4) The date of 1 April 2004 provided for in Article 3(b) of Directive 2001/15/EC makes it necessary that the present Directive should be transposed within a short deadline.
- (5) Therefore, a derogation from Directive 2001/15/EC should be provided for.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

- (a) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of the substance in the manufacture of foods for particular nutritional uses to which Directive 2001/15/EC applies;
- (b) the substance in question is used in the manufacture of one or more foods for particular nutritional uses marketed in the Community on the date of entry into force of this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2004 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 52, 22.2.2001, p. 19.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 January 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

SUBSTANCES THAT MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES TO FOODS FOR PARTICULAR NUTRITIONAL USES COVERED BY DIRECTIVE 2001/15/EC**Category 1. Vitamins**

VITAMIN E

- D-alpha-tocopheryl polyethylene glycol 1000 succinate

Category 2. Minerals

BORON

- boric acid
- sodium borate

CALCIUM

- amino acid chelate
- pidolate

CHROMIUM

- amino acid chelate

COPPER

- amino acid chelate

IRON

- ferrous hydroxide
- ferrous pidolate
- amino acid chelate

SELENIUM

- enriched yeast

MAGNESIUM

- amino acid chelate
- pidolate

MANGANESE

- amino acid chelate

ZINC

- amino acid chelate
-

CORRIGENDA**Corrigendum to Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses***(Official Journal of the European Communities L 52 of 22 February 2001)*

On page 24 in the table in the Annex under Category 3. Amino acids, 10th and 11th entries:

for:

'— glycine — L-isoleucine	×	×
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read:

'— glycine — L-isoleucine	×	×
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Corrigendum to Commission Decision 2001/497/EC of 15 June 2001 on standard contractual clauses for the transfer of personal data to third countries, under Directive 95/46/EC*(Official Journal of the European Communities L 181 of 4 July 2001)*

On page 26, in the Annex, in subparagraph 2 of Clause 6, last sentence:

for: 'In the event of such a violation, the data exporter or the data importer or both.'

read: 'In the event of such a violation, the data subject may bring an action before a court against either the data exporter or the data importer or both.'
