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Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption

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COUNCIL DIRECTIVE of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (89/107/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

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

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

Whereas the approximation of these laws is therefore necessary;

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

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

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

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

Whereas it must be possible to adopt the list of authorized additives to scientific and technical developments; whereas in that case, it may be appropriate also to have, in addition to

the rules of procedure laid down by the Treaty, a system permitting the Member States to contribute, by the adoption of temporary national measures, to the search for a Community solution;

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

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

Whereas, in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure instituting close cooperation between

Member States and the Commission within the Standing Committee on Foodstuffs set up by Commission Decision 69/414/EEC (4),

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

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

3. This Directive shall not apply to:

(a) processing aids (5);

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

(c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC (6);

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

Article 2

1. In respect of any category of food additive listed in Annex I for which lists have been drawn up pursuant to Article 3 (8), only those food additives included in such lists may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

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

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

Article 3

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

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

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

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

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

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

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

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

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

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

Article 4

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive, or the comprehensive directive referred to in Article 3, was adopted, has detailed grounds for considering that the use of additives in food, although it complies with this Directive or any list drawn up under Article 3, endangers human health, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine the grounds given by the Member State referred to in Paragraph 1 as soon as possible within the Standing Committee on Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

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

Article 5

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

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

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

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

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

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

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

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

5. N° new authorization for the same additive may be granted unless the scientific or technical development made since the cancellation provided for in paragraph 4 so justifies.

Article 6

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

Article 7

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

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

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

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

- or the statement 'restricted use in food',

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

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

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

(e) a mark identifying the batch or lot;

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

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

(h) the net quantity;

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

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

Article 8

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

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

(b) the information required by Article 7 (l) (a) to (f), and (h):

(c) the date of minimum durability within the meaning of Article 9 of Council Directive 79/112/EEC (7):

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

Article 9

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

Article 10

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

The particulars provided for in Articles 7 and 8 shall appear in a language easily understandable to purchasers unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 11

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

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

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

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

Article 12

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

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

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

Article 13

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

Article 14

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

- authorize, two years after notification of this Directive the marketing and use of food additives complying with this Directive;
- prohibit, not later than three years after notification (8) of this Directive, the marketing and use of food additives which do not comply with this Directive.

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

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

Or the Council

The President

V. PAPANDREOU

(1) OJ, N° C 99, 13. 4. 1987, p. 65 and OJ N° C 12, 16. 1. 1989.

(2) OJ, N° C 328, 22. 12. 1986, p. 5.

(3) OJ N° L 136, 20. 5. 1974, p. 1

(4) OJ N° L 291, 19. 11. 1969, p. 9

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

(6) OJ N° L 184, 15. 7. 1988, p.61.

(7) OJ N° L 33, 8. 2. 1979, p. 1.

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

ANNEX I

Categories of food additives

Colour

Preservative

Anti-oxidant

Emulsifier

Emulsifying salt

Thickener

Gelling agent

Stabilizer (1)

Flavour enhancer
Acid
Acidity regulator (2)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (3)
Flour treatment agent
Firming agent
Humectant
Sequestrant (4)
Enzyme (4) (5)
Bulking agent

Propellant gas and Packaging gas

(1) This category also comprises foam stabilizers.

(2) These can act as two-way acidity regulators.

(3) These substances include lubricants.

(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.

(5) Only those used as additives.

ANNEX II

General criteria for the use of food additives

1. Food additives can be approved only provided that:

- there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically Practicable,
- they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,
- they do not mislead the consumer.

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

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

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

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

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

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

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

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

6. Approval for food additives must:

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

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

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

31994L0034

European Parliament and Council Directive 94/34/EC of 30 June 1994 amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorized for use in foodstuffs intended for human consumption

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EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/34/EC

of 30 June 1994

amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorized for use in foodstuffs intended for human consumption

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 referred to in Article 189b of the Treaty (3),

Whereas rules for harmonization in the field of additives should not affect the application of provisions of Member States existing on 1 January 1992, which prohibit the use of certain additives in certain specific foodstuffs which are considered as traditional and are produced on their territory, provided that those provisions do not cover a whole series of foodstuffs including foodstuffs which do not come under this Directive but regarding which Community provisions provide for authorization of additives;

Whereas these products could be distinguished by an appropriate labelling;

Whereas the free circulation of foodstuffs conforming with directives concerning additives should not be affected;

Whereas the freedom of establishment, the production and sale on the territory of each Member State of foodstuffs conforming with Directives concerning additives should not be affected,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The following Article 3a shall be inserted in Directive 89/107/EEC (4):

'Article 3a

1. By way of derogation from Article 3 (2) (a) and (b), the Council shall, acting on a proposal from the Commission pursuant to the procedure laid down in Article 100a of the Treaty, authorize the Member States to maintain the prohibition on the use of certain additives in the production of certain foodstuffs considered as traditional provided that:

- this prohibition existed on 1 January 1992,

- the Member States concerned authorize on their territory the production and sale of all foodstuffs not considered as traditional which conform to the rules provided for in Article 3.

2. Without prejudice to Regulations (EEC) No 2081/92 (1) and (EEC) No 2082/92 (2), before 1 July 1994, Member States shall communicate to the list of foodstuffs which they consider as traditional, giving their reasons in detail, together with the relevant legislative provisions prohibiting the use of certain additives in such foodstuffs.

Before 1 April 1995, the Commission shall submit a proposal to the Council on the criteria to be applied for deciding whether or not a product is traditional and on the national prohibitions which may be maintained in conformity with these criteria.

The Council shall act on the proposal before 1 April 1996.

3. Until such time as the Council has ruled on paragraph 2, Member States may maintain any prohibitions which have been communicated to the Commission pursuant to the first subparagraph of paragraph 2, provided that they comply with the general conditions laid down in paragraph 1.

(1) Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ No L 208, 24. 7. 1992, p. 1).

(2) Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs (OJ No L 208, 24. 7. 1992, p. 9).'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference when they are officially published. The methods of making such 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 Brussels, 30 June 1994.

For the European Parliament

The President

E. KLEPSCH

For the Council

The President

A. BALTAS

(1) OJ No C 206, 13. 8. 1992, p. 1.

(2) OJ No C 73, 15. 3. 1993, p. 4.

(3) Opinion of the European Parliament of 26 May 1993 (OJ No C 176, 28. 6. 1993, p. 117), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), Council common position of 9 March 1994 (not yet published in the Official Journal) and Decision of the European Parliament of 9 March 1994 (OJ No C 91, 28. 3. 1994, p. 75).

(4) OJ No L 40, 11. 2. 1989, p. 27.

I

(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.

CORRIGENDA**Corrigendum to Commission Regulation (EC) No 2510/97 of 15 December 1997 concerning the classification of certain goods in the Combined Nomenclature**

(Official Journal of the European Communities L 345 of 16 December 1997)

On page 46, in the Annex, under column (2),

for: '1104 29 19',

read: '1104 29 11'.

Corrigendum to Commission Regulation (EC) No 293/98 of 4 February 1998 determining the operative events applicable to products in the fruit and vegetables sector, to processed fruit and vegetable products and partly to live plants and floricultural products and to certain products listed in Annex II to the EC Treaty, and repealing Regulation (EEC) No 1445/93

(Official Journal of the European Communities L 30 of 5 February 1998)

On page 24, in the first line of Article 17:

for: '... the conversion rate ...',

read: '... the agricultural conversion rate ...'.

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 boatmasters' 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.

31994L0035**European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs***Official Journal L 237 , 10/09/1994 P. 0003 - 0012**Finnish special edition: Chapter 13 Volume 27 P. 0005**Swedish special edition: Chapter 13 Volume 27 P. 0005*

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs

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 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (2) thereof,

Having regard to the proposal from the Commission (2),

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

After consultation of the Scientific Committee for Food,

Acting in accordance with the procedure referred to in Article 189b of the Treaty (4),

Whereas differences between national laws relating to sweeteners and their conditions of use hinder the free movement of foodstuffs; whereas this situation may create conditions of unfair competition;

Whereas the prime consideration for any rules on sweeteners and their conditions of use should be the need to protect and inform the consumer;

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

Whereas this Directive does not affect rules relating to functions other than the sweetening properties of the substances covered by this Directive;

Whereas the use of sweeteners to replace sugar is justified for the production of energy-reduced food, non-cariogenic foodstuffs or food without added sugars, for the extension of shelf life through the replacement of sugar, and for the production of dietetic products,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific directive forming a part of the comprehensive directive within the meaning of Article 3 of Directive 89/107/EEC.

2. This Directive shall apply to food additives, hereinafter referred to as 'sweeteners', which are used:

- to impart a sweet taste to foodstuffs,
- as table-top sweeteners.

3. For the purposes of this Directive, 'with no added sugar` and 'energy-reduced` in column III of the Annex shall be defined as follows:

- 'with no added sugar` : without any added mono- or disaccharides or any other foodstuff used for its sweetening properties,

- 'energy-reduced` : with an energy value reduced by at least 30 % compared with the original foodstuff or a similar product.

4. This Directive shall not apply to foodstuffs with sweetening properties.

Article 2

1. Only sweeteners listed in the Annex may be placed on the market with a view to:

- sale to the ultimate consumer,

or

- use in the manufacture of foodstuffs.

2. Sweeteners referred to in the second indent of paragraph 1 may only be used in the manufacture of the foodstuffs listed in the Annex under the conditions specified therein.

3. Except where specially provided for, sweeteners may not be used in foods for infants or young children, as specified in Directive 89/398/EEC (5).

4. The maximum usable doses indicated in the Annex refer to ready-to-eat foodstuffs prepared according to the instructions for use.

Article 3

1. This Directive shall apply without prejudice to specific directives permitting additives listed in the Annex to be used for purposes other than sweetening.

2. This Directive shall also apply without prejudice to Community provisions governing the composition and the description of foodstuffs.

Article 4

Where there are differences of opinion as to whether sweeteners can be used in a given foodstuff under the terms of this Directive, it may be decided by the procedure laid down in Article 7 whether that foodstuff is to be considered as belonging to one of the categories listed in column III of the Annex.

Article 5

1. The sales description of a table-top sweetener must include the term '...-based table-top sweetener`, using the name(s) of the sweetening substance(s) used in its composition.

2. The labelling of a table-top sweetener containing polyols and/or aspartame must bear the following warnings:

- polyols: 'excessive consumption may induce laxative effects`,

- aspartame: 'contains a source of phenylalanine`.

Article 6

Provisions concerning:

- the details which must appear on the labelling of foodstuffs containing sweeteners in order to make their presence clear,

- warnings concerning the presence of certain sweeteners in foodstuffs,

shall be adopted in accordance with the procedure laid down in Article 7 before expiry of the time limit laid down in the first indent of Article 9 (1).

Article 7

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

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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

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

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

Article 8

1. Within three years of adoption of this Directive, in accordance with the general criteria of point 4 of Annex II to Directive 89/107/EEC, Member States shall establish a system of consumer surveys to monitor sweetener consumption.

The details of this monitoring system shall be coordinated in accordance with the procedure laid down in Article 7.

2. Within five years of adoption of this Directive, the Commission shall submit to the European Parliament and the Council a report, based on information obtained through the monitoring system referred to in paragraph 1, on changes in the sweeteners market, levels of use, and whether there is a further need to restrict conditions of use, including by means of appropriate warnings to consumers, to ensure that use does not exceed the acceptable daily intake. If necessary, the report shall be accompanied by proposals for amendment to this Directive.

Article 9

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1995. These measures are intended to:

- allow, not later than 31 December 1995, trade in and use of products conforming to this Directive,
- prohibit, not later than 30 June 1996, trade in and use of products not conforming to this Directive; products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

They shall inform the Commission forthwith thereof.

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

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 30 June 1994.

For the European Parliament

The President

E. KLEPSCH

For the Council

The President

A. BALTAS

(1) OJ No L 40, 11. 2. 1989, p. 27. Directive as amended by Directive 94/34/EC (see page 1 of this Official Journal).

(2) OJ No C 206, 13. 8. 1992, p. 3.

(3) OJ No C 332, 16. 12. 1992, p. 10.

(4) Opinion of the European Parliament of 29 October 1993 (OJ No C 305, 23. 11. 1993), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), Council common position of 11 November 1993 (not yet published in the Official Journal) and Decision of the European Parliament of 9 March 1994 (OJ No C 91, 28. 3. 1994, p. 81).

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

ANNEX

>TABLE>

31996L0083**Directive 96/83/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 94/35/EC on sweeteners for use in foodstuffs***Official Journal L 048 , 19/02/1997 P. 0016 - 0019*

DIRECTIVE 96/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 December 1996 amending Directive 94/35/EC on sweeteners for use in foodstuffs

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 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (2) thereof,

Having regard to the proposal from the Commission,

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 since the adoption of Directive 94/35/EC (4) there have been many technical developments in the field of sweeteners;

Whereas the Directive should be adapted to take account of these developments;

Whereas the Scientific Committee for Food set up by Commission Decision 95/273/EC (5) was consulted before the adoption of provisions liable to have an effect on public health,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 94/35/EC is hereby amended as follows:

1. the following paragraph shall be added to Article 1:

'5. This Directive shall also apply to the corresponding foodstuffs intended for particular nutritional uses within the meaning of Directive 89/398/EEC.';

2. Article 2 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Sweeteners may not be used in food for infants and young children as referred to in Directive 89/398/EEC, including food for infants and young children who are not in good health, unless otherwise laid down in specific provisions.';

(b) the following paragraph shall be added:

'5. In the Annex "quantum satis" means that no maximum level is specified. However, sweeteners shall be used in accordance with good manufacturing practice, at a dose level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.';

3. the following Article shall be added:

'Article 2a

Without prejudice to other Community provisions, the presence of a sweetener in a foodstuff is permissible:

- in compound foodstuffs with no added sugar or energy-reduced, in compound dietary foodstuffs intended for a low-calorie diet and in compound foodstuffs with a long shelf-life, other than those mentioned in Article 2 (3), insofar as the sweetener is permitted in one of the ingredients of the compound foodstuff, or

- if the foodstuff is intended to be used solely in the preparation of a compound foodstuff which conforms to this Directive.` ;

4. the category 'Vitamins and dietary preparations` in the Annex shall be renamed 'Food supplements/diet integrators based on vitamins and/or mineral elements, syrup-type or chewable` ;

5. the table in the Annex shall be supplemented by the table in the Annex to this Directive.

Article 2

Member States shall, where necessary, amend their laws, regulations or administrative provisions in order to:

- authorize trade in products conforming to this Directive, by 19 December 1997 at the latest;

- prohibit trade in products not conforming to this Directive from 19 June 1998. However, products placed on the market or labelled before that date which do not comply with this Directive may be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

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

Article 3

This Decision shall enter into force on the seventh 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 L 40, 11. 2. 1989, p. 27. Directive as last amended by Directive 94/34/EC (OJ No L 237, 10. 9. 1994, p. 1).

(2) OJ No C 174, 17. 6. 1996, p. 1.

(3) Opinion of the European Parliament of 12 March 1996 (OJ No C 96, 1. 4. 1996, p. 24). Council Common Position of 25 June 1996 (OJ No C 315, 24. 10. 1996, p. 12) 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 237, 10. 9. 1994, p. 3.

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

ANNEX

Note:

1. For the substance E 952, cyclamic acid and its Na and Ca salts, maximum usable doses are expressed in free acid.
2. For the substance E 954, saccharin and its Na, K and Ca salts, maximum usable doses are expressed in free imide.

>TABLE>

I

(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 boatmasters' 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.

DIRECTIVE 2003/115/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 December 2003
amending Directive 94/35/EC on sweeteners for use in foodstuffs

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 European Economic and Social Committee ⁽²⁾,

After consultation of the Scientific Committee on Food, pursuant to Article 6 of 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⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽⁴⁾,

Whereas:

- (1) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽⁵⁾ lays down a list of sweeteners that may be used in the Community and their conditions of use.
- (2) Since 1996, two new sweeteners, sucralose and the salt of aspartame and acesulfame, have been found acceptable for use in food by the Scientific Committee on Food.
- (3) The opinion of the Scientific Committee on Food on cyclamic acid and its sodium and calcium salts (which led to the establishment of a new acceptable daily intake (ADI)) and recent studies on the intake of cyclamates lead to a reduction of the maximum usable doses of cyclamic acid and its sodium and calcium salts.
- (4) The designation of certain food categories in Directive 94/35/EC should be adapted to take into account Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽⁶⁾ and of specific directives adopted for some groups of foodstuffs listed in Annex I to Council Directive 89/398/EEC ⁽⁷⁾.

(5) The use of the food additives concerned complies with the general criteria laid down in Annex II to Directive 89/107/EEC.

(6) Articles 53 and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽⁸⁾ establish procedures for taking emergency measures in relation to food of Community origin or imported from a third country. They allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

(7) The measures necessary for implementation of Directive 94/35/EC should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁹⁾.

(8) Directive 94/35/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 94/35/EC is hereby amended as follows:

1. Article 4 shall be replaced by the following:

'Article 4

It may be decided in accordance with the procedure laid down in Article 7:

— where there are differences of opinion as to whether sweeteners can be used in a given foodstuff under the terms of this Directive, whether that foodstuff is to be considered as belonging to one of the categories listed in the third column of the Annex, and

⁽¹⁾ OJ C 262 E of 29.10.2002, p. 429.

⁽²⁾ OJ C 85, 8.4.2003, p. 34.

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

⁽⁴⁾ Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council Common Position of 25 June 2003 (OJ C 277 E, 18.11.2003, p. 1) and position of the European Parliament of 22 October 2003 (not yet published in the Official Journal).

⁽⁵⁾ OJ L 237, 10.9.1994, p. 3. Directive as amended by Directive 96/83/EC (OJ L 48, 19.2.1997, p. 16).

⁽⁶⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁷⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Directive 1999/41/EC of the European Parliament and of the Council (OJ L 172, 8.7.1999, p. 38).

⁽⁸⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁹⁾ OJ L 184, 17.7.1999, p. 23.

— whether a food additive listed in the Annex and authorised at “quantum satis” is used in accordance with the criteria referred to in Article 2.’;

2. a third indent shall be added to Article 5(2):

‘— salt of aspartame and acesulfame: “contains a source of phenylalanine”.’;

3. Article 7 shall be 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 pursuant to 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).’

4. the Annex shall be amended in accordance with the Annex to this Directive.

Article 2

By 29 January 2006 at the latest, the Commission shall submit a report to the European Parliament and the Council outlining the progress made in the re-evaluations of additives under way and setting out a provisional calendar for future re-evaluations, especially those for sucralose and salt of aspartame-acesulfame. These re-evaluations shall be carried out on the basis of consumer data supplied by the Member States and shall take account of the effects of additives on vulnerable population groups.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

— authorise trade in and use of products conforming with this Directive by 29 January 2005 at the latest,

— prohibit trade in and use of products not conforming with this Directive by 29 July 2005 at the latest; however, products placed on the market before that date which do not comply with this Directive may be marketed until 29 January 2006.

They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such 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 day of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2003.

For the European Parliament

The President

P. COX

For the Council

The President

A. MATTEOLI

ANNEX

The Annex to Directive 94/35/EC is hereby amended as follows:

1. in the third column of the tables the following categories of foodstuffs shall be renamed:

- (a) instead of 'Complete formulae for weight control intended to replace total daily food intake or an individual meal' to read 'Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC (*)';
- (b) instead of 'Complete formulae and nutritional supplements for use under medical supervision' to read 'Dietary foods for special medical purposes as defined in Directive 1999/21/EC (**);
- (c) instead of 'Liquid food supplements/dietary integrators' to read 'Food supplements as defined in Directive 2002/46/EC (***) supplied in a liquid form';
- (d) instead of 'Solid food supplements/dietary integrators' to read 'Food supplements as defined in Directive 2002/46/EC supplied in a solid form';
- (e) instead of 'Food supplements/dietary integrators based on vitamins and/or mineral elements, syrup-type or chewable' to read 'Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form';

2. the following footnotes shall be added after the tables:

- (*) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).
- (**) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).
- (***) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).'

3. for E 951 'Aspartame' the following category shall be added under 'Confectionery':

'— Essoblatten	1 000 mg/kg'
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4. for E 952 cyclamic acid and its sodium and calcium salts:

- (a) for the following categories of foodstuffs, the maximum usable dose of '400 mg/l' shall be replaced by '250 mg/l':
 - Water-based flavoured drinks, energy-reduced or with no added sugar;
 - Milk- and milk derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar;
- (b) the following categories of foodstuffs and maximum usable doses shall be deleted:

'— Confectionery with no added sugar	500 mg/kg
— Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	500 mg/kg
— Starch-based confectionery, energy-reduced or with no added sugar	500 mg/kg
— Chewing gum with no added sugar	1 500 mg/kg
— Breath-freshening micro-sweets, with no added sugar	2 500 mg/kg
— Edible ices, energy-reduced or with no added sugar	250 mg/kg'

5. the following tables shall be added:

'EC No	Name	Foodstuffs	Maximum usable dose
E 955	Sucralose	Non-alcoholic drinks	
		— Water-based flavoured drinks, energy-reduced or with no added sugar	300 mg/l
		— Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	300 mg/l
		Desserts and similar products	
		— Water-based flavoured desserts, energy-reduced or with no added sugar	400 mg/kg
		— Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar	400 mg/kg
		— Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	400 mg/kg
		— Egg-based desserts, energy-reduced or with no added sugar	400 mg/kg
		— Cereal-based desserts, energy-reduced or with no added sugar	400 mg/kg
		— Fat-based desserts, energy-reduced or with no added sugar	400 mg/kg
		— "Snacks": certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts	200 mg/kg
		Confectionery	
		— Confectionery with no added sugar	1 000 mg/kg
		— Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	800 mg/kg
		— Starch-based confectionery, energy-reduced or with no added sugar	1 000 mg/kg
		— Cornets and wafers, for ice cream, with no added sugar	800 mg/kg
		— <i>Essoblaten</i>	800 mg/kg
		— Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar	400 mg/kg
		— Breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar	400 mg/kg
		— Breath-freshening micro-sweets with no added sugar	2 400 mg/kg
		— Strongly flavoured freshening throat pastilles with no added sugar	1 000 mg/kg
		— Chewing gum with no added sugar	3 000 mg/kg
		— Energy-reduced tablet form confectionery	200 mg/kg
		— Cider and Perry	50 mg/l
		— Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	250 mg/l
		— Spirit drinks containing less than 15 % alcohol by volume	250 mg/l
		— Alcohol-free beer or with an alcohol content not exceeding 1,2 % vol	250 mg/l

EC No	Name	Foodstuffs	Maximum usable dose
		<ul style="list-style-type: none"> — 'Bière de table/Tafelbier/Table beer' (original wort content less than 6 %) except for 'Obergäriges Einfachbier' — Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH — Brown beers of the 'oud bruin' type — Energy-reduced beer — Edible ices, energy-reduced or with no added sugar — Canned or bottled fruit, energy-reduced or with no added sugar — Energy-reduced jams, jellies and marmalades — Energy-reduced fruit and vegetable preparations — Sweet-sour preserves of fruit and vegetables — <i>Feinkostsalat</i> — Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs — Energy-reduced soups — Sauces — Mustard — Fine bakery products for special nutritional uses — Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC — Dietary foods for special medical purposes as defined in Directive 1999/21/EC — Food supplements as defined in Directive 2002/46/EC supplied in a liquid form — Food supplements as defined in Directive 2002/46/EC supplied in a solid form — Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form 	<ul style="list-style-type: none"> 250 mg/l 250 mg/l 250 mg/l 10 mg/l 320 mg/kg 400 mg/kg 400 mg/kg 400 mg/kg 180 mg/kg 140 mg/kg 120 mg/kg 45 mg/l 450 mg/kg 140 mg/kg 700 mg/kg 320 mg/kg 400 mg/kg 240 mg/l 800 mg/kg 2 400 mg/kg
E 962	Salt of aspartame-acesulfame1 (*)	<p>Non-alcoholic drinks</p> <ul style="list-style-type: none"> — Water-based flavoured drinks, energy-reduced or with no added sugar — Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar <p>Desserts and similar products</p> <ul style="list-style-type: none"> — Water-based flavoured desserts, energy-reduced or with no added sugar — Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar — Fruit- and vegetable-based desserts, energy-reduced or with no added sugar 	<ul style="list-style-type: none"> 350 mg/l (a) 350 mg/l (a) 350 mg/kg (a) 350 mg/kg (a) 350 mg/kg (a)

EC No	Name	Foodstuffs	Maximum usable dose
		— Egg-based desserts, energy-reduced or with no added sugar	350 mg/kg (a)
		— Cereal-based desserts, energy-reduced or with no added sugar	350 mg/kg (a)
		— Fat-based desserts, energy-reduced or with no added sugar	350 mg/kg (a)
		— 'Snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	500 mg/kg (b)
		Confectionery	
		— Confectionery with no added sugar	500 mg/kg (a)
		— Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	500 mg/kg (a)
		— Starch-based confectionery, energy-reduced or with no added sugar	1 000 mg/kg (a)
		— <i>Essoblaten</i>	1 000 mg/kg (b)
		— Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar	1 000 mg/kg (b)
		— Breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar	1 000 mg/kg (b)
		— Breath-freshening micro-sweets with no added sugar	2 500 mg/kg (a)
		— Chewing gum with no added sugar	2 000 mg/kg (a)
		— Cider and perry	350 mg/l (a)
		— Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	350 mg/l (a)
		— Spirit drinks containing less than 15 % alcohol by volume	350 mg/l (a)
		— Alcohol-free beer or with an alcohol content not exceeding 1,2 % vol	350 mg/l (a)
		— 'Bière de table/Tafelbier/Table beer' (original wort content less than 6 %) except for 'Obergäriges Einfachbier'	350 mg/l (a)
		— Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	350 mg/l (a)
		— Brown beers of the ' <i>oud bruin</i> ' type	350 mg/l (a)
		— Energy-reduced beer	25 mg/l (b)
		— Edible ices, energy-reduced or with no added sugar	800 mg/kg (b)
		— Canned or bottled fruit, energy-reduced or with no added sugar	350 mg/kg (a)
		— Energy-reduced jams, jellies and marmalades	1 000 mg/kg (b)
		— Energy-reduced fruit and vegetable preparations	350 mg/kg (a)
		— Sweet-sour preserves of fruit and vegetables	200 mg/kg (a)
		— Feinkostsalat	350 mg/kg (b)

EC No	Name	Foodstuffs	Maximum usable dose
		— Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	200 mg/kg (a)
		— Energy-reduced soups	110 mg/l (b)
		— Sauces	350 mg/kg (b)
		— Mustard	350 mg/kg (b)
		— Fine bakery products for special nutritional uses	1 000 mg/kg (a)
		— Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC	450 mg/kg (a)
		— Dietary foods for special medical purposes as defined in Directive 1999/21/EC	450 mg/kg (a)
		— Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	350 mg/l (a)
		— Food supplements as defined in Directive 2002/46/EC supplied in a solid form	500 mg/kg (a)
		— Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	2 000 mg/kg (a)

(*) Maximum usable doses for the salt of aspartame-acesulfame are derived from the maximum usable doses for its constituent parts, aspartame (E951) and acesulfame-K (E950). The maximum usable doses for both aspartame (E951) and acesulfame-K (E950) are not to be exceeded by use of the salt of aspartame-acesulfame, either alone or in combination with E950 or E951. Limits in this column are expressed either as (a) acesulfame-K equivalents or (b) aspartame equivalents.

CORRIGENDA**Corrigendum to Decision No 1919/2002/EC of the European Parliament and of the Council of 21 October 2002
amending Council Decision 96/411/EC on improving Community agricultural statistics**

(Official Journal of the European Communities L 293 of 29 October 2002)

On page 6:

for: 'For the Council

The President

M. FISCHER BOEL',

read: 'For the Council

The President

P. S. MØLLER'.

31994L0036

European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs

Official Journal L 237 , 10/09/1994 P. 0013 - 0029

Finnish special edition: Chapter 13 Volume 27 P. 0015

Swedish special edition: Chapter 13 Volume 27 P. 0015

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/36/EC

of 30 June 1994

on colours for use in foodstuffs

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 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (2) thereof,

Having regard to the proposal from the Commission (2),

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

Acting in accordance with the procedure referred to in Article 189b of the Treaty (4),

Whereas differences between national laws relating to the conditions of use of colours in food hinder the free movement of foodstuffs; whereas this may create conditions of unfair competition;

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

Whereas a food additive may only be used when there is evidence that it is technologically necessary and that its use is not harmful to health;

Whereas colours are used to restore original appearance of food whose colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;

Whereas colours are used to make food more visually appealing and help identify flavours normally associated with particular foods and to give colour to food otherwise colourless;

Whereas it is necessary to include certain colours intended for health marking of meat under the responsibility of the official veterinarian pursuant to the requirements of Directive 91/497/EEC (5), in particular Chapter XI of Annex I thereto;

Whereas only those colours authorized by this Directive should be used for the decoration of eggs or for the stamping of eggs as provided in Regulation (EEC) No 1274/91 (6);

Whereas colours are used to reinforce colours already present in food;

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

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

Whereas it is necessary to lay down strict rules for the use of additives in food for infants and young children;

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

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

Whereas this Directive replaces partially the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (7);

Whereas the modification of existing purity criteria on colouring matters and new specification for those where no purity criteria exist, will be proposed in accordance with the procedure of Article 11 of Directive 89/107/EEC;

Whereas, in order to protect consumers, the Community should promote research into the possible effects (including those of a cumulative and synergic nature) on human health of colours used in foodstuffs, with special reference to those whose harmlessness is in doubt,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific directive forming a part of the comprehensive directive within the meaning of Article 3 of Directive 89/107/EEC.

2. For the purposes of this Directive, 'colours' are substances which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food.

Preparations obtained from foodstuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Directive.

3. However, the following substances shall not be considered colours for the purposes of this Directive:

- foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron,
- colours used for the colouring of the inedible external parts of foodstuffs, such as cheese coatings and sausage casings.

Article 2

1. Only the substances listed in Annex I may be used as colours in foodstuffs.

2. Colours may be used only in the foodstuffs listed in Annexes III, IV and V and under the conditions specified therein; colours may be used in those same foodstuffs when they are intended for particular uses in accordance with Directive 89/398/EEC (1).

3. Colours may not be used in the foodstuffs listed in Annex II except where specifically provided for in Annex III, IV or V.

4. Colours permitted for certain uses only are listed in Annex IV.

5. Colours permitted in general in foodstuffs and the conditions of use therefor are listed in Annex V.

6. The maximum levels indicated in the Annexes:

- relate to ready-to-eat foodstuffs prepared according to the instructions for use,
- refer to the quantities of colouring principle contained in the colouring preparation.

7. In the Annexes to this Directive 'quantum satis' means that no maximum level is specified. However, colouring matters shall be used according to good manufacturing practice at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

8. For the purpose of health marking as provided in Directive 91/497/EEC and other marking required on meat products, only E 155 Brown HT, E 133 Brilliant Blue FCF or E 129 Allura Red AC or an appropriate mixture of E 133 Brilliant Blue FCF and E 129 Allura Red AC may be used.

9. Only those colours mentioned in Annex I may be used for the decorative colouring of eggshells or for the stamping of eggshells as provided in Regulation (EEC) No 1274/91.

10. Only those colours listed in Annex I, except E 123, E 127, E 128, E 154, E 160b, E 161g, E 173 and E 180, may be sold directly to consumers.

11. Within the meaning of this Directive 'unprocessed' means not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs. However, they may have been for example divided, parted, servered, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen, frozen, chilled, milled or husked, packed or unpacked.

Article 3

Without prejudice to other Community provisions, the presence of a colour in a foodstuff is permissible:

- in a compound foodstuff other than one mentioned in Annex II to the extent that the colour is permitted in one of the ingredients of the compound foodstuff,

or

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

Article 4

It may be decided by the procedure laid down in Article 5, whether a particular foodstuff belongs to a category of foods mentioned in the Annexes, and whether substances are colours in the meaning of Article 1.

Article 5

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee on Foodstuffs, set up pursuant to Decision 69/414/EEC (1), hereinafter referred to as 'the Committee'.
2. The chairman shall refer the matter to the Committee either on his own initiative or at the request of the representative of a Member State.
3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set down in that Article. The chairman shall not vote.
4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the Committee's opinion.

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

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

Article 6

Member States shall, within three years of the adoption of this Directive, establish systems to monitor the consumption and use of colours and report their findings to the Commission.

The Commission shall report to the European Parliament within five years of the adoption of the Directive on changes which have taken place in the colours market, the levels of use and consumption.

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

Article 7

Articles 1 to 7, Article 8 (1), second indent and (2), and Articles 9 to 15 of the Directive of 23 October 1962 on colouring matters in foodstuffs are hereby repealed.

References to the repealed provisions shall be construed as references to the corresponding provisions of this Directive.

Article 8

The Commission shall, to coincide with the date of entry into force of this Directive, launch a campaign, in conjunction with the European Parliament, national ministries, the food and retail industries and consumer bodies, to inform consumers about the evaluation and authorization procedures for permitted colours, and the meaning of the 'E' number system.

Article 9

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1995 in order to:

- allow, not later than 31 December 1995, trade in and use of products conforming to this Directive,
- prohibit, not later than 30 June 1996, trade in and use of products not conforming to this Directive; products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

They shall at once inform the Commission thereof.

2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 30 June 1994.

For the European Parliament

The President

E. KLEPSCH

For the Council

The President

A. BALTAS

(1) OJ No L 40, 11. 2. 1989, p. 27. Directive as amended by Directive 94/34/EC (see page 1 of this Official Journal).

(2) OJ No C 12, 8. 1. 1992, p. 7.

(3) OJ No C 313, 30. 11. 1992, p. 1.

(4) Opinion of the European Parliament of 10 March 1993 (OJ No C 115, 26. 4. 1993, p. 105), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), Council common position of 9 March 1994 (not yet published in the Official Journal) and Decision of the European Parliament of 9 March 1994 (OJ No C 91, 28. 3. 1994, p. 79).

(5) OJ No 268, 24. 9. 1991, p. 69. Directive as amended by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1).

(6) Commission Regulation (EEC) No 1274/91 of 15 May 1991 introducing detailed rules for implementing Regulation (EEC) No 1907/90 on certain marketing standards for eggs (OJ No L 121, 16. 5. 1991, p. 11). Regulation as last amended by Regulation (EC) No 1259/94 (OJ No L 137, 1. 6. 1994, p. 54).

(7) OJ No 115, 11. 11. 1962, p. 2645/62. Directive as last amended by Directive 85/7/EEC (OJ No L 2, 3. 1. 1985, p. 22).

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

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

ANNEX I

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ANNEX II

FOODSTUFFS WHICH MAY NOT CONTAIN ADDED COLOURS, EXCEPT WHERE SPECIFICALLY PROVIDED FOR IN ANNEX III, IV OR V

(The designations used in Annex II do not prejudice the 'carry over' principle in cases where products contain ingredients with legitimate colouring in their own right.)

1. Unprocessed foodstuffs
2. All bottled or packed waters
3. Milk, semi-skimmed and skimmed milk, pasteurized or sterilized (including UHT sterilization) (unflavoured)
4. Chocolate milk
5. Fermented milk (unflavoured)
6. Preserved milks as mentioned in Directive 76/118/EEC
7. Butter-milk (unflavoured)
8. Cream and cream powder (unflavoured)
9. Oils and fats of animal or vegetable origin

10. Eggs and egg products as defined in Article 2 (1) of Directive 89/437/EEC
11. Flour and other milled products and starches
12. Bread and similar products
13. Pasta and gnocchi
14. Sugar, including all mono- and disaccharides
15. Tomato paste and canned and bottled tomatoes
16. Tomato-based sauces
17. Fruit juice and fruit nectar as mentioned in Directive 75/726/EEC and vegetable juice
18. Fruit, vegetables (including potatoes) and mushrooms - canned, bottled or dried; processed fruit, vegetables (including potatoes) and mushrooms
19. Extra jam, extra jelly, and chestnut purée as mentioned in Directive 79/693/EEC; crème de pruneaux
20. Fish, molluscs and crustaceans, meat, poultry and game as well as their preparations, but not including prepared meals containing these ingredients
21. Cocoa products and chocolate components in chocolate products as mentioned in Directive 73/241/EEC
22. Roasted coffee, tea, chicory; tea and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
23. Salt, salt substitutes, spices and mixtures of spices
24. Wine and other products defined by Regulation (EEC) No 822/87
25. Korn, Kornbrand, fruit spirit drinks, fruit spirits, Ouzo, Grappa, Tsikoudia from Crete, Tsipouro from Macedonia, Tsipouro from Thessaly, Tsipouro from Tyrnavos, Eau de vie de marc Marque nationale luxembourgeoise, Eau de vie de seigle Marque nationale luxembourgeoise, London gin, as defined in Regulation (EEC) No 1576/89
26. Sambuca, Maraschino and Mistra as defined in Regulation (EEC) No 1180/91
27. Sangria, Clarea and Zurra as mentioned in Regulation (EEC) No 1601/91
28. Wine vinegar
29. Foods for infants and young children as mentioned in Directive 89/398/EEC including foods for infants and young children not in good health
30. Honey
31. Malt and malt products
32. Ripened and unripened cheese (unflavoured)
33. Butter from sheep and goats' milk

ANNEX III

>TABLE>

ANNEX IV

>TABLE>

ANNEX V

COLOURS PERMITTED IN FOODSTUFFS OTHER THAN THOSE MENTIONED IN ANNEXES II AND III

Part 1

The following colours may be used in foodstuffs mentioned in Annex V Part 2 and in all other foodstuffs other than those listed in Annexes II and III at quantum satis.

- E 101 (i) Riboflavin (ii) Riboflavin-5'-phosphate
- E 140 Chlorophylls and chlorophyllins
- E 141 Copper complexes of chlorophylls and chlorophyllins
- E 150a Plain caramel
- E 150b Caustic sulphite caramel
- E 150c Ammonia caramel
- E 150d Sulphite ammonia caramel
- E 153 Vegetable carbon
- E 160a Carotenes
- E 160c Paprika extract, capsanthin, capsorubin
- E 162 Beetroot Red, betanin
- E 163 Anthocyanins
- E 170 Calcium carbonate
- E 171 Titanium dioxide
- E 172 Iron oxides and hydroxides

Part 2

The following colours may be used singly or in combination in the following foods up to the maximum level specified in the table. However, for non-alcoholic flavoured drinks, edible ices, desserts, fine bakery wares and confectionery, colours may be used up to the limit indicated in the appropriate table but the quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l.

- E 100 Curcumin
- E 102 Tartrazine
- E 104 Quinoline Yellow
- E 110 Sunset Yellow FCF Orange Yellow S
- E 120 Cochineal, Carminic acid, Carmines
- E 122 Azorubine, Carmoisine
- E 124 Ponceau 4R, Cochineal Red A
- E 129 Allura Red AC
- E 131 Patent Blue V
- E 132 Indigotine, Indigo carmine
- E 133 Brilliant Blue FCF
- E 142 Green S

E 151 Brilliant Black BN, Black PN

E 155 Brown HT

E 160d Lycopene

E 160e Beta-apo-8'-carotenal (C 30)

E 160f Ethyl ester of Beta-apo-8'-carotenic acid (C 30)

E 161b Lutein

>TABLE>

CORRIGENDA**Corrigendum to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs**

(Official Journal of the European Communities L 109 of 6 May 2000)

On page 39,

Annex III (published in error in French in the English version) shall read as follows:

‘ANNEX III

Designation of flavourings in the list of ingredients

1. Flavourings shall be designated either by the word “flavouring(s)” or by a more specific name or description of the flavouring.
2. The word “natural” or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1(2)(b)(i) of 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⁾ and/or flavouring preparations as defined in Article 1(2)(c) of the said Directive.
3. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substances, the word “natural” or any other word having substantially the same meaning may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

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

31995L0002

European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners

Official Journal L 061 , 18/03/1995 P. 0001 - 0040

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners

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),

Having regard to the Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (4), and in particular Article 3 (2) thereof,

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

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

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

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

Whereas it is necessary to lay down strict rules for the use of food additives in infant formulae, follow-on formulae and weaning foods, as referred to in 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 (5), and in particular Article 4 (1) (e) thereof;

Whereas this Directive is not intended to affect rules relating to sweeteners and colours;

Whereas, pending specific provisions pursuant to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (6), and pursuant to 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 (7), certain substances belonging to this category are provisionally covered by this Directive;

Whereas the Commission is to adapt Community provisions to accord with the rules laid down in this Directive;

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

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

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

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

Whereas the Scientific Committee for Food has not yet given an opinion on flour treatment agents; whereas those agents will be the subject of a separate Directive;

Whereas this Directive replaces Directives 64/54/EEC (8), 70/357/EEC (9), 74/329/EEC (10) and 83/463/EEC (11); whereas those Directives are hereby repealed,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

2. Only additives which satisfy the requirements laid down by the Scientific Committee for Food may be used in foodstuffs.

3. For the purpose of this Directive:

(a) 'preservatives' are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) 'antioxidants' are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

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

(d) 'acids' are substances which increase the acidity of a foodstuff and/or impart a sour taste to it;

(e) 'acidity regulators' are substances which alter or control the acidity or alkalinity of a foodstuff;

(f) 'anti-caking agents' are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

(g) 'anti-foaming agents' are substances which prevent or reduce foaming;

(h) 'bulking agents' are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

(i) 'emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

(j) 'emulsifying salts' are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

(k) 'firming agents' are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel;

(l) 'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff;

(m) 'foaming agents' are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

(n) 'gelling agents' are substances which give a foodstuff texture through formation of a gel;

(o) 'glazing agents' (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

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

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

(r) 'packaging gases' are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

(s) 'propellants' are gases other than air which expel a foodstuff from a container;

(t) 'raising agents' are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

(u) 'sequestrants' are substances which form chemical complexes with metallic ions;

(v) 'stabilizers' are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff and include also substances which stabilize, retain or intensify an existing colour of a foodstuff;

(w) 'thickeners' are substances which increase the viscosity of a foodstuff.

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

5. For the purposes of this Directive the following are not considered as food additives:

(a) substances used for treatment of drinking water as provided for in Directive 80/778/EEC (12);

(b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization with sodium or potassium salts ('liquid pectin');

(c) chewing gum bases;

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

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

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

(h) caseinates and casein;

(i) inulin.

Article 2

1. Only substances listed in Annexes I, III, IV and V may be used in foodstuffs for the purposes mentioned in Article 1 (3).

2. Food additives listed in Annex I are permitted in foodstuffs, for the purposes mentioned in Article 1 (3), with the exception of those foodstuffs listed in Annex II, following the 'quantum satis' principle.

3. Except where specifically provided for, paragraph 2 does not apply to:

(a) - unprocessed foodstuffs,

- honey as defined in Directive 74/409/EEC (13)

- non-emulsified oils and fats of animal or vegetable origin,

- butter,

- pasteurized and sterilized (including UHT sterilization) milk and cream (including skimmed, plain and semi-skimmed),

- unflavoured, live fermented milk products,

- natural mineral water as defined in Directive 80/777/EEC (14) and spring water,

- coffee (excluding flavoured instant coffee) and coffee extracts,

- unflavoured leaf tea,

- sugars as defined in Directive 73/437/EEC (15),

- dry pasta,

- natural unflavoured buttermilk (excluding sterilized buttermilk).

Within the meaning of this Directive, the term 'unprocessed' means not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs; however, the foodstuffs may have been, for example, divided, parted, severed, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen or frozen, chilled, milled or husked, packed or unpacked;

(b) foods for infants and young children as referred to in Directive 89/398/EEC, including foods for infants and young children not in good health; these foodstuffs are subject to the provisions of Annex VI;

(c) the foodstuffs listed in Annex II, which may contain only those additives referred to in that Annex and those additives referred to in Annexes III and IV under the conditions specified therein.

4. Additives listed in Annexes III and IV may only be used in the foodstuffs referred to in those Annexes and under the conditions specified therein.

5. Only those additives listed in Annex V may be used as carriers or carrier solvents for food additives and must be used under the conditions specified therein.

6. The provisions of this Directive shall also apply to the corresponding foodstuffs intended for particular nutritional uses in accordance with Directive 89/398/EEC.

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

8. In the Annexes to this Directive, 'quantum satis' means that no maximum level is specified. However, additives shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

Article 3

1. The presence of a food additive in a foodstuff is permissible:

- in a compound foodstuff other than one mentioned in Article 2 (3) to the extent that the food additive is permitted in one of the ingredients of the compound foodstuff, or
- if the foodstuff is destined to be used solely in the preparation of a compound foodstuff and to an extent such that the compound foodstuff conforms to the provisions of this Directive.

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

Article 4

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

Article 5

Where necessary, it may be decided by the procedure laid down in Article 6 of this Directive:

- whether a particular foodstuff not categorized at the moment this Directive was adopted belongs to a category of foodstuffs referred to in Article 2 or in one of the Annexes, or
- whether a food additive listed in the Annexes and authorized at 'quantum satis' is used in accordance with the criteria referred to in Article 2, or
- whether a substance is a food additive within the meaning of Article 1.

Article 6

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee for Foodstuffs, set up under Decision 69/414/EEC (16), hereinafter referred to as 'the Committee'.

2. The Chairman shall refer the matter to the Committee either on his own initiative or at the request of the representative of a Member State.

3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

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

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

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

Article 7

Member States shall, within three years of the entry into force of this Directive, establish systems to monitor the consumption and use of food additives and report their findings to the Commission.

The Commission shall report to the European Parliament and the Council within five years of the entry into force of this Directive on the changes which have taken place in the food additives market, the levels of use and consumption.

In accordance with the general criteria in point 4 of Annex II to Directive 89/107/EEC, within five years of the entry into force of this Directive, the Commission shall review the conditions of use referred to in this Directive, and propose amendments where necessary.

Article 8

1. Directives 64/54/EEC, 70/357/EEC, 74/329/EEC and 83/463/EEC are hereby repealed.
2. References to these repealed Directives and to the purity criteria for certain food additives referred to in them shall henceforth be construed as references to this Directive.

Article 9

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 25 September 1996 in order to:

- allow, by 25 September 1996 at the latest, trade in and use of products conforming to this Directive,
- prohibit by 25 March 1997 at the latest, trade in and use of products not conforming to this Directive; products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

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

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 20 February 1995.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President

J. PUECH

(1) OJ No C 206, 13. 8. 1992, p. 12, and OJ No C 189, 13. 7. 1993, p. 11.

(2) OJ No C 108, 19. 4. 1993, p. 26.

(3) Opinion of the European Parliament of 26 May 1993 (OJ No C 176, 28. 6. 1993, p. 117), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), common position of the Council of 10 March 1994 (OJ No C 172, 24. 6. 1994, p. 4) and decision of the European Parliament of 16 November 1994 (OJ No C 341, 5. 12. 1994)

(4) OJ No L 40, 11. 2. 1989, p. 27.

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

(6) OJ No L 230, 19. 8. 1991, p. 1. Directive as last amended by Commission Regulation (EEC) No 3600/92 (OJ No L 366, 15. 12. 1992, p. 10).

- (7) OJ No L 350, 14. 12. 1990, p. 71.
- (8) OJ No 12, 27. 1. 1964, p. 161/64.
- (9) OJ No L 157, 18. 7. 1970, p. 31.
- (10) OJ No L 189, 12. 7. 1974, p. 1.
- (11) OJ No L 255, 15. 9. 1983, p. 1.
- (12) OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).
- (13) OJ No L 221, 12. 8. 1974, p. 10.
- (14) OJ No L 229, 30. 8. 1980, p. 1.
- (15) OJ No L 356, 27. 12. 1973, p. 71.
- (16) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX I

FOOD ADDITIVES GENERALLY PERMITTED FOR USE IN FOODSTUFFS NOT REFERRED TO IN ARTICLE 2 (3)

Note

1. Substances on this list may be added to all foodstuffs with the exception of those referred to in Article 2 (3) following the quantum satis principle.

2. The substances listed under numbers E 407 and E 440 may be standardized with sugars, on condition that this is stated in addition to the number and designation.

3. Explanation of symbols used:

*The substances E 290, E 938, E 939, E 941, E 942 and E 948 may also be used in the foodstuffs referred to in Article 2 (3).

>REFERENCE TO A GRAPHIC> The substances E 410, E 412, E 415 and E 417 may not be used to produce dehydrated foodstuffs intended to rehydrate on ingestion.

>TABLE>

ANNEX II

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

>TABLE>

ANNEX III

CONDITIONALLY PERMITTED PRESERVATIVES AND ANTIOXIDANTS

PART A Sorbates, benzoates and p-hydroxybenzoates

>TABLE>

>TABLE>

PART B Sulphur dioxide and sulphites

>TABLE>

>TABLE>

PART C Other preservatives

>TABLE>

>TABLE>

>TABLE>

PART D Other antioxidants

Note

The * in the table refers to the proportionality rule: when combinations of gallates, BHA and BHT are used, the individual levels must be reduced proportionally.

>TABLE>

ANNEX IV

OTHER PERMITTED ADDITIVES

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

>TABLE>

ANNEX V

PERMITTED CARRIERS AND CARRIER SOLVENTS

Note

Not included in this list are:

1. Substances generally considered as foodstuffs;
2. Substances referred to in Article 1 (5);
3. Substances having primarily an acid or acidity regulator function, such as citric acid and ammonium hydroxide.

>TABLE>

ANNEX VI

FOOD ADDITIVES PERMITTED IN FOODS FOR INFANTS AND YOUNG CHILDREN

Note

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

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

PART 1 FOOD ADDITIVES PERMITTED IN INFANT FORMULAE FOR INFANTS IN GOOD HEALTH

Notes

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

>TABLE>

PART 2 FOOD ADDITIVES PERMITTED IN FOLLOW-ON FORMULAE FOR INFANTS IN GOOD HEALTH

Note

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

>TABLE>

PART 3 FOOD ADDITIVES PERMITTED IN WEANING FOODS FOR INFANTS AND YOUNG CHILDREN IN GOOD HEALTH

>TABLE>

PART 4 FOOD ADDITIVES PERMITTED IN FOODS FOR INFANTS AND YOUNG CHILDREN FOR SPECIAL MEDICAL PURPOSES

The tables in Parts 1 to 3 of Annex VI are applicable.

31996L0085

Directive 96/85/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 95/2/EC on food additives other than colours and sweeteners

Official Journal L 086 , 28/03/1997 P. 0004 - 0004

DIRECTIVE 96/85/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 December 1996 amending Directive 95/2/EC on food additives other than colours and sweeteners

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 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (2) thereof,

Having regard to the proposal from the Commission (2),

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

Acting in accordance with the procedure laid down in Article 189b of the Treaty (4),

Whereas processed Eucheuma seaweed constitutes a new food additive the use of which is justified on technological grounds;

Whereas it is necessary to adapt the list of permitted food additives contained in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (5) in order to permit the use of this additive;

Whereas the Scientific Committee for Food has been consulted;

Whereas purity criteria will be adopted in accordance with the procedure laid down in Article 11 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The following food additive is hereby inserted after E-No 407 in the table in Annex I to Directive 95/2/EC:

>TABLE>

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than three months after its publication in order to allow trade in, and use of, products conforming to this Directive.

They shall forthwith inform the Commission thereof.

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

Article 3

This Directive shall enter into force on the seventh 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 L 40, 11. 2. 1989, p. 27. Directive as last amended by Directive 94/34/EC (OJ No L 237, 10. 9. 1994, p. 1).

(2) OJ No C 163, 29. 6. 1995, p. 12 and OJ No C 208, 19. 7. 1996, p. 15.

(3) OJ No C 18, 22. 1. 1996, p. 20.

(4) Opinion of the European Parliament of 28 March 1996 (OJ No C 117, 22. 4. 1996, p. 36), common position of the Council of 25 June 1996 (OJ No C 315, 24. 10. 1996, p. 9) and Decision of the European Parliament of 23 October 1996 (OJ No C 347, 18. 11. 1996). Council Decision of 9 December 1996.

(5) OJ No L 61, 18. 3. 1995, p. 1.

31998L0072

Directive 98/72/EC of the European Parliament and of the Council of 15 October 1998 amending Directive 95/2/EC on food additives other than colours and sweeteners

Official Journal L 295 , 04/11/1998 P. 0018 - 0030

DIRECTIVE 98/72/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 October 1998 amending Directive 95/2/EC on food additives other than colours and sweeteners

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 referred to in Article 189b of the Treaty (3),

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (4), and in particular Article 3(2) thereof,

Whereas there have been technical developments in the field of food additives since the adoption of Directive 95/2/EC (5);

Whereas Directive 95/2/EC should be adapted to take account of these developments;

Whereas the Scientific Committee for Food, set up by Decision 74/234/EEC (6), was consulted before the adoption of provisions liable to have an effect on public health;

Whereas specific provisions on thiabendazole have been laid down in Council Directive 95/38/EC of 17 July 1995 amending Annexes I and II to Directive 90/642/EEC on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables, and providing for the establishment of a list of maximum levels (7); whereas the entry on thiabendazole should now be repealed,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is hereby amended as follows:

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

'1. This Directive is a specific Directive forming a part of the comprehensive Directive, within the meaning of Article 3 of Directive 89/107/EEC, and applies to additives other than colours and sweeteners. It does not apply to enzymes other than those mentioned in the Annexes,` ;

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

'1. Only substances listed in Annexes I, III, IV and V may be used in foodstuffs for the purposes mentioned in Article 1(3) and Article 1(4),` ;

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

'2. Food additives listed in Annex I are permitted in foodstuffs, for the purposes mentioned in Article 1(3) and Article 1(4), with the exception of those foodstuffs listed in Annex II, following the "quantum satis" principle,` ;

4. The fifth indent of Article 2(3)(a) shall be replaced by:

'- pasteurised and sterilised (including UHT) milk (including plain, skimmed and semi-skimmed) and plain pasteurised cream,` ;

5. The eleventh indent of Article 2(3)(a) shall be replaced by:

'- dry pasta, excluding gluten-free and/or pasta intended for hypoproteic diets, in accordance with Directive 89/398/EEC,` ;

6. The tables of the Annexes shall be amended in accordance with the provisions contained in the Annex to this Directive.

Article 2

1. Member States shall, where necessary, amend their laws, regulations and administrative provisions in order to:

- authorise trade in products conforming with this Directive, by 4 May 2000 at the latest,
- prohibit trade in products not conforming with this Directive from 4 November 2000. However, products placed on the market or labelled before that date which do not comply with the Directive may be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

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

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field covered by this Directive.

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, 15 October 1998.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

C. EINEM

(1) OJ C 76, 11. 3. 1997, p. 34, and OJ C 77, 12. 3. 1998, p. 7.

(2) OJ C 75, 10. 3. 1997, p. 1.

(3) Opinion of the European Parliament of 23 October 1997 (OJ C 339, 10. 11. 1997, p. 1), Council common position of 23 March 1998 (OJ C 161, 27. 5. 1998, p. 29) and Decision of the European Parliament of 15 July 1998 (OJ C 292, 21. 9. 1998). Council Decision of 28 September 1998.

(4) OJ L 40, 11. 2. 1989, p. 27. Directive as last amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10. 9. 1994, p. 1).

(5) OJ L 61, 18. 3. 1995, p. 1. Directive as amended by Directive 96/85/EC (OJ L 86, 28. 3. 1997, p. 4).

(6) OJ L 136, 20. 5. 1974, p. 1.

(7) OJ L 197, 22. 8. 1995, p. 14.

ANNEX

1. In Annex I, the following additives shall be added:

>TABLE>

2. In Annex II:

(a) the list of additives and the maximum level for 'Jam, jellies and marmalades as defined in Directive 79/693/EEC and other similar fruit spreads including low-calorie products` shall be supplemented as follows:

>TABLE>

(b) the table concerning 'Sterilised, pasteurised and UHT cream, low-calorie cream and pasteurised low-fat cream` shall be replaced by the following:

>TABLE>

(c) the designation 'Frozen and deep-frozen unprocessed fruit and vegetables` shall be amended as follows:

'Frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption and prepacked unprocessed and peeled potatoes.`;

(d) the following table shall be inserted after the table concerning 'Non-emulsified oils and fats of animal or vegetable origin` :

>TABLE>

(e) the list of additives and the maximum level for 'Mozzarella and whey cheese` shall be supplemented as follows:

>TABLE>

(f) the list of additives and the maximum level for 'Canned and bottled fruit and vegetables` shall be supplemented as follows:

>TABLE>

(g) the list of additives and the maximum level for 'Gehakt` shall be supplemented as follows:

>TABLE>

(h) the following table shall be added at the end of the Annex:

>TABLE>

3. In Annex III, Part A:

(a) the maximum levels for 'Olives and olive-based preparations`, 'Emulsified sauces with a fat content of 60 % or more` and 'Emulsified sauces with a fat content less than 60 %` shall be replaced by the following:

>TABLE>

(b) at the end of this part, the following table shall be added:

>TABLE>

4. In Annex III, Part B:

(a) the presentation of the following foodstuffs and maximum levels:

>TABLE>

shall be as follows:

>TABLE>

(b) the maximum level for the entry 'Sugars as defined in Directive 73/437/EEC except glucose syrup, whether or not dehydrated` shall be replaced by the following:

>TABLE>

(c) the following foodstuffs and maximum levels:

>TABLE>

shall be replaced by the following:

>TABLE>

(d) at the end of this Part, the following foodstuffs and maximum levels shall be added:

>TABLE>

5. In Annex III, Part C:

(a) the following foodstuff and maximum level shall be added to E 234:

>TABLE>

(b) the following foodstuffs and maximum levels shall be added to E 251 and E 252:

>TABLE>

(c) the following foodstuffs and maximum levels shall be added to E 280, E 281, E 282 and E 283:

>TABLE>

(d) the following table shall be deleted:

>TABLE>

6. The designation 'Dehydrated granulated potatoes` contained in the table in Annex III Parts B and D in the foodstuffs column shall be replaced by 'Dehydrated potatoes`.

7. In Annex IV:

(a) the designation 'Instant tea powder` concerning E 297 Fumaric acid and the maximum level of 1 g/l shall be replaced by 'Instant products for preparation of flavoured tea and herbal infusions with the maximum level: 1 g/kg` ;

(b) the table concerning E 338 to E 452 shall be replaced by the following:

>TABLE>

(c) the following additive shall be added:

>TABLE>

(d) the designation 'Minarine` concerning E 385 shall be amended as follows:

>TABLE>

(e) the following foodstuff and maximum level shall be added to E 405:

>TABLE>

(f) the designation in the 12th section, third column, concerning E 442, shall be amended as follows:

'Cocoa and chocolate products as defined in Directive 73/241/EEC including fillings`

'Confectionery based on these products` ;

(g) the following foodstuff and maximum level shall be added to E 445:

>TABLE>

(h) the following foodstuffs and maximum levels shall be added to E 473 and E 474:

>TABLE>

(i) the designation 'Low and very low fat spreads and dressings` concerning E 476 shall be amended as follows:

>TABLE>

(j) the following foodstuffs and maximum levels concerning E 551 to E 559 shall be added:

>TABLE>

(k) the designation 'Sliced hard cheese and sliced processed cheese` concerning E 551 to E 559 shall be amended as follows:

>TABLE>

(l) the following foodstuff and maximum level shall be added to E 900:

>TABLE>

(m) the following foodstuffs and maximum levels shall be added to E 901, E 902, E 903 and E 904:

>TABLE>

(n) the following foodstuffs and maximum levels shall be added to E 912 and E 914:

>TABLE>

(o) the following foodstuffs and maximum levels shall be added to E 957:

>TABLE>

(p) the designation 'Margarine` and 'Minarine` concerning E 959 shall be amended as follows:

>TABLE>

(q) the following foodstuff and maximum level shall be added to E 999:

>TABLE>

(r) the following table shall be added:

>TABLE>

(s) the following table shall be added:

>TABLE>

8. In Annex V, the following table shall be added:

>TABLE>

9. In Annex VI:

(a) the first subparagraph of the introductory note shall be replaced by the following:

'Formulae and weaning foods for infants and young children may contain E 414 (acacia gum, gum arabic) and E 551 (silicon dioxide) resulting from the addition of nutrient preparations containing not more than 150 g/kg of E 414 and 10 g/kg of E 551, as well as E 421 (mannitol) when used as a carrier for vitamin B12 (not less than one part vitamin B12 to 1 000 parts mannitol). The carry over of E 414 in the product ready for consumption should not be more than 10 mg/kg.

Formulae and weaning foods for infants and young children may contain E 301 (sodium L-ascorbate), used at QS level in coatings of nutrient preparations containing polyunsaturated fatty acids. The carry over of E 301 in the product ready for consumption should not be more than 75 mg/l.`;

(b) in Part 1, note 2 shall be replaced by the following:

'2. If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.`;

(c) in Part 1, the following table shall be added:

>TABLE>

(d) in Part 2, note 2 shall be replaced by the following:

'2. If more than one of the substances E 322, E 471, E 472c and E 473 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.`;

(e) in Part 2, the following table shall be added:

>TABLE>

(f) in Part 3, the following table shall be added:

>TABLE>

(g) in Part 4, the following table shall be added:

>TABLE>

DIRECTIVE 2001/5/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 12 February 2001
amending Directive 95/2/EC on food additives other than colours and sweeteners

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 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 ⁽¹⁾, and in particular Articles 3(2) and 5(3) thereof,

Having regard to the proposal from the Commission ⁽²⁾,

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

Acting in accordance with the procedure referred to in Article 251 of the Treaty ⁽⁴⁾,

Whereas:

- (1) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽⁵⁾ lays down a list of food additives that may be used in the Community and the conditions for their use.
- (2) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC.
- (3) Directive 95/2/EC should be adapted to take account of these developments.
- (4) Food additives may be approved for use in foodstuffs only if they comply with the general criteria laid down in Annex II to Directive 89/107/EEC.
- (5) According to Article 5(1) of Directive 89/107/EEC, a Member State may authorise the use of a new food additive for a two-year period in its territory.
- (6) In accordance with requests from Member States, the following nationally authorised additives should be approved at Community level: propane, butane and iso-butane; these products should be labelled according to Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers ⁽⁶⁾.
- (7) The Scientific Committee on Food, established under Commission Decision 97/579/EC ⁽⁷⁾, has been consulted on the adoption of provisions liable to have an effect on public health, pursuant to Article 6 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The Annexes to Directive 95/2/EC are hereby amended as follows:

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

⁽²⁾ OJ C 21 E, 25.1.2000, p. 42 and OJ C 337 E, 28.11.2000, p. 238.

⁽³⁾ OJ C 51, 23.2.2000, p. 27.

⁽⁴⁾ Opinion of the European Parliament of 11 April 2000 (not yet published in the Official Journal), Council Common Position of 20 July 2000 (OJ C 300, 20.10.2000, p. 45) and decision of the European Parliament of 14 December 2000 (not yet published in the Official Journal). Decision of the Council of 19 January 2001.

⁽⁵⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 98/72/EC (OJ L 295, 4.11.1998, p. 18).

⁽⁶⁾ OJ L 147, 9.6.1975, p. 40. Directive as last amended by Commission Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

⁽⁷⁾ OJ L 237, 28.8.1997, p. 18.

1. Annex I shall be amended as follows:

(a) the following additive shall be inserted in the table:

'E 949 Hydrogen *'

(b) in point 3 of the note, the following shall be inserted in the text corresponding to the symbol *:

'E 949'

2. in Annex IV

(a) the following shall be added in the third and fourth columns to the row for 'E 445: Glycerol esters of wood rosin':

'Cloudy spirit drinks in accordance with Council Regulation (EEC) No 1576/89 laying down general rules on the definition, description and presentation of spirit drinks (*)	100 mg/l
Cloudy spirit drinks containing less than 15 % alcohol by volume	100 mg/l
(*) OJ L 160, 12.6.1989, p. 1.	

(b) The following rows shall be added:

'E 650	Zinc acetate	Chewing gum	1 000 mg/kg
E 943a	Butane	Vegetable oil pan spray (for professional use only) Water-based emulsion spray	'quantum satis'
E 943b	Iso-butane		
E 944	Propane		

3. in Annex V the first row shall be replaced by the following:

'E 1520	Propane-1,2-diol (propylene glycol)	Colours, emulsifiers, antioxidants and enzymes (maximum 1 g/kg in the foodstuff)
---------	-------------------------------------	--

Article 2

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive by 24 August 2002 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 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 domestic law which they adopt in the field covered by this Directive.

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 Brussels, 12 February 2001.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

T. ÖSTROS

DIRECTIVE 2003/52/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 June 2003
amending Directive 95/2/EC as regards the conditions of use for a food additive E 425 konjac
(Text with EEA relevance)

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 European Economic and Social Committee ⁽²⁾,

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

Whereas:

- (1) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽⁴⁾ authorises the use of the food additive E 425 konjac in foodstuffs under certain conditions.
- (2) The Commission has taken measures to suspend temporarily the placing on the market of jelly mini-cups containing E 425 konjac because they have been found to be dangerous as they have caused the death of several children and elderly persons in third countries through choking.
- (3) Some manufacturers of jelly mini-cups recognise the risk to human health by affixing a warning on the food package, highlighting the risk for children and the elderly.
- (4) On the basis of the information provided by the Member States which adopted measures at national level, it can be concluded that jelly mini-cups containing E 425 konjac constitute a life-threatening risk. In addition to their shape and size, the chemical and physical properties of konjac are the cause for jelly mini-cups to constitute a serious risk to human health.
- (5) In the present case, warning through labelling is not sufficient to protect human health, especially with regard to children.
- (6) It is necessary to modify the conditions of use for E 425 konjac as regards its use in jelly confectionery, including jelly-mini cups.

- (7) Directive 95/2/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Annex IV to Directive 95/2/EC in the row for E 425: Konjac: (i) Konjac gum (ii) Konjac glucomannane the text 'Foodstuffs in general (except those referred to in Article 2(3))' shall be replaced by the text 'Foodstuffs in general (except those referred to in Article 2(3) and jelly confectionery including jelly-mini-cups)'.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 17 January 2004. They shall forthwith inform the Commission thereof.

When Member States adopt those measures, 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 day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 18 June 2003.

For the European Parliament
The President
P. COX

For the Council
The President
G. DRYG

⁽¹⁾ OJ C 331 E, 31.12.2002, p. 124.

⁽²⁾ OJ C 85, 8.4.2003, p. 39.

⁽³⁾ Opinion of the European Parliament of 11 February 2003 (not yet published in the Official Journal), and Council Decision of 19 May 2003.

⁽⁴⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2001/5/EC (OJ L 55, 24.2.2001, p. 59).

I

(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 boatmasters' 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.

DIRECTIVE 2003/114/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 December 2003
amending Directive 95/2/EC on food additives other than colours and sweeteners

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,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

- (1) Food additives may be approved for use in foodstuffs only if they comply with Annex II to 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⁾.
- (2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽⁴⁾ lays down a list of food additives that may be used in the Community and the conditions for their use.
- (3) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC. That Directive should be adapted to take account of those developments.
- (4) 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 ⁽⁵⁾ provides for the adoption of a list of additives necessary for the storage and use of flavourings, and the adoption of any special conditions for the use of such additives that may be necessary for the protection of public health and to ensure fair trade.

(5) It is desirable to incorporate into Directive 95/2/EC those measures on additives necessary for the storage and use of flavourings, in order to contribute to transparency and consistency of Community legislation, and to facilitate compliance with Community legislation on food additives by food manufacturers, especially by small and medium-sized enterprises. In addition, according to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽⁶⁾, flavourings fall within the definition of 'food'.

(6) While the use of additives which are necessary to ensure the safety and quality of flavourings and to facilitate their storage and use should be authorised, the levels of additives present in such flavourings should be the minimum required to achieve the intended purpose. In addition, consumers should be guaranteed correct, adequate and non-misleading information on the use of additives.

(7) The presence of an additive in a foodstuff, due to the use of a flavouring, is generally low and the additive does not have a technological function in the foodstuff. However, if under certain circumstances the additive does have a technological function in the compound foodstuff, it should be considered as an additive of the compound foodstuff and not as an additive of the flavouring, and the relevant rules relating to the additive in the particular foodstuff should apply, including the labelling rules laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽⁷⁾.

(8) In accordance with Directive 88/388/EEC, food manufacturers should be informed about the concentrations of all additives in flavourings in order to enable them to comply with Community legislation. That Directive also requires quantitative labelling of each component subject to a quantitative limitation in a foodstuff. A quantitative limitation is expressed either numerically or by the 'quantum satis' principle.

⁽¹⁾ OJ C 208, 3.9.2003, p. 30.

⁽²⁾ Opinion of the European Parliament of 3 July 2003 (not yet published in the Official Journal), and Decision of the Council of 1 December 2003.

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

⁽⁴⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/52/EC (OJ L 178, 17.7.2003, p. 23).

⁽⁵⁾ OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

⁽⁶⁾ OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁽⁷⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

- (9) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring market unity and a high level of consumer protection to lay down rules on the use of additives in flavourings. This Directive does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (10) In accordance with a request from a Member State and the opinion of the Scientific Committee on Food, established by Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety ⁽¹⁾, hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be authorised at Community level.
- (11) Biphenyl (E 230), orthophenyl phenol (E 231) and sodium orthophenyl phenol (E 232) are listed as preservatives in and on citrus fruits in Directive 95/2/EC. However, they fall under the definition of 'plant protection products' in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽²⁾. Therefore, they should no longer come within the scope of Directive 95/2/EC. The Member States and the Commission should take all possible steps to ensure that there is no legal vacuum with regard to these substances. Authorisation to place on the market these substances as plant protection products should be dealt with as swiftly as possible.
- (12) On 4 April 2003, the Scientific Committee on Food stated that the temporary acceptable daily intake for E 214 to E 219 p-hydroxybenzoic acid alkyl esters and their sodium salts should be withdrawn if no further data are submitted in respect of intake and toxicity.
- (13) Directive 95/2/EC should therefore be amended accordingly.
- (14) Council Directive 67/427/EEC of 27 June 1967 on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit ⁽³⁾ lays down the control measures on preservatives in and on citrus fruits. Since those preservatives are no longer authorised for use in citrus fruits by Directive 95/2/EC, it is necessary to repeal Directive 67/427/EEC.
- (15) The Scientific Committee on Food has been consulted on the adoption of provisions that may have an effect upon public health, pursuant to Article 6 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is hereby amended as follows:

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

'(v) "stabilisers" are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food;'

2. Article 3 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The presence of a food additive is permissible:

- (a) in a compound foodstuff other than one mentioned in Article 2(3), to the extent to which the food additive is permitted in one of the ingredients of the compound foodstuff;
- (b) in a foodstuff where a flavouring has been added, to the extent to which the food additive is permitted in the flavouring in compliance with this Directive and has been carried over to the foodstuff via the flavouring, provided the food additive has no technological function in the final foodstuff; or
- (c) if the foodstuff is destined to be used solely in the preparation of a compound foodstuff and to an extent such that the compound foodstuff conforms to the provisions of this Directive;'

(b) the following paragraph shall be added:

'3. The level of additives in flavourings shall be limited to the minimum necessary to guarantee the safety and quality of flavourings and to facilitate their storage. Furthermore, the presence of additives in flavourings must not mislead consumers or present a hazard to their health. If the presence of an additive in a foodstuff, as a consequence of adding flavourings, has a technological function in the foodstuff, it shall be considered as an additive of the foodstuff and not as an additive of the flavouring;'

3. the Annexes shall be amended as set out in the Annex to this Directive.

Article 2

1. Before 1 July 2004, the Commission and the European Food Safety Authority shall review the conditions for the use of additives E 214 to E 219.

⁽¹⁾ OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

⁽²⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽³⁾ OJ L 148, 11.7.1967, p. 1.

2. Before 27 January 2006, the Commission shall submit to the European Parliament and the Council a report on the progress of the re-evaluation of additives. This re-evaluation shall in particular focus on E 432 to E 436 (polysorbates) as well as E 251 and E 252 (nitrates) and E 249 and E 250 (nitrites).

Article 3

Directive 67/427/EEC shall be repealed.

Article 4

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

- authorise trade in and use of products conforming with this Directive by 27 July 2005 at the latest,
- prohibit trade in and use of products not conforming with this Directive by 27 January 2006 at the latest; however, products placed on the market or labelled before that date which do not comply with this Directive may be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

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

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2003.

For the European Parliament

The President

P. COX

For the Council

The President

A. MATTEOLI

ANNEX

The Annexes to Directive 95/2/EC shall be amended as follows:

1. in Annex I:

(a) Note 2 shall be replaced by the following:

'2. The substances listed under numbers E 407, E 407a and E 440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.';

(b) in the list of additives:

- the entire entry for E 170 shall be replaced by 'E 170 Calcium carbonate';
- in the entry for E 466, the name 'Cellulose gum' shall be added,
- in the entry for E 469, the name 'Enzymatically hydrolysed cellulose gum' shall be added;

2. in Annex II:

(a) the name 'E 170 Calcium carbonates' shall be replaced throughout by 'E 170 Calcium carbonate';

(b) the following shall be added to the list of additives and the maximum levels concerning 'Cocoa and chocolate products as defined in Directive 2000/36/EC':

	'E 472c Citric acid esters of mono- and diglycerides of fatty acids'	quantum satis'
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(c) the following shall be inserted in the list of additives and the maximum level for 'Frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption and prepacked, unprocessed and peeled potatoes':

	'E 296 Malic acid'	quantum satis (only for peeled potatoes)'
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(d) the following shall be added to the list of additives and the maximum level for 'Fruit compote':

	'E 440 Pectin E 509 Calcium chloride'	quantum satis (only for fruit compote other than apple)'
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(e) the following shall be inserted in the list of additives and the maximum level for 'Mozzarella and whey cheese':

	'E 460ii Powdered cellulose'	quantum satis (only for grated and sliced cheese)'
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(f) the following rows shall be added at the end of the Annex:

'UHT goat milk'	E 331 Sodium citrates	4 g/l
Chestnuts in liquid	E 410 Locust bean gum E 412 Guar gum E 415 Xanthane gum	quantum satis'

3. in Annex III:

A. part A shall be amended as follows:

(a) the designation 'Partially baked, pre-packed bakery wares intended for retail sale' shall be replaced by the following: 'Partially baked, pre-packed bakery wares intended for retail sale and energy-reduced bread intended for retail sale';

(b) at the end of this part, the following rows shall be added:

'Crayfish tails, cooked, and prepacked marinated cooked molluscs'	2 000					
Flavourings				1 500'		

B. part C shall be amended as follows:

(a) the following rows shall be deleted:

E 230	Biphenyl, diphenyl	Surface treatment of citrus fruit	70 mg/kg
E 231	Orthophenyl phenol (*)	} Surface treatment of citrus fruit	12 mg/kg individually or in combination expressed as orthophenyl phenol
E 232	Sodium orthophenyl phenol (*)		

(*) The deletion of E 231 orthophenyl phenol and E 232 sodium orthophenyl phenol shall enter into force as soon as requirements for the labelling of foodstuffs treated with these substances become applicable by virtue of Community legislation on maximum residue limits for pesticides.'

(b) the following foodstuff shall be added to E 1105:

		'Wine in accordance with Regulation (EC) No 1493/1999 (*) and its implementing Regulation (EC) No 1622/2000 (**)	Pro memoria
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(*) Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine (OJ L 179, 14.7.1999, p.1). Regulation as last amended by Commission Regulation (EC) No 1795/2003 (OJ L 262, 14.10.2003, p. 1).

(**) Commission Regulation (EC) No 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes (OJ L 194, 31.7.2000, p.1). Regulation as last amended by Regulation (EC) No 1410/2003 (OJ L 201, 8.8.2003, p. 9).'

C. part D shall be amended as follows:

(a) the following foodstuffs and maximum levels shall be added at the end of this part:

E 310	Propyl gallate	Essential oils	1 000 mg/kg (gallates and BHA, individually or in combination)
E 311	Octyl gallate		
E 312	Dodecyl gallate		
E 320	Butylated hydroxyanisole (BHA)	Flavourings other than essential oils	100 mg/kg (gallates, individually or in combination) or 200 mg/kg (BHA)'

(b) in the list of foodstuffs concerning E 315 and E 316, the designation 'Semi-preserved and preserved meat products' shall be replaced by the following: 'Cured meat products and preserved meat products';

4. in Annex IV:

(a) the following foodstuff and maximum level concerning E 338 to E 452 shall be added:

		'Flavourings	40 g/kg'
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(b) the following foodstuff and maximum level concerning E 338 to E 452 shall be deleted:

		'Cider and perry	2 g/l'
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(c) the following foodstuff and maximum level shall be added to E 416:

		'Flavourings	50 g/kg'
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(d) the following foodstuffs and maximum levels concerning E 432 to E 436 shall be added:

		'Flavourings, except liquid smoke flavourings and flavourings based on spice oleoresins (*)	10 g/kg
		Foodstuffs containing liquid smoke flavourings and flavourings based on spice oleoresins	1 g/kg

(*) Spice oleoresins are defined as extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice.'

(e) the following foodstuff and maximum level concerning E 444 shall be added:

		'Flavoured cloudy spirit drinks containing less than 15 % alcohol by volume	300 mg/l'
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(f) the following entry concerning E 551 shall be inserted after the list of foodstuffs and maximum levels for E 535 to E 538:

'E 551	Silicon dioxide	Flavourings	50 g/kg'
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(g) the following foodstuff and maximum level shall be added to E 900:

		'Flavourings	10 mg/kg'
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(h) in the list of foodstuffs and maximum levels for E 901 to E 904, the entry: 'E 903 Carnauba wax' shall be deleted and the following entry concerning E 903 shall be added after the entry 'E 904 shellac':

'E 903	Carnauba wax	As glazing agents only:	
		— confectionery (including chocolate)	500 mg/kg
			1 200 mg/kg (only for chewing gum)
		— small products of fine bakery wares coated with chocolate	200 mg/kg
		— snacks	200 mg/kg
		— nuts	200 mg/kg
		— coffee beans	200 mg/kg
		— dietary food supplements	200 mg/kg
		— fresh citrus fruits, melons, apples, pears, peaches and pineapples (surface treatment only)	200 mg/kg'

(i) the following foodstuffs and maximum levels shall be added to E 459:

		'Encapsulated flavourings in	
		— flavoured teas and flavoured powdered instant drinks	500 mg/l
		— flavoured snacks	1 g/kg in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer'

(j) the following rows shall be added at the end of the Annex:

'E 907	Hydrogenated poly-1-decene	As glazing agent for	
		— sugar confectionery	2 g/kg
		— dried fruits	2 g/kg
E 1505	Triethyl citrate	Flavourings	3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination. In the case of beverages, the maximum level of E 1520 shall be 1 g/l.
E 1517	Glyceryl diacetate (diacetin)		
E 1518	Glyceryl triacetate (triacetin)		
E 1520	Propan-1,2-diol (propylene glycol)		
E 1519	Benzyl alcohol	Flavourings for	
		— liqueurs, aromatised wines, aromatised wine-based drinks and aromatised wine-products cocktails	100 mg/l
		— confectionery including chocolate and fine bakery wares	250 mg/kg from all sources in foodstuffs as consumed or as reconstituted according to instruction of the manufacturer'

5. in Annex V:

(a) the following row shall be added at the end of the Annex:

'E 555	Potassium aluminium silicate	In E 171 titanium dioxide and E 172 iron oxides and hydroxides (max 90 % relative to the pigment)
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(b) for E 468, the name 'Cross-linked cellulose gum' shall be added;

6. in Annex VI:

(a) in the introductory note, the following subparagraph shall be inserted after the first subparagraph:

'Formulae and weaning foods for infants and young children may contain E 1450 starch sodium octenyl succinate resulting from the addition of vitamin preparations or polyunsaturated fatty acid preparations. The carry over of E 1450 in the product ready for consumption is not to be more than 100 mg/kg from vitamin preparations and 1 000 mg/kg from polyunsaturated fatty acid preparations.'

(b) in part 4

— the title shall be replaced by the following:

'FOOD ADDITIVES PERMITTED IN DIETARY FOODS FOR INFANTS AND YOUNG CHILDREN FOR SPECIAL MEDICAL PURPOSES AS DEFINED IN DIRECTIVE 1999/21/EC (*)

(*) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, (OJ L 91, 7.4.1999, p. 29).'

— the following shall be added to the table:

'E 472c	Citric acid esters of mono- and diglycerides of fatty acids	7,5 g/l sold as powder 9 g/l sold as liquid	From birth onwards'
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31967L0427

Council Directive 67/427/EEC of 27 June 1967 on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit

Official Journal 148 , 11/07/1967 P. 0001 - 0009

Finnish special edition: Chapter 13 Volume 1 P. 0090

Danish special edition: Series I Chapter 1967 P. 0154

Swedish special edition: Chapter 13 Volume 1 P. 0090

English special edition: Series I Chapter 1967 P. 0169 - 0177

Greek special edition: Chapter 03 Volume 2 P. 0120

Spanish special edition: Chapter 13 Volume 1 P. 0039

Portuguese special edition Chapter 13 Volume 1 P. 0039

COUNCIL DIRECTIVE of 27 June 1967 on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit (67/427/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

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

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament (1);

Having regard to the Opinion of the Economic and Social Committee (2);

Whereas, under Article 5 of the Council Directive of 5 November 1963 (3) on the approximation of the laws of the Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption, as last amended by Article 1 of the Council Directive of 14 December 1966, (4) Member States may, until 30 June 1967, maintain in force the provisions of their national laws relating to the surface treatment of citrus fruit with biphenyl (diphenyl), orthophenylphenol and sodium orthophenylphenate;

Whereas the use of those substances for the surface treatment of citrus fruit does not constitute a danger to health where the residual amount per kilogramme of whole fruit does not exceed 70 milligrammes of biphenyl and 12 milligrammes of orthophenylphenol and sodium orthophenylphenate, expressed as orthophenylphenol;

Whereas, moreover, the treatment carried out should be indicated in an appropriate manner at all stages of marketing;

Whereas, if the three substances in question are to be authorised at Community level, common rules must be laid down for the official control of treated citrus fruit;

Whereas a transitional period is necessary before the provisions of this Directive can be implemented by the Member States ; whereas the provisions of national laws relating to the surface treatment of citrus fruit with the three preservatives in question should therefore be maintained in force until the end of that period;

Whereas a Member State should not be required to authorise the use of a preservative in foodstuffs produced and consumed in its own territory when there is no technological reason to justify such use;

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Council Directive of 5 November 1963 on the approximation of the laws of the Member States Concerning the preservatives authorised for use in foodstuffs for human consumption is hereby amended as follows: 1. In Article 2 (2), for the second sentence there shall be substituted the following:

"However, the laws of a Member State may totally exclude the use of any of the preservatives listed in the Annex only where there is no technological reason for using such preservative foodstuffs produced and consumed in its own territory."

2. The following preservatives shall be added to those listed in Section I of the Annex: (1) OJ No 63, 3.4.1967, p. 990/67. (2) OJ No 64, 5.4.1967, p. 1005/67. (3) OJ No 12, 27.1.1964, p. 161/64. (4) OJ No 233, 20.12.1966, p. 3947/66 >PIC FILE= "T0001696">

3. Subparagraph (b) of Article 5 shall be deleted.

Article 2

The Member States shall take all measures necessary to ensure that the taking of samples and the qualitative and quantitative analysis of biphenyl, orthophenylphenol and sodium orthophenylphenate in and on citrus fruit are carried out in accordance with the provisions of Annexes I, II, III and IV to this Directive.

Article 3

1. Member States shall, not later than 1 July 1968, bring into force the measures necessary to comply with this Directive and shall forthwith inform the Commission thereof.

2. Until 1 July 1968 Member States may maintain in force the provisions of their national laws relating to the surface treatment of citrus fruit with biphenyl, orthophenylphenol and sodium orthophenylphenate.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 June 1967.

For the Council

The President

R. VAN ELSLANDE

ANNEX I PROCEDURE FOR TAKING SAMPLES OF CITRUS FRUIT FOR PRESERVATIVE CONTROL

A. Taking of samples

I. Samples shall be taken using scientific methods which ensure that the samples are representative of the lot to be analysed.

II. The samples must satisfy at least the following requirements: 1. Packaged goods (crates, paperboard boxes, and similar containers) >PIC FILE= "T0001697">

2. Goods in bulk >PIC FILE= "T0001698">

III. By "lot" is meant : a part of a consignment, which part has the same characteristics, such as variety, degree of ripeness, type of packaging.

B. Packaging and delivery of samples

1. The samples shall be placed in air-tight containers;

2. The containers shall be sealed;

3. The samples thus packaged shall be delivered as quickly as possible to the test laboratories.

ANNEX II QUALITATIVE ANALYSIS FOR RESIDUES OF BIPHENYL, ORTHOPHENYLPHENOL AND SODIUM ORTHOPHENYLPHENATE IN CITRUS FRUIT PEEL

1. Purpose and scope

The method described below enables the presence of residues of biphenyl, orthophenylphenol (OPP) or sodium orthophenylphenate in the peel of citrus fruit to be detected. The sensitivity limit of this method, in absolute terms, is approximately 5 µg for biphenyl and 1 milligramme for OPP or sodium orthophenylphenate, which is the equivalent of 5 µg of biphenyl (5 ppm) and 1 milligramme of OPP (1 ppm) respectively in the peel of 1 kilogramme of citrus fruit.

When citrus fruit is treated with the above-mentioned products the residues deposited are found largely in the peel of the fruit. Quantitative analysis of such residues in the whole fruit therefore seems necessary only if they are found in the peel.

2. Principle

An extract is prepared from the peel using dichloromethane in an acid medium. The extract is concentrated and separated by thin layer chromatography using silica gel. The presence of biphenyl, orthophenylphenol or sodium orthophenylphenate is shown by fluorescence and colour tests.

3. Reagents

cyclohexane A.R.

dichloromethane A.R.

hydrochloric acid 25 % (w/v)

silica gel GF 254 Merck or equivalent

0.5 % solution of 2,4,7-trinitrofluorenone (Fluka, B.D.H or equivalent) (TNF) in acetone

0.1 % solution of 2,6-dibromo-benzoquinone-4-chloroimide in ethanol (stable for up to one week if kept in the refrigerator)

concentrated solution of ammonia, S.G. : 0.9

standard 1 % solution of pure biphenyl in cyclohexane

standard 1 % solution of pure orthophenylphenol in cyclohexane

4. Apparatus

mixer

250 ml flask with ground glass joint and with a cooled reflux condenser

reduced pressure evaporator

micropipettes

thin layer chromatographic apparatus with plates measuring 20 X 20 cm

U.V. lamp (254 nm) : the intensity should be such that a spot of 5 µg of biphenyl is visible

equipment for pulverising reagents

oven

5. Method

(a) Preparation of the sample and extraction

All the fruit in the sample for testing is cut in half. Half of each piece of fruit is kept for quantitative determination of residues of biphenyl and/or orthophenylphenol. Pieces of peel are taken from the other halves to give a sample of about 80 grammes. These pieces are chopped,

crushed in the mixer and placed in the 250 ml flask ; to this is added 1 ml of 25 % hydrochloric acid and 100 ml of dichloromethane. The mixture is heated under reflux for ten minutes. After cooling and rinsing of the condenser with about 5 ml of dichloromethane, the mixture is filtered through a fluted filter. The solution is transferred to the evaporator and some porous granules are added. The solution is concentrated at reduced pressure at a temperature of 60 °C to a final volume of about 10 ml. If a rotary evaporator is used, the flask should be kept in a fixed position to avoid loss of biphenyl through the formation of a film of the product on the upper wall of the flask.

(b) Chromatography

30 grammes of silica gel and 60 ml of water are placed in a mixer and mixed for one minute. The mixture is then poured on to 5 chromatographic plates and spread to form a layer approximately 0.250 mm thick. The plates covered with this layer are subjected for fifteen minutes to a stream of hot air and then placed in an oven where they are kept for thirty minutes at a temperature of 110 °C.

After cooling each plate is divided into strips 2 cm wide, by parallel lines penetrating the covering layer down to the surface of the plate. 50 µl of the extract to be analysed are put, as a row of drops, close together on to each strip, approximately 1.5 cm from the edge. At least one strip is kept for the controls consisting of a deposit of 1 µl (that is, 10 µg) of the standard solutions of biphenyl and orthophenylphenol.

The chromatographic plates are developed in a mixture of cyclohexane and dichloromethane (25 : 95) in dishes previously lined with filter paper.

(c) Detection and identification

The presence of biphenyl and orthophenylphenol is shown by the appearance of spots in U.V. light (254 nm). The sodium orthophenylphenate has changed into orthophenylphenol during the extraction in an acid medium, and its presence can not therefore be distinguished from that of orthophenylphenol. The products are identified in the following manner: (i) biphenyl gives a yellow spot in daylight when sprayed with the TNF solution;

(ii) orthophenylphenol gives a blue spot when sprayed with the solution of 2,6-dibromobenzoquinone-4-chlorimide, followed by rapid passage through a stream of hot air and exposure to an ammonia-saturated atmosphere.

ANNEX III QUANTITATIVE ANALYSIS OF THE RESIDUES OF BIPHENYL IN CITRUS FRUIT

1. Purpose and scope

The method described below gives a quantitative analysis of the residues of biphenyl in citrus fruit (whole fruit). The accuracy of the method is $\pm 10\%$ for a biphenyl content greater than 10 milligrammes per kilogramme of fruit (10 ppm).

2. Principle

After distillation in an acid medium and extraction by cyclohexane, the extract is chromatographed in a thin layer on silica gel. The chromatogram is developed and the biphenyl is eluted and determined spectrophotometrically at 248 nm.

3. Reagents

concentrated sulphuric acid solution

silicone-based anti-foaming emulsion

cyclohexane A.R.

hexane A.R.

ethanol A.R.

anhydrous sodium sulphate

silica gel GF 254 Merck or equivalent

standard 1 % solution of pure biphenyl in cyclohexane : dilute with cyclohexane to obtain the following three solutions:

(a) 0.6 $\mu\text{g}/\mu\text{l}$ (b) 1 $\mu\text{g}/\mu\text{l}$ (c) 1.4 $\mu\text{g}/\mu\text{l}$

4. Apparatus

1 mixer (1 litre capacity)

2-litre distillation flask with modified Clevenger-type separator (1) and cooled reflux condenser

10 ml graduated flask (1) See figure on page 180.

50 μl micropipettes

thin layer chromatographic apparatus with 20 X 20 cm plates

oven

centrifuge with 15 ml conical tubes

U.V. spectrophotometer

5. Method (a) Preparation of the sample and extraction

All the fruit in the sample for testing is cut in half.

Half of each piece of fruit is kept for qualitative analysis for residues of biphenyl, OPP or sodium orthophenylphenate. The other halves are put all together and shredded in a mill or crushed until a homogeneous mixture is obtained. From this at least two subsamples of 200 grammes are taken for analysis in the following manner. Each subsample is placed in a mixer with 100 ml of water and mixed at slow speed for several seconds. Water is added until the volume of the mixture reaches three-quarters of the capacity of the mixer, and the mixture is then mixed for five minutes at full speed. The resulting purée is transferred to the 2-litre distillation flask. The mixer is rinsed with water and the rinsings added to the contents of the flask. (The total quantity of water to be used in the mixing and rinsing is 1 l). To the mixture are added 2 ml sulphuric acid, 1 ml anti-foaming emulsion and several porous granules. The separator and reflux condenser are fitted on to the flask. Distilled water is poured into the separator until the water level is well past the lower arm of the lateral return tube, followed by 7 ml of cyclohexane. This is distilled for about two hours. The contents of the separator are then collected in the 10 ml graduated flask, the separator is rinsed with about 1.5 ml of cyclohexane and the rinsings added to the contents of the flask, which are then brought up to volume with cyclohexane. Finally a little anhydrous sodium sulphate is added and the mixture is shaken.

(b) Chromatography

30 grammes of silica gel and 60 ml of water are placed in a mixer and mixed for one minute. The mixture is then poured on to 5 chromatographic plates and spread to form a layer approximately 0.250 mm thick. The plates covered with this layer are subjected for fifteen minutes to a stream of hot air and then placed in an oven where they are kept for thirty minutes at a temperature of 110 °C. After cooling each plate is divided into four strips 4.5 cm wide, by parallel lines penetrating the covering layer down to the surface of the plate. 50 μl of the extract to be analysed are put, as a row of drops, close together on to one of the strips approximately 1.5 cm from the edge of the plate. On to each of the three other strips are put in the same way 50 μl of the standard solutions (a), (b) and (c), corresponding respectively to 30, 50 and 70 μl levels of biphenyl.

If the analyses are made in series, standard solutions need not be put on to each plate and a standard curve may be produced from the average of the values obtained from at least five plates, with the same standard amounts.

(c) Development of chromatograms and elution

The chromatograms are developed with hexane to a height of 17 cm in dishes previously lined with filter paper. The plates are air dried. The areas in which the biphenyl is localised are picked out in U.V. light (254 nm), and marked off in rectangles of equal areas.

The areas thus marked off are immediately scraped clean with a spatula, through the full thickness of the supporting layer. The biphenyl is extracted from this by 10 ml of ethanol, for ten minutes, shaking several times. The mixture is transferred to the centrifuge tubes and centrifuged for five minutes at 2500 r.p.m.

A sample control area of the same size is taken by the same method. If the analyses are made in series, this control area is taken from an unused strip of the plate ; if the analyses are made individually, it is taken from one of the strips containing a standard solution located below the area containing the biphenyl.

(d) Spectrophotometric determination

The supernatant liquid is decanted into the spectrophotometer cells and the extinction determined at 248 nm and compared with a control extract from a chromatographic area free from biphenyl.

6. Calculation of results

A standard curve is drawn, plotting the biphenyl values of 30, 50 and 70 µg against the corresponding extinctions, as determined on the spectrophotometer. This gives a straight line which passes through the origin. This graph allows the biphenyl content of the samples to be read directly in ppm from the extinction value of their extracts.

ANNEX IV QUANTITATIVE ANALYSIS OF THE RESIDUES ORTHOPHENYLPHENOL AND SODIUM ORTHOPHENYLPHENATE IN CITRUS FRUIT

1. Purpose and scope

The method described below enables a quantitative analysis of the residues of orthophenylphenol (OPP) and sodium orthophenylphenate in citrus fruit (whole fruit) to be made. The method gives results which for an OPP or sodium orthophenylphenate content of the order of 12 ppm are low by an average value of between 10 % and 20 %.

2. Principle

After distillation in an acid medium and extraction by di-isopentyl ether, the extract is purified and treated with a solution of 4-amino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one (= 4-aminoantipyrine). A red colour develops the intensity of which is measured by spectrophotometry at 510 nm.

3. Reagents

70 % orthophosphoric acid

silicone-based anti-foaming emulsion

di-isopentyl ether A.R.

purified cyclohexane ; shake three times with a 4 % solution of sodium hydroxide, wash three times with distilled water

4 % sodium hydroxide solution

buffer solution at pH 10.4 : into a 2-litre graduated flask put 6.64 grammes of boric acid, 8.00 grammes of potassium chloride and 93.1 ml of N sodium hydroxide solution : mix and bring up to calibration mark with distilled water

reagent I : dissolve 1.0 grammes of 4-amino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one (= 4-aminotipyrine) in 100 ml of distilled water

reagent II : dissolve 2.0 grammes of potassium ferrocyanide in 100 ml of distilled water.
Reagents I and II must be kept in brown glass flasks and are only stable for approximately fourteen days

silica gel

standard solution : dissolve 10 milligrammes of pure OPP in 1 ml of 0.1 N NaOH ; dilute to 100 ml with a 0.2 m sodium borate solution (1 ml = 100 µg). For the standard solution, dilute 1 : 10 with the buffer solution.

4. Apparatus

shredding or crushing mill

mixer

1-litre distillation flask with modified Clevenger type separator (1) and reflux condenser

infra-red bath

200 ml separating funnel

graduated cylinders of 25 and 100 ml

graduated flasks of 25 and 100 ml

1 to 10 ml pipettes

0.5 ml graduated pipettes

spectrophotometer with 5 cm cells

5. Method

All the fruit in the sample for checking is cut in half. Half of each piece of fruit is kept for qualitative analysis for residues of biphenyl, OPP or sodium orthophenylphenate. The other halves are put all together and shredded in a mill or crushed until a homogeneous mixture is obtained. From this at least two sub-samples of 250 grammes are taken for analysis in the following manner.

Each sub-sample is placed in a mixer with 500 ml of water and mixed until a very fine homogeneous mixture is obtained in which the oily cells are no longer perceptible. A sample of 150 to 300 grammes of the purée is taken, depending on the presumed OPP content and placed in the 1-litre distillation flask with a quantity of water sufficient to dilute the mixture to 500 grammes in the flask. After the addition of 10 ml of 70 % orthophosphoric acid, several porous granules and 0.5 ml of anti-foaming emulsion, the separator and the reflux condenser are fitted on to the flask. 10 ml of di-isopentyl ether is put into the separator and the flask is heated gently in the infra-red bath, without allowing the purée to boil or foam. After distilling for about six hours, the contents of the separator are poured into the 200 ml separating funnel, and the separator and the condenser are rinsed with 60 ml of cyclohexane and then with 60 ml of water. The rinsings are added to the contents of the separating funnel. The mixture is shaken vigorously and when the phases have separated the aqueous phase is discarded.

To extract the OPP, the organic phase is shaken vigorously five times, each time for three minutes, with 10 ml of 4 % sodium hydroxide. The alkaline solutions are combined, neutralised to pH 9-10 with orthophosphoric acid in the presence of phenolphthalein paper, and diluted to 100 ml with distilled water. A pinch of silica gel is added in order to clarify the solution which will have a slightly cloudy appearance. The solution is then shaken and filtered through a dry, fine-grain filter. Since the colouring is developed with the maximum of accuracy and precision using quantities of OPP of between 10 and 70 µg, an aliquot sample of between 0.5 and 10 ml of solution is taken with a pipette, taking into account the quantities of OPP which might be expected to be found. The sample is placed in a 25 ml graduated flask ; to this are added 0.5 ml of reagent I, 10 ml of the buffer solution and then 0.5 ml of reagent II. The mixture is made up to the calibration mark with the buffer solution and shaken vigorously.

After five minutes the extinction of the red colouring at 510 nm is measured with the spectrophotometer in comparison with a control containing no extract. The colour does not lose intensity within thirty minutes. Evaluation is made by referring to a standard curve drawn under the same conditions using the standard OPP solution.

6. Observations

For each analysis it is recommended that the spectrophotometric determination be made in duplicate with different volumes of the neutralised alkaline extract.

Non-treated citrus fruit give by this method a "blank" reading of up to 0.5 ppm for oranges and 0.8 ppm for lemons. (1) See figure on page 180.

CLEVENGER

(Annex III, Chapter 4;

Annex IV, Chapter 4)

>PIC FILE= "T0001699">

31978L0663

Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

Official Journal L 223 , 14/08/1978 P. 0007 - 0029

Finnish special edition: Chapter 13 Volume 9 P. 0003

Greek special edition: Chapter 03 Volume 22 P. 0104

Swedish special edition: Chapter 13 Volume 9 P. 0003

Spanish special edition: Chapter 13 Volume 8 P. 0242

Portuguese special edition Chapter 13 Volume 8 P. 0242

COUNCIL DIRECTIVE of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (78/663/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (1), as last amended by Directive 78/612/EEC (2), and in particular Article 7 (1) thereof,

Having regard to the proposal from the Commission,

Whereas under Article 6 of Directive 74/329/EEC emulsifiers, stabilizers, thickeners and gelling agents must satisfy specific criteria of purity established in accordance with Article 7 (1) of that Directive,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The specific criteria of purity referred to in Article 6 (1) (b) of Directive 74/329/EEC are given in the Annex to this Directive.

Article 2

As regards the substances referred to in the Annex under numbers E 474 and E 477, the Council may, acting unanimously on a proposal from the Commission, decide on any necessary amendments by 31 December 1981 following an enquiry by the Commission.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months after the notification of this Directive. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1978.

For the Council

The President

H.J. ROHR (1)OJ No L 189, 12.7.1974, p. 1. (2)OJ No L 197, 22.7.1978, p. 22.

ANNEX SPECIFIC CRITERIA OF PURITY FOR EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS FOR USE IN FOODSTUFFS

General observations (a) Where interpretation of the criteria set out below requires the definition of certain technical details, reference should be made to the methods of analysis established pursuant to Article 7 (2) of Directive 74/329/EEC.

(b) Unless otherwise stated, the quantities and percentages shall be calculated in terms of weight of the product as such.

(c) The specific criteria of purity applicable to substances E 322, E 339 (i), (ii) and (iii), E 340 (i), (ii) and (iii) and E 341 (i) and (ii) are laid down by Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption (1). The regime applicable to hydrolysed lecithins is set out in the same Directive.

>PIC FILE= "T0013353"> (1)See page 30 of this Official Journal.

>PIC FILE= "T0013354">

>PIC FILE= "T0013355">

>PIC FILE= "T0013356">

>PIC FILE= "T0013357">

>PIC FILE= "T0013358">

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>PIC FILE= "T0013361">

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>PIC FILE= "T0013370">

>PIC FILE= "T0013371">

>PIC FILE= "T0013372">

>PIC FILE= "T0013373">

>PIC FILE= "T0013374">

31982L0504

Council Directive 82/504/EEC of 12 July 1982 amending Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs^M

Official Journal L 230 , 05/08/1982 P. 0035 - 0037

Finnish special edition: Chapter 13 Volume 12 P. 0103

Spanish special edition: Chapter 13 Volume 12 P. 0245

Swedish special edition: Chapter 13 Volume 12 P. 0103

Portuguese special edition Chapter 13 Volume 12 P. 0245

COUNCIL DIRECTIVE of 12 July 1982 amending Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (82/504/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (1), as last amended by Directive 80/597/EEC (2), and in particular Article 7 (1) thereof,

Having regard to the proposal from the Commission,

Whereas Council Directive 78/663/EEC (3) lays down specific criteria of purity for emulsifiers, stabilizers, thickness and gelling agents for use in foodstuffs;

Whereas Directive 80/597/EEC has amended Annex I to Directive 74/329/EEC so as to authorize Xanthan gum (E 415) and powdered cellulose (E 460 - (ii)) and, for this reason, the criteria of purity of these substances should be defined and the nomenclature of E 460 amended in consequence;

Whereas Directive 78/663/EEC provides that, as regards substances E 474 and E 477, the Council may, acting unanimously on a proposal from the Commission, decide on any necessary amendments by 31 December 1981;

Whereas the criteria of purity for substances E 400, E 401, E 402, E 403, E 404 and E 405 should be modified to take account of scientific developments, particularly of methods of analysis,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 78/663/EEC is hereby amended as follows: 1. Article 2 shall be replaced by the following:

"Article 2

As regards the substances referred to in the Annex under E 477, Member States may, until 31 December 1984, authorize for use in foodstuffs a product containing not more than 4 % dimer and trimer of propane-1,2-diol."

2. The Annex shall be amended as follows: (a) Under E 400, E 401, E 402, E 403, E 404 and E 405, the entries relating to insoluble matter in dilute NaOH shall be deleted, and the text of the entries relating to acid-insoluble ash shall be replaced by "Not more than 2 %". (1) OJ No L 189, 12.7.1974, p. 1. (2) OJ No L 155, 23.6.1980, p. 23. (3) OJ No L 223, 14.8.1978, p. 7.

(b) The following shall be inserted between E 414 and E 420 - (i): >PIC FILE= "T0022631">

(c) The number "E 460" shall become "E 460 - (i)".

(d) The following shall be inserted between E 460 - (i) and E 461: >PIC FILE= "T0022632">

(e) Under E 474:

- The last sentence of the text of the entry relating to chemical description shall be replaced by the following:

"No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, isobutanol and isopropanol."

- The following new entry shall be added: >PIC FILE= "T0022633">

(f) Under E 477, the entry relating to dimer and trimer of propane-1,2-diol shall be replaced by the following:

"Not more than 0.75 %."

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1984. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 12 July 1982.

For the Council

The President

J. NØRGAARD

31990L0612

Commission Directive 90/612/EEC of 26 October 1990 amending Council Directive 78/663/EEC laying down specific purity criteria for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

Official Journal L 326 , 24/11/1990 P. 0058 - 0059

Finnish special edition: Chapter 13 Volume 19 P. 0255

Swedish special edition: Chapter 13 Volume 19 P. 0255

COMMISSION DIRECTIVE of 26 October 1990 amending Council Directive 78/663/EEC laying down specific purity criteria for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (90/612/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (3) thereof,

Whereas it is necessary to take into consideration the revised Codex Alimentarius specifications for substances E407 and E466, authorize new techniques for the production of E473 and draw a distinction between substance E407 as described in the Annex to Council Directive 78/663/EEC (2), as amended by Directive 82/504/EEC (3), and similar products not covered by that Annex;

Whereas the Scientific Committee for Food has been consulted, in accordance with Article 6 of Directive 89/107/EEC, on those provisions likely to affect public health;

Whereas the measures laid down by this Directive comply with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 78/663/EEC is hereby amended as set out 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 12 months after notification of the present Directive. 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 procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 26 October 1990.

For the Commission

Martin BANGEMANN

Vice-President

(1) OJ No L 40, 11. 2. 1989, p. 27.

(2) OJ No L 223, 14. 8. 1978, p. 7.

(3) OJ No L 230, 5. 8. 1982, p. 35.

ANNEX 1. Under E 407 - Carrageenan, the point concerning ash insoluble in 1 % v/v sulphuric acid shall be replaced by the following:

'acid-insoluble ash (insoluble in 10 % w/v hydrochloric acid) not more than 1 % dry matter acid-insoluble matter (insoluble in 1 % v/v sulphuric acid) not more than 2 % dry matter.'

2. Under E 466 - Carboxymethylcellulose, the point concerning molecular weight shall be replaced by the following:

'higher than approximately 17 000 (degree of polymerization approximately 100)'.

3. Under E 473 - Sucrose esters:

(a) the last sentence of the point concerning the chemical description shall be replaced by the following sentence:

'No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, isopropanol and isobutanol may be used for their preparation';

(b) below the point concerning sulphated ash, the following point shall be added:

'dimethylsulphoxide content not more than 2 mg/kg';

(c) below the point concerning the methanol content, the following point shall be added:

'isobutanol content not more than 10 mg/kg'.

31992L0004

Commission Directive 92/4/EEC of 10 February 1992 amending Council Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

Official Journal L 055 , 29/02/1992 P. 0096 - 0097

Finnish special edition: Chapter 13 Volume 22 P. 0004

Swedish special edition: Chapter 13 Volume 22 P. 0004

COMMISSION DIRECTIVE 92/4/EEC of 10 February 1992 amending Council Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (3) thereof,

Whereas taking into account the specifications as adopted by the Codex Alimentarius and to take into account new production techniques, it is necessary to amend Council Directive 78/663/EEC (2), as last amended by Commission Directive 90/612/EEC (3);

Whereas, in pursuance of Article 6 of Directive 89/107/EEC, the Scientific Committee of Foodstuffs was consulted on the provisions likely 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

The Annex to Directive 78/663/EEC is hereby amended as set out 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 by 1 June 1993, at the latest, and shall forthwith inform the Commission thereof.

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

Article 3

This Directive is addressed to the Member States. Done at Brussels, 10 February 1992. For the Commission

Martin BANGEMANN

Vice-President

(1) OJ No L 40, 11. 2. 1989, p. 27. (2) OJ No L 223, 14. 8. 1978, p. 7. (3) OJ No L 326, 24. 11. 1990, p. 58.

ANNEX

The Annex to Directive 78/663/EEC is amended as follows:

Under E 473 - Sucrose esters:

(a) the final sentence in the item on the chemical description is replaced by the following sentence:

'No organic solvent other than dimethylsulphoxide, diméthylformamide, ethyl acetate, isopropanol, isobutanol and methylethylketon may be used in their preparation.'

(b) below the point concerning the isobutanol content, the following point is added:

'Methylethylketon content / not more than 10 mg/kg.'

31996L0077

Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance)

Official Journal L 339 , 30/12/1996 P. 0001 - 0069

COMMISSION DIRECTIVE 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), as amended by European Parliament and Council Directive 94/34/EC (2), and in particular Article 3 (3) (a) thereof,

After consulting the Scientific Committee for Food,

Whereas it is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (3);

Whereas it is necessary to replace the purity criteria set out in Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorized for use in foodstuffs intended for human consumption (4), as last amended by Directive 86/604/EEC (5);

Whereas it is necessary to replace the purity criteria set out in Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption (6), as amended by Directive 82/712/EEC (7);

Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;

Whereas it is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, if prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3 (3) (a) of Directive 89/107/EEC for food additives other than colours and sweeteners, as mentioned in Directive 95/2/EC, are set out in the Annex hereto.

Article 2

Directives 65/66/EEC and 78/664/EEC are hereby repealed.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall immediately 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 procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before 1 July 1997 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 2 December 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 27.

(2) OJ No L 237, 10. 9. 1994, p. 1.

(3) OJ No L 61, 18. 3. 1995, p. 1.

(4) OJ No 22, 9. 2. 1965, p. 373.

(5) OJ No L 352, 13. 12. 1986, p. 45.

(6) OJ No L 223, 14. 8. 1978, p. 30.

(7) OJ No L 297, 23. 10. 1982, p. 31.

ANNEX

>TABLE>

31998L0086

Commission Directive 98/86/EC of 11 November 1998 amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance)

Official Journal L 334 , 09/12/1998 P. 0001 - 0063

COMMISSION DIRECTIVE 98/86/EC of 11 November 1998 amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 (1), as amended by European Parliament and Council Directive 94/34/EC (2) and in particular Article 3(3)(a) thereof;

After consulting the Scientific Committee for Food;

Whereas, it is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (3), as last amended by Directive 98/72/EC (4);

Whereas, it is necessary to replace the purity criteria set out in Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents which may be used in foodstuffs intended for human consumption (5), as last amended by Commission Directive 92/4/EEC (6);

Whereas Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners (7) set out a first list of purity criteria for a number of food additives; whereas this list should now be complemented with the newly established purity criteria for other additives;

Whereas it is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

Whereas food additives, if prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/77/EC shall be amended as follows:

1. Article 2 is replaced by the following:

'Article 2

The purity criteria referred to in Article 1 replace the purity criteria set out in Directives 65/66/EEC, 78/663/EEC and 78/664/EEC.'

2. In the Annex, the text of the Annex to this Directive shall be added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1999. They shall immediately 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 procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before 1 July 1999 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 3

This Directive shall enter into force on the 20th 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, 11 November 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 40, 11.2.1989, p. 27.

(2) OJ L 237, 10.9.1994, p. 1.

(3) OJ L 61, 18.3.1995, p. 1.

(4) OJ L 295, 4.11.1998, p. 18.

(5) OJ L 223, 14.8.1978, p. 7.

(6) OJ L 55, 29.2.1992, p. 96.

(7) OJ L 339, 30.12.1996, p. 1.

ANNEX

'Ethylene oxide may not be used for sterilising purposes in food additives

>TABLE>

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32000L0063

Commission Directive 2000/63/EC of 5 October 2000 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance.)

Official Journal L 277 , 30/10/2000 P. 0001 - 0061

Commission Directive 2000/63/EC

of 5 October 2000

amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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(1), as amended by Directive of the European Parliament and of the Council 94/34/EC(2) and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee for Food,

Whereas:

(1) It is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in 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), as last amended by Directive 98/72/EC(4).

(2) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners(5), as amended by Directive 98/86/EC(6) set out purity criteria for a number of food additives. This Directive should now be completed with purity criteria for the remaining food additives mentioned in Directive 95/2/EC.

(3) It is necessary, in the light of technical development, to amend the purity criteria set out in Directive 96/77/EC for butylated hydroxyanisole (BHA). It is consequently necessary to adapt that Directive.

(4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(5) Food additives, if prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for safety evaluation by the Scientific Committee for Food with emphasis on the purity criteria.

(6) 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 96/77/EC shall be amended as follows:

1. In the Annex, the text concerning E 320 - butylated hydroxyanisole (BHA) shall be replaced by the text in Annex I to this Directive.
2. In the Annex, the text of Annex II to this Directive shall be added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 31 March 2001. They shall immediately inform the Commission thereof.
2. 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.
3. Products put on the market or labelled before 31 March 2001 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 3

This Directive shall enter into force on the twentieth 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, 5 October 2000.

For the Commission

David Byrne

Member of the Commission

(1) OJ L 40, 11.2.1989, p. 27.

(2) OJ L 237, 10.9.1994, p. 1.

(3) OJ L 61, 18.3.1995, p. 1.

(4) OJ L 295, 4.11.1998, p. 18.

(5) OJ L 339, 30.12.1996, p. 1.

(6) OJ L 334, 9.12.1998, p. 1.

ANNEX I

">TABLE>"

ANNEX II

">TABLE>"

I

(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2001/30/EC**of 2 May 2001****amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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⁽¹⁾, as amended by Directive 94/34/EC of the European Parliament and of the Council⁽²⁾ and in particular Article 3(3)(a) thereof,

After consulting Scientific Committee on Food,

Whereas:

- (1) It is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in 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⁾, as last amended by Directive 2001/5/EC⁽⁴⁾.
- (2) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners⁽⁵⁾, as last amended by Directive 2000/63/EC⁽⁶⁾ set out purity criteria for a number of food additives. This Directive should now be completed with purity criteria for the remaining food additives mentioned in Directive 95/2/EC.
- (3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/77/EC is hereby amended as follows:

In the Annex, the text of the Annex to this Directive shall be added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 June 2002 at the latest. They shall forthwith inform the Commission thereof.

2. 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.

3. Products put on the market or labelled before 1 June 2002 which do not comply with this Directive may be marketed until stocks are exhausted.

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 May 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 55, 24.2.2001, p. 59.

⁽⁵⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁶⁾ OJ L 227, 30.10.2000, p. 1.

ANNEX

E 170 (i) CALCIUM CARBONATE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs ⁽¹⁾.

⁽¹⁾ OJ L 226, 22.9.1995, p. 13.

E 353 METATARTARIC ACID**Synonyms**

Ditartaric acid

Definition*Chemical name*

Metatartaric acid

Chemical formula $C_4H_6O_6$ *Assay*

Not less than 99,5 %

Description

Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel

Identification

A.

Very soluble in water and ethanol.

B.

Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulfuric acid and 2 drops of sulpho-resorcinol reagent. When heated to 150 °C, an intense violet coloration appears

Purity

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 354 CALCIUM TARTRATE**Synonyms**

L-Calcium tartrate

Definition*Chemical name*

Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate

Chemical formula $C_4H_4CaO_6 \cdot 2H_2O$ *Molecular weight*

224,18

Assay

Not less than 98,0 %

Description

Fine crystalline powder with a white or off-white colour

Identification

A. Slightly soluble in water. Solubility approximately 0,01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids

B. Specific rotation $[\alpha]^{20}_D$	+7,0° to +7,4° (0,1 % in a 1N de HCl solution)
C. pH of a 5 % slurry	Between 6,0 and 9,0
Purity	
Sulphates (as H ₂ SO ₄)	Not more than 1 g/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 356 SODIUM ADIPATE**Definition**

<i>Chemical name</i>	Sodium adipate
EINECS	231-293-5
<i>Chemical formula</i>	C ₆ H ₈ Na ₂ O ₄
<i>Molecular weight</i>	190,11
<i>Assay</i>	Content not less than 99,0 % (on anhydrous basis)
<i>Description</i>	White odourless crystals or crystalline powder

Identification

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium	

Purity

Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 357 POTASSIUM ADIPATE**Definition**

<i>Chemical name</i>	Potassium adipate
EINECS	242-838-1
<i>Chemical formula</i>	C ₆ H ₈ K ₂ O ₄
<i>Molecular weight</i>	222,32
<i>Assay</i>	Content not less than 99,0 % (on anhydrous basis)
<i>Description</i>	White odourless crystals or crystalline powder

Identification

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium	

Purity

Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 420(i) SORBITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽¹⁾.

E 420(ii) SORBITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 421 MANNITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

⁽¹⁾ OJ L 178, 28.7.1995, p. 1.

E 425(i) KONJAC GUM**Definition**

Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac*. The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by $\beta(1-4)$ -glycosidic bonds. Shorter side chains are attached through $\beta(1-3)$ -glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units.

Molecular weight	The main component, glucomannan, has an average molecular weight of 200 000 to 2 000 000
Assay	Not less than 75 % carbohydrate
Description	A white to cream to light tan powder

Identification

A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0
B. Gel formation	Add 5 ml of a 4 % sodium borate solution to a 1 % solution of the sample in a test tube, and shake vigorously. A gel forms
C. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
D. Viscosity (1 % solution)	Not less than 3 kgm ⁻¹ s ⁻¹ at 25 °C

Purity

Loss on drying	Not more than 12 % (105 °C, 5 h)
Starch	Not more than 3 %
Protein	Not more than 3 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,1 %
Total ash	Not more than 5,0 % (800 °C, 3 to 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

E 425(ii) KONJAC GLUCOMANNAN**Definition**

Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated

Molecular weight	500 000 to 2 000 000
Assay	Total dietary fibre: not less than 95 % on a dry weight basis
Description	White to slightly brownish fine particle size, free flowing and odourless powder

Identification

A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation
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B. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
C. Viscosity (1 % solution)	Not less than 20 kgm ⁻¹ s ⁻¹ at 25 °C
Purity	
Loss on drying	Not more than 8 % (105 °C, 3h)
Starch	Not more than 1 %
Protein	Not more than 1,5 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,5 %
Sulphite (as SO ₂)	Not more than 4 mg/kg
Chloride	Not more than 0,02 %
50 % Alcohol-soluble	Not more than 2,0 % material
Total ash	Not more than 2,0 % (800 °C, 3 to 4h)
Lead	Not more than 1 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

E 504(ii) MAGNESIUM HYDROXIDE CARBONATE

Synonyms	Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide
Definition	
<i>Chemical name</i>	Magnesium carbonate hydroxide hydrated
EINECS	235-192-7
<i>Chemical formula</i>	4MgCO ₃ Mg(OH) ₂ 5H ₂ O
<i>Molecular weight</i>	485
<i>Assay</i>	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO
<i>Description</i>	Light, white friable mass or bulky white powder
Identification	
A. Positive tests for magnesium and for carbonate	
B. Solubility	Practically insoluble in water. Insoluble in ethanol

Purity

Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1,0 %
Calcium	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 553b TALC**Synonyms**

Talcum

Definition

Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite

Chemical name

Magnesium hydrogen metasilicate

EINECS

238-877-9

Chemical formula $\text{Mg}_3(\text{Si}_4\text{O}_{10})(\text{OH})_2$ *Molecular weight*

379,22

Description

Light, homogeneous, white or almost white powder, greasy to the touch

Identification

A. IR absorption

Characteristic peaks at 3 677, 1 018 and 669 cm^{-1}

B. X-ray diffraction

Peaks at 9,34 / 4,66 / 3,12 Å

C. Solubility

Insoluble in water and ethanol

Purity

Loss on drying	Not more than 0,5 % (105 °C, 1h)
Acid-soluble matter	Not more than 6 %
Water-soluble matter	Not more than 0,2 %
Acid-soluble iron	Not detectable
Arsenic	Not more than 10 mg/kg
Lead	Not more than 5 mg/kg

E 554 SODIUM ALUMINIUM SILICATE**Synonyms**

Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate

Definition*Chemical name*

Sodium aluminium silicate

Assay

Content on the anhydrous basis:

— as SiO_2 not less than 66,0 % and not more than 88,0 %— as Al_2O_3 not less than 5,0 % and not more than 15,0 %*Description*

Fine white amorphous powder or beads

Identification

A. Positive tests for sodium, for aluminium and for silicate

B. pH of a 5 % slurry

Between 6,5 and 11,5

Purity

Loss on drying

Not more than 8,0 % (105 °C, 2h)

Loss on ignition

Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C, constant weight)

Sodium

Not less than 5 % and not more than 8,5 % (as Na_2O) on the anhydrous basis

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 555 POTASSIUM ALUMINIUM SILICATE**Synonyms**

Mica

Definition

Natural mica consists of mainly potassium aluminium silicate (muscovite)

EINECS

310-127-6

Chemical name

Potassium aluminium silicate

Chemical formulae $\text{KAl}_2[\text{AlSi}_3\text{O}_{10}](\text{OH})_2$ *Molecular weight*

398

Assay

Content not less than 98 %

Description

Light grey to white crystalline platelets or powder

Identification

A. Solubility

Insoluble in water, diluted acids and alkali and organic solvents

Purity

Loss on drying

Not more than 0,5 % (105 °C, 2h)

Antimony

Not more than 20 mg/kg

Zinc

Not more than 25 mg/kg

Barium	Not more than 25 mg/kg
Chromium	Not more than 100 mg/kg
Copper	Not more than 25 mg/kg
Nickel	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Lead	Not more than 10 mg/kg

E 556 CALCIUM ALUMINIUM SILICATE**Synonyms**

Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate

Definition*Chemical name*

Calcium aluminium silicate

Assay

Content on the anhydrous basis:

- as SiO_2 not less than 44,0 % and not more than 50,0 %
- as Al_2O_3 not less than 3,0 % and not more than 5,0 %
- as CaO not less than 32,0 % and not more than 38,0 %

Description

Fine white, free-flowing powder

Identification

A. Positive tests for calcium, for aluminium and for silicate

Purity

Loss on drying

Not more than 10,0 % (105 °C, 2h)

Loss on ignition

Not less than 14,0 % and not more than 18,0 on the anhydrous basis (1 000 °C, constant weight)

Fluoride

Not more than 50 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

E 558 BENTONITE**Definition**

Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms were naturally replaced by other atoms such as magnesium and iron. Calcium and sodium ions are trapped between the mineral layers. There are four common types of bentonite: natural sodium bentonite, natural calcium bentonite, sodium-activated bentonite and acid-activated bentonite

EINECS

215-108-5

Chemical formula $(\text{Al, Mg})_8(\text{Si}_4\text{O}_{10})_4(\text{OH})_8 \cdot 12\text{H}_2\text{O}$ *Molecular weight*

819

Assay

Montmorillonite content not less than 80 %

Description

Very fine, yellowish or greyish white powder or granules. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties)

Identification

A. Methylene blue test

B. X-Ray diffraction

Characteristic peaks at 12,5/15 Å

C. IR absorption

Peaks at 428/470/530/1 110-1 020/3 750 — 3 400 cm^{-1} **Purity**

Loss on drying

Not more than 15,0 % (105 °C, 2h)

Arsenic

Not more than 2 mg/kg

Lead

Not more than 20 mg/kg

E 559 ALUMINIUM SILICATE (KAOLIN)**Synonyms**

Kaolin, light or heavy

Definition

Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination

EINECS

215-286-4 (kaolinite)

Chemical formula $\text{Al}_2\text{Si}_2\text{O}_5(\text{OH})_4$ (kaolinite)*Molecular weight*

264

Assay

Content not less than 90 % (sum of silica and alumina, after ignition)

Silica (SiO_2) Between 45 % and 55 %Alumina (Al_2O_3) Between 30 % and 39 %*Description*

Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes

Identification

A. Positive tests for alumina and for silicate

B. X-ray diffraction:

characteristic peaks at 7,18 / 3,58 / 2,38 / 1,78 Å

C. IR absorption:

peaks at 3 700 and 3 620 cm^{-1}

Purity

Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
Water soluble matter	Not more than 0,3 %
Acid soluble matter	Not more than 2,0 %
Iron	Not more than 5 %
Potassium oxide (K ₂ O)	Not more than 5 %
Carbon	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 620 GLUTAMIC ACID**Synonyms**L-Glutamic acid, L- α -aminoglutaric acid**Definition**

Chemical name L-Glutamic acid, L-2-amino-pentanedioic acid

EINECS

200-293-7

Chemical formula

C₅H₉NO₄

Molecular weight

147,13

Assay

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

Description

White crystals or crystalline powder

Identification

A. Positive test for glutamic acid by thin layer chromatography

B. Specific rotation $[\alpha]_D^{20}$

Between + 31,5° and + 32,2°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

C. pH of a saturated solution

Between 3,0 and 3,5

Purity

Loss on drying	Not more than 0,2 % (80 °C, 3h)
Sulphated ash	Not more than 0,2 %
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 621 MONOSODIUM GLUTAMATE**Synonyms**

Sodium glutamate, MSG

Definition*Chemical name*

Monosodium L-glutamate monohydrate

EINECS

205-538-1

Chemical formula $C_5H_8NaNO_4 \cdot H_2O$ *Molecular weight*

187,13

Assay

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

Description

White, practically odourless crystals or crystalline powder

Identification

A. Positive test for sodium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation $[\alpha]_D^{20}$ Between + 24,8° and + 25,3°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

D. pH of a 5 % solution

Between 6,7 and 7,2

Purity

Loss on drying

Not more than 0,5 % (98 °C, 5h)

Chloride

Not more than 0,2 %

Pyrrolidone carboxylic acid

Not more than 0,2 %

Lead

Not more than 2 mg/kg

E 622 MONOPOTASSIUM GLUTAMATE**Synonyms**

Potassium glutamate, MPG

Definition*Chemical name*

Monopotassium L-glutamate monohydrate

EINECS

243-094-0

Chemical formula $C_5H_8KNO_4 \cdot H_2O$ *Molecular weight*

203,24

Assay

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

Description

White, practically odourless crystals or crystalline powder

Identification

- A. Positive test for potassium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation $[\alpha]_D^{20}$
- D. pH of a 2 % solution

Between + 22,5° and + 24,0°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

Between 6,7 and 7,3

Purity

- Loss on drying
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 0,2 % (80 °C, 5h)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

E 623 CALCIUM DIGLUTAMATE**Synonyms**

Calcium glutamate

Definition

Chemical name

Monocalcium di-L-glutamate

EINECS

242-905-5

Chemical formula

$C_{10}H_{16}CaN_2O_8 \cdot x H_2O$ (x = 0, 1, 2 or 4)

Molecular weight

332,32 (anhydrous)

Assay

Content not less than 98,0 % and not more than 102,0 % on the anhydrous basis

Description

White, practically odourless crystals or crystalline powder

Identification

- A. Positive test for calcium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation $[\alpha]_D^{20}$

Between + 27,4 and + 29,2 (for calcium diglutamate with x = 4) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

Purity

- Water
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 19,0 % (for calcium diglutamate with x = 4) (Karl Fischer)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

E 624 MONOAMMONIUM GLUTAMATE**Synonyms**

Ammonium glutamate

Definition*Chemical name*

Monoammonium L-glutamate monohydrate

EINECS

231-447-1

Chemical formula $C_5H_{12}N_2O_4 \cdot H_2O$ *Molecular weight*

182,18

Assay

Content not less than 99,0 % and not more 101,0 % on the anhydrous basis

Description

White, practically odourless crystals or crystalline powder

Identification

A. Positive test for ammonium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation $[\alpha]_D^{20}$ Between + 25,4° and + 26,4°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

D. pH of a 5 % solution

Between 6,0 and 7,0

Purity

Loss on drying

Not more than 0,5 % (50 °C, 4h)

Sulphated ash

Not more than 0,1 %

Pyrrolidone carboxylic acid

Not more than 0,2 %

Lead

Not more than 2 mg/kg

E 625 MAGNESIUM DIGLUTAMATE**Synonyms**

Magnesium glutamate

Definition*Chemical name*

Monomagnesium di-L-glutamate tetrahydrate

EINECS

242-413-0

Chemical formula $C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$ *Molecular weight*

388,62

Assay

Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis

Description

Odourless, white or off-white crystals or powder

Identification

- A. Positive test for magnesium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation $[\alpha]_D^{20}$
- D. pH of a 10 % solution

Between + 23,8° and + 24,4°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

Between 6,4 and 7,5

Purity

- Water
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 24 % (Karl Fischer)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

E 626 GUANYLIC ACID**Synonyms**

Guanylic acid

Definition

Chemical name

Guanosine-5'-monophosphoric acid

EINECS

201-598-8

Chemical formula

$C_{10}H_{14}N_5O_8P$

Molecular weight

363,22

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, colourless or white crystals or white crystalline powder

Identification

- A. Positive test for ribose and for organic phosphate
- B. pH of a 0,25 % solution
- C. Spectrometry:

Between 1,5 and 2,5

maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

Purity

- Loss on drying
- Other nucleotides
- Lead

Not more than 1,5 % (120 °C, 4h)

Not detectable by thin-layer chromatography

Not more than 2 mg/kg

E 627 DISODIUM GUANYLATE**Synonyms**

Sodium guanylate, sodium 5'-guanylate

Definition

<i>Chemical name</i>	Disodium guanosine-5'-monophosphate
EINECS	221-849-5
<i>Chemical formula</i>	$C_{10}H_{12}N_5Na_2O_8P \cdot x H_2O$ (x = ca. 7)
<i>Molecular weight</i>	407,19 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder

Identification

A. Positive test for ribose, for organic phosphate, and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

Purity

Loss on drying	Not more than 25 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 628 DIPOTASSIUM GUANYLATE**Synonyms**

Potassium guanylate, potassium 5'-guanylate

Definition

<i>Chemical name</i>	Dipotassium guanosine-5'-monophosphate
EINECS	226-914-1
<i>Chemical formula</i>	$C_{10}H_{12}K_2N_5O_8P$
<i>Molecular weight</i>	439,40
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder

Identification

A. Positive test for ribose, for organic phosphate, and for potassium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

Purity

Loss on drying	Not more than 5 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 629 CALCIUM GUANYLATE**Synonyms**

Calcium 5'-guanylate

Definition*Chemical name*

Calcium guanosine-5'-monophosphate

Chemical formula $C_{10}H_{12}CaN_5O_8P \cdot nH_2O$ *Molecular weight*

401,20 (anhydrous)

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, white or off-white crystals or powder

Identification

A. Positive test for ribose, for organic phosphate, and for calcium

B. pH of a 0,05 % solution

Between 7,0 and 8,0

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

Purity

Loss on drying

Not more than 23,0 % (120 °C, 4h)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

E 630 INOSINIC ACID**Synonyms**

5'-Inosinic acid

Definition*Chemical name*

Inosine-5'-monophosphoric acid

EINECS

205-045-1

Chemical formula $C_{10}H_{13}N_4O_8P$ *Molecular weight*

348,21

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, colourless or white crystals or powder

Identification

A. Positive test for ribose, and for organic phosphate

B. pH of a 5 % solution

Between 1,0 and 2,0

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Loss on drying	Not more than 3,0 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 631 DISODIUM INOSINATE**Synonyms**

Sodium inosinate, sodium 5'-inosinate

Definition

<i>Chemical name</i>	Disodium inosine-5'-monophosphate
EINECS	225-146-4
<i>Chemical formula</i>	$C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$
<i>Molecular weight</i>	392,17 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or powder

Identification

A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Water	Not more than 28,5 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 632 DIPOTASSIUM INOSINATE**Synonyms**

Potassium inosinate, potassium 5'-inosinate

Definition

<i>Chemical name</i>	Dipotassium inosine-5'-monophosphate
EINECS	243-652-3
<i>Chemical formula</i>	$C_{10}H_{11}K_2N_4O_8P$
<i>Molecular weight</i>	424,39
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or powder

Identification

- A. Positive test for ribose, and for organic phosphate and for potassium
- B. pH of a 5 % solution
- C. Spectrometry:

Between 7,0 and 8,5

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Water

Not more than 10,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

E 633 CALCIUM INOSINATE**Synonyms**

Calcium 5'-inosinate

Definition*Chemical name*

Calcium inosine-5'-monophosphate

Chemical formula $C_{10}H_{11}CaN_4O_8P \cdot nH_2O$ *Molecular weight*

386,19 (anhydrous)

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, colourless or white crystals or powder

Identification

- A. Positive test for ribose, and for organic phosphate and for calcium
- B. pH of a 0,05 % solution
- C. Spectrometry:

Between 7,0 and 8,0

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Water

Not more than 23,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

E 634 CALCIUM 5'-RIBONUCLEOTIDE**Definition***Chemical name*

Calcium 5'-ribonucleotide is essentially a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate

Chemical formula $C_{10}H_{11}N_4CaO_8P \cdot nH_2O$ y $C_{10}H_{12}N_5CaO_8P \cdot nH_2O$

Assay	Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis
Description	Odourless, white or nearly white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
Purity	
Water	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 635 DISODIUM 5'-RIBONUCLEOTIDE

Synonyms	Sodium 5'-ribonucleotide
Definition	
Chemical name	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4O_8P \cdot nH_2O$ and $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$
Assay	Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis
Description	Odourless, white or nearly white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
Purity	
Water	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax
Definition	Microcrystalline wax is a refined mixture of solid, saturated hydrocarbons, mainly branched paraffin, obtained from petroleum
Description	White to amber, odourless wax

Identification

A. Solubility

Insoluble in water, very slightly soluble in ethanol

B. Refractive Index

 n_D^{100} 1,434-1,448**Purity**

Molecular weight

Average not less than 500

Viscosity at 100 °C

Not less than $1,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$

Residue on ignition

Not more than 0,1 %

Carbon number at 5 %
distillation point

Not more than 5 % of molecules with carbon number less than 25

Colour

Passes test

Sulphur

Not more than 0,4 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 3 mg/kg

Polycyclic aromatic compounds

The polycyclic aromatic hydrocarbons, obtained by extraction with dimethyl sulfoxide, shall meet the following ultraviolet absorbency limits:

nm	Maximum absorbance per cm path length
280-289	0,15
290-299	0,12
300-359	0,08
360-400	0,02

E 912 MONTAN ACID ESTERS**Definition**

Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol

Chemical name

Montan acid esters

Description

Almost white to yellowish flakes, powder, granules or pellets

Identification

A. Density (20 °C)

Between 0,98 and 1,05

B. Drop point

Greater than 77 °C

Purity

Acid value

Not more than 40

Glycerol

Not more than 1 % (by gas chromatography)

Other polyols

Not more than 1 % (by gas chromatography)

Other wax types	Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
Arsenic	Not more than 2 mg/kg
Chromium	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

E 914 OXIDISED POLYETHYLENE WAX**Definition**

Polar reaction products from mild oxidation of polyethylene

Chemical name

Oxidised polyethylene

Description

Almost white flakes, powder, granules or pellets

Identification

A. Density (20 °C)

Between 0,92 and 1,05

B. Drop point

Greater than 95 °C

Purity

Acid value

Not more than 70

Viscosity at 120 °C

Not less than $8,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$

Other wax types

Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)

Oxygen

Not more than 9,5 %

Chromium

Not more than 5 mg/kg

Lead

Not more than 2 mg/kg

E 950 ACESULFAME K

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 951 ASPARTAME

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 953 ISOMALT

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC, as amended by Directive 98/66/EC, laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 957 THAUMATIN

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 959 NEOHESPERIDINE DIHYDROCHALCONE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(i) MALTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(ii) MALTITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 966 LACTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 967 XYLITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

I

(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2002/82/EC**of 15 October 2002****amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 ⁽¹⁾, as amended by Directive 94/34/EC of the European Parliament and of the Council ⁽²⁾ and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) 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⁾, as last amended by Directive 2001/5/EC ⁽⁴⁾, lists those substances which may be used as additives other than colours and sweeteners in foodstuffs.
- (2) Commission Directive 96/77/EC ⁽⁵⁾, as last amended by Directive 2001/30/EC ⁽⁶⁾ sets out the purity criteria for the additives other than colours and sweeteners mentioned in Directive 95/2/EC.
- (3) It is necessary to adapt to technical progress existing purity criteria set out in Directive 96/77/EC and to establish new purity criteria for those food additives for which these were failing.

(4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(5) Directive 96/77/EC should therefore 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 96/77/EC is amended as set out 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 by 31 August 2003 at the latest. 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 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 twentieth day following that of its publication in the *Official Journal of the European Communities*.

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 55, 24.2.2001, p. 59.

⁽⁵⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁶⁾ OJ L 146, 31.5.2001, p. 1.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 October 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

- (1) The text concerning E 338 Phosphoric acid, E 339 (i) Monosodium Phosphate, E 339 (ii) Disodium Phosphate, E 339 (iii) Trisodium Phosphate, E 340 (i) Monopotassium Phosphate, E 340 (ii) Dipotassium Phosphate, E 340 (iii) Tripotassium Phosphate, E 341 (i) Monocalcium Phosphate, E 341 (ii) Dicalcium Phosphate, E 341 (iii) Tricalcium Phosphate, E 450 (i) Disodium Diphosphate, E 450 (ii) Trisodium Diphosphate, E 450 (iii) Tetrasodium Diphosphate, E 450 (v) Tetrapotassium Diphosphate, E 450 (vi) Dicalcium Diphosphate, E 450 (vii) Calcium Dihydrogen Diphosphate, E 451 (i) Pentasodium Triphosphate and E 451 (ii) Pentapotassium Triphosphate, E 452 (i) Sodium Polyphosphate, E 452 (ii) Potassium Polyphosphate and E 452 (iv) Calcium Polyphosphate is replaced by the following:

E 338 PHOSPHORIC ACID**Synonyms**

Orthophosphoric acid

Monophosphoric acid

Definition*Chemical name*

Phosphoric acid

EINECS

231-633-2

Chemical formula H_3PO_4 *Molecular weight*

98,00

Assay

Phosphoric acid is commercially available as an aqueous solution at variable concentrations. Content not less than 67,0 % and not more than 85,7 %.

Description

Clear, colourless, viscous liquid

Identification

A. Positive tests for acid and for phosphate

Purity

Volatile acids

Not more than 10 mg/kg (as acetic acid)

Chlorides

Not more than 200 mg/kg (expressed as chlorine)

Nitrates

Not more than 5 mg/kg (as $NaNO_3$)

Sulphates

Not more than 1 500 mg/kg (as $CaSO_4$)

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

Note:

This specification refers to a 75 % aqueous solution.

E 339 (i) MONOSODIUM PHOSPHATE**Synonyms**

Monosodium monophosphate
 Acid monosodium monophosphate
 Monosodium orthophosphate
 Monobasic sodium phosphate
 Sodium dihydrogen monophosphate

Definition*Chemical name*

Sodium dihydrogen monophosphate

EINECS

231-449-2

*Chemical formula*Anhydrous: NaH_2PO_4 Monohydrate: $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ Dihydrate: $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ *Molecular weight*

Anhydrous: 119,98

Monohydrate: 138,00

Dihydrate: 156,01

*Assay*After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH_2PO_4 *P₂O₅ content*

Between 58,0 % and 60,0 % on the anhydrous basis

Description

A white odourless, slightly deliquescent powder, crystals or granules

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol or ether

C. pH of a 1 % solution

Between 4,1 and 5,0

Purity

Loss on drying

The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, and the dihydrate not more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 339 (ii) DISODIUM PHOSPHATE**Synonyms**

Disodium monophosphate
 Secondary sodium phosphate
 Disodium orthophosphate
 Acid disodium phosphate

Definition*Chemical name*

Disodium hydrogen monophosphate
 Disodium hydrogen orthophosphate

EINECS

231-448-7

Chemical formula

Anhydrous: Na_2HPO_4
 Hydrat: $\text{Na}_2\text{HPO}_4 \cdot n\text{H}_2\text{O}$ ($n = 2, 7$ or 12)

Molecular weight

141,98 (anhydrous)

Assay

After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na_2HPO_4

P₂O₅ content

Between 49 % and 51 % on the anhydrous basis

Description

Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol

C. pH of a 1 % solution

Between 8,4 and 9,6

Purity

Loss on drying

When dried at 40 °C for three hours and then at 105°C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE**Synonyms**

Sodium phosphate
 Tribasic sodium phosphate
 Trisodium orthophosphate

Definition

Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H₂O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains ¼ molecule of NaOH

Chemical name

Trisodium monophosphate
 Trisodium phosphate
 Trisodium orthophosphate

EINECS

231-509-8

Chemical formula

Anhydrous: Na₃PO₄
 Hydrated: Na₃PO₄ · nH₂O (n = 1/2, 1, 6, 8, or 12)

Molecular weight

163,94 (anhydrous)

Assay

Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na₃PO₄ calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na₃PO₄ calculated on the ignited basis

P₂O₅ content

Between 40,5 % and 43,5 % on the anhydrous basis

Description

White odourless crystals, granules or crystalline powder

Identification

- A. Positive tests for sodium and for phosphate
- B. Solubility
- C. pH of a 1 % solution

Freely soluble in water. Insoluble in ethanol
 Between 11,5 and 12,5

Purity*Loss on ignition*

When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %

Water insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 340 (i) MONOPOTASSIUM PHOSPHATE**Synonyms**

Monobasic potassium phosphate
 Monopotassium monophosphate
 Potassium orthophosphate

Definition*Chemical name*

Potassium dihydrogen phosphate
 Monopotassium dihydrogen orthophosphate
 Monopotassium dihydrogen monophosphate

EINECS

231-913-4

Chemical formula KH_2PO_4 *Molecular weight*

136,09

Assay

Content not less than 98,0 % after drying at 105 °C for four hours

P₂O₅ content

Between 51,0 % and 53,0 % on the anhydrous basis

Description

Odourless, colourless crystals or white granular or crystalline powder,
 hygroscopic

Identification

A. Positive tests for potassium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol

C. pH of a 1 % solution

Between 4,2 and 4,8

Purity

Loss on drying

Not more than 2,0 % determined by drying at 105 °C for four hours

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 340 (ii) DIPOTASSIUM PHOSPHATE**Synonyms**

Dipotassium monophosphate
 Secondary potassium phosphate
 Dipotassium acid phosphate
 Dipotassium orthophosphate
 Dibasic potassium phosphate

Definition*Chemical name*

Dipotassium hydrogen monophosphate
 Dipotassium hydrogen phosphate
 Dipotassium hydrogen orthophosphate

EINECS

231-834-5

Chemical formula

K_2HPO_4

Molecular weight

174,18

Assay

Content not less than 98 % after drying at 105°C for four hours

P₂O₅ content

Between 40,3 % and 41,5 % on the anhydrous basis

Description

Colourless or white granular powder, crystals or masses; deliquescent substance

Identification

A. Positive tests for potassium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol

C. pH of a 1 % solution

Between 8,7 and 9,4

Purity

Loss on drying

Not more than 2,0 % determined by drying at 105 °C for four hours

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 340 (iii) TRIPOTASSIUM PHOSPHATE**Synonyms**

Potassium phosphate
 Tribasic potassium phosphate
 Tripotassium orthophosphate

Definition*Chemical name*

Tripotassium monophosphate
 Tripotassium phosphate
 Tripotassium orthophosphate

EINECS

231-907-1

Chemical formula

Anhydrous: K_3PO_4
 Hydrated: $K_3PO_4 \cdot nH_2O$ ($n = 1$ or 3)

Molecular weight

212,27 (anhydrous)

Assay

Content not less than 97 % calculated on the ignited basis

P₂O₅ content

Between 30,5 % and 33,0 % on the ignited basis

Description

Colourless or white, odourless hygroscopic crystals or granules.
 Hydrated forms available include the monohydrate and trihydrate

Identification

A. Positive tests for potassium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol

C. pH of a 1 % solution

Between 11,5 and 12,3

Purity

Loss on ignition

Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %.
 Determined by drying at 105 °C for one hour and then ignite at about 800 °C ± 25 °C for 30 minutes

Water insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE**Synonyms**

Monobasic calcium phosphate
Monocalcium orthophosphate

Definition*Chemical name*

Calcium dihydrogen phosphate

EINECS

231-837-1

*Chemical formula*Anhydrous: $\text{Ca}(\text{H}_2\text{PO}_4)_2$ Monohydrate: $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$ *Molecular weight*

234,05 (anhydrous)

252,08 (monohydrate)

Assay

Content not less than 95 % on the dried basis

P₂O₅ content

Between 55,5 % and 61,1 % on the anhydrous basis

Description

Granular powder or white, deliquescent crystals or granules

Identification

A. Positive tests for calcium and for phosphate

B. CaO content

Between 23,0 % and 27,5 % (anhydrous)

Between 19,0 % and 24,8 % (monohydrate)

Purity

Loss on drying

Not more than 14 % determined by drying at 105 °C for four hours (anhydrous)

Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)

Loss on ignition

Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous)

Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)

Fluoride

Not more than 30 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE**Synonyms**

Dibasic calcium phosphate
Dicalcium orthophosphate

Definition*Chemical name*

Calcium monohydrogen phosphate
Calcium hydrogen orthophosphate
Secondary calcium phosphate

EINECS

231-826-1

Chemical formula

Anhydrous: CaHPO_4
Dihydrate: $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$

Molecular weight

136,06 (anhydrous)
172,09 (dihydrate)

Assay

Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of CaHPO_4

P₂O₅ content

Between 50,0 % and 52,5 % on the anhydrous basis

Description

White crystals or granules, granular powder or powder

Identification

A. Positive tests for calcium and for phosphate

B. Solubility tests

Sparingly soluble in water. Insoluble in ethanol

Purity

Loss on ignition

Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes

Fluoride

Not more than 50 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 341 (iii) TRICALCIUM PHOSPHATE**Synonyms**

Calcium phosphate, tribasic
 Calcium orthophosphate
 Pentacalcium hydroxy monophosphate
 Calcium hydroxyapatite

Definition

Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of $10\text{CaO} \cdot 3\text{P}_2\text{O}_5 \cdot \text{H}_2\text{O}$

Chemical name

Pentacalcium hydroxy monophosphate
 Tricalcium monophosphate

EINECS

235-330-6 (*Pentacalcium hydroxy monophosphate*)
 231-840-8 (*Calcium orthophosphate*)

Chemical formula

$\text{Ca}_5(\text{PO}_4)_3 \cdot \text{OH}$ or $\text{Ca}_3(\text{PO}_4)_2$

Molecular weight

502 or 310

Assay

Content not less than 90 % calculated on the ignited basis

P₂O₅ content

Between 38,5 % and 48,0 % on the anhydrous basis

Description

A white, odourless powder which is stable in air

Identification

A. Positive tests for calcium and for phosphate

B. Solubility

Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid

Purity

Loss on ignition

Not more than 8 % after ignition at $800\text{ }^\circ\text{C} \pm 25\text{ }^\circ\text{C}$, to constant weight

Fluoride

Not more than 50 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (i) DISODIUM DIPHOSPHATE**Synonyms**

Disodium dihydrogen diphosphate
Disodium dihydrogen pyrophosphate
Sodium acid pyrophosphate
Disodium pyrophosphate

Definition*Chemical name*

Disodium dihydrogen diphosphate

EINECS

231-835-0

Chemical formula $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ *Molecular weight*

221,94

Assay

Content not less than 95 % of disodium diphosphate.

P₂O₅ Content

Not less than 63,0 % and not more than 64,5 %

Description

White powder or grains

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Soluble in water

C. pH of a 1 % solution

Between 3,7 and 5,0

Purity

Loss on drying

Not more than 0,5 % (105 °C, four hours)

Water-insoluble matter

Not more than 1 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE**Synonyms**

Acid trisodium pyrophosphate
Trisodium monohydrogen diphosphate

Definition*EINECS*

238-735-6

Chemical formula

Monohydrate: $\text{Na}_3\text{HP}_2\text{O}_7 \cdot \text{H}_2\text{O}$
Anhydrous: $\text{Na}_3\text{HP}_2\text{O}_7$

Molecular weight

Monohydrate: 261,95
Anhydrous: 243,93

Assay

Content not less than 95 % on the anhydrous basis

P₂O₅ content

Not less than 57 % and not more than 59 %

Description

White powder or grains, occurs anhydrous or as a monohydrate

Identification

A. Positive tests for sodium and for phosphate

B. Soluble in water

C. pH of a 1 % solution

Between 6,7 and 7,5

Purity

Loss on ignition

Not more than 4,5 % on the anhydrous compound
Not more than 11,5 % on the monohydrous basis

Loss on drying

Not more than 0,5 % (105 °C, four hours)

Water-insoluble matter

Not more than 0,2 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (iii) TETRASODIUM DIPHOSPHATE**Synonyms**

Tetrasodium pyrophosphate
Sodium pyrophosphate

Definition*Chemical name*

Tetrasodium diphosphate

EINECS

231-767-1

Chemical formula

Anhydrous: $\text{Na}_4\text{P}_2\text{O}_7$
Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10\text{H}_2\text{O}$

Molecular weight

Anhydrous: 265,94
Decahydrate: 446,09

*Assay*Content not less than 95 % of $\text{Na}_4\text{P}_2\text{O}_7$ on the ignited basis *P_2O_5 content*

Not less than 52,5 % and not more than 54,0 %

Description

Colourless or white crystals, or a white crystalline or granular powder.
The decahydrate effloresces slightly in dry air

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Soluble in water. Insoluble in ethanol

C. pH of a 1 % solution

Between 9,8 and 10,8

Purity

Loss on ignition

Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes

Water-insoluble matter

Not more than 0,2 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE**Synonyms**

Potassium pyrophosphate
Tetrapotassium pyrophosphate

Definition

Chemical name

Tetrapotassium diphosphate

EINECS

230-785-7

Chemical formula

$K_4P_2O_7$

Molecular weight

330,34 (anhydrous)

Assay

Content not less than 95 % on the ignited basis

P₂O₅ content

Not less than 42,0 % and not more than 43,7 % on the anhydrous basis

Description

Colourless crystals or white, very hygroscopic powder

Identification

A. Positive tests for potassium and for phosphate

B. Solubility

Soluble in water, insoluble in ethanol

C. pH of a 1 % solution

Between 10,0 and 10,8

Purity

Loss on ignition

Not more than 2 % after drying at 105 °C for four hours and then ignition at 550 °C for 30 minutes

Water-insoluble substances

Not more than 0,2 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE**Synonyms**

Calcium pyrophosphate

Definition*Chemical name*

Dicalcium diphosphate

Dicalcium pyrophosphate

EINECS

232-221-5

Chemical formula $\text{Ca}_2\text{P}_2\text{O}_7$ *Molecular weight*

254,12

Assay

Content not less than 96 %

P₂O₅ content

Not less than 55 % and not more than 56 %

Description

A fine, white, odourless powder

Identification

A. Positive tests for calcium and for phosphate

B. Solubility

Insoluble in water. Soluble in dilute hydrochloric and nitric acids

C. pH of a 10 % suspension in water

Between 5,5 and 7,0

Purity

Loss on ignition

Not more than 1,5 % at 800 °C ± 25 °C for 30 minutes

Fluoride

Not more than 50 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE**Synonyms**

Acid calcium pyrophosphate
Monocalcium dihydrogen pyrophosphate

Definition

Chemical name

Calcium dihydrogen diphosphate

EINECS

238-933-2

Chemical formula

$\text{CaH}_2\text{P}_2\text{O}_7$

Molecular weight

215,97

Assay

Content not less than 90 % on the anhydrous basis

P₂O₅ content

Not less than 61 % and not more than 64 %

Description

White crystals or powder

Identification

A. Positive tests for calcium and for phosphate

Purity

Acid-insoluble matter

Not more than 0,4 %

Fluoride

Not more than 30 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 451 (i) PENTASODIUM TRIPHOSPHATE**Synonyms**

Pentasodium tripolyphosphate
Sodium tripolyphosphate

Definition*Chemical name*

Pentasodium triphosphate

EINECS

231-838-7

Chemical formula $\text{Na}_5\text{O}_{10}\text{P}_3 \cdot n\text{H}_2\text{O}$ (n = 0 or 6)*Molecular weight*

367,86

Assay

Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)

P₂O₅ content

Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)

Description

White, slightly hygroscopic granules or powder

Identification

A. Solubility

Freely soluble in water. Insoluble in ethanol

B. Positive tests for sodium and for phosphate

C. pH of a 1 % solution

Between 9,1 and 10,2

Purity

Loss on drying

Anhydrous: Not more than 0,7 % (105 °C, one hour)
Hexahydrate: Not more than 23,5 % (60 °C, one hour, followed by drying at 105 °C, four hours)

Water-insoluble substances

Not more than 0,1 %

Higher polyphosphates

Not more than 1 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE**Synonyms**

Pentapotassium triphosphate

Potassium triphosphate

Potassium tripolyphosphate

Definition*Chemical name*

Pentapotassium triphosphate

Pentapotassium tripolyphosphate

EINECS

237-574-9

Chemical formula $K_5O_{10}P_3$ *Molecular weight*

448,42

Assay

Content not less than 85 % on the anhydrous basis

P₂O₅ content

Not less than 46,5 % and not more than 48 %

Description

White, very hygroscopic powder or granules

Identification

A. Solubility

Very soluble in water

B. Positive tests for potassium and for phosphate

C. pH of a 1 % solution

Between 9,2 and 10,5

Purity

Loss on ignition

Not more than 0,4 % (after drying at 105 °C, four hours, followed by ignition at 550 °C, 30 minutes)

Water-insoluble matter

Not more than 2 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE**1. SOLUBLE POLYPHOSPHATE****Synonyms**

Sodium hexametaphosphate
Sodium tetrapolyphosphate
Graham's salt
Sodium polyphosphates, glassy
Sodium polymetaphosphate
Sodium metaphosphate

Definition

Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, $(\text{NaPO}_3)_x$ where $x \geq 2$, terminated by Na_2PO_4 groups. These substances are usually identified by their $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio or their P_2O_5 content. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratios vary from about 1,3 for sodium tetrapolyphosphate, where $x =$ approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where $x = 13$ to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where $x = 20$ to 100 or more. The pH of their solutions varies from 3,0 to 9,0

Chemical name

Sodium polyphosphate

EINECS

272-808-3

Chemical formula

Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2

Molecular weight $(102)_n$ *Assay P_2O_5 content*

Not less than 60 % and not more than 71 % on the ignited basis

Description

Colourless or white, transparent platelets, granules, or powders

Identification

A. Solubility

Very soluble in water

B. Positive tests for sodium and for phosphate

C. pH of a 1 % solution

Between 3,0 and 9,0

Purity

Loss on ignition

Not more than 1 %

Water-insoluble matter

Not more than 0,1 %

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

2. INSOLUBLE POLYPHOSPHATE

Synonyms

Insoluble sodium metaphosphate
Maddrell's salt
Insoluble sodium polyphosphate, IMP

Definition

Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(\text{NaPO}_3)_x$ that spiral in opposite directions about a common axis. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5

Chemical name

Sodium polyphosphate

EINECS

272-808-3

Chemical formula

Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2

Molecular weight $(102)_n$ *P₂O₅ content*

Not less than 68,7 % and not more than 70,0 %

Description

White crystalline powder

Identification

A. Solubility

Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides

B. Positive tests for sodium and for phosphate

C. pH of 1 in 3 suspension in water

About 6,5

Purity

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 452 (ii) POTASSIUM POLYPHOSPHATE**Synonyms**

Potassium metaphosphate
Potassium polymetaphosphate
Kurrol salt

Definition*Chemical name*

Potassium polyphosphate

EINECS

232-212-6

Chemical formula $(\text{KPO}_3)_n$

Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2

Molecular weight $(118)_n$ *P₂O₅ content*

Not less than 53,5 % and not more than 61,5 % on the ignited basis

Description

Fine white powder or crystals or colourless glassy platelets

Identification

A. Solubility

1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate

B. Positive tests for potassium and for phosphate

C. pH of a 1 % suspension

Not more than 7,8

Purity

Loss on ignition

Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)

Cyclic phosphate

Not more than 8 % on P₂O₅ content

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATE**Synonyms**

Calcium metaphosphate
Calcium polymetaphosphate

Definition*Chemical name*

Calcium polyphosphate

EINECS

236-769-6

Chemical formula $(\text{CaP}_2\text{O}_6)_n$

Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(n+1)}$ where 'n' is not less than 2

Molecular weight $(198)_n$ *P₂O₅ content*

Not less than 71 % and not more than 73 % on the ignited basis

Description

Odourless, colourless crystals or white powder

Identification

A. Solubility

Usually sparingly soluble in water. Soluble in acid medium

B. Positive tests for calcium and for phosphate

C. CaO content

27 to 29,5 %

Purity

Loss on ignition

Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)

Cyclic phosphate

Not more than 8 % on P₂O₅ content

Fluoride

Not more than 30 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg'

- (2) The following text relating to E 650 Zinc acetate, E 943a Butane, E 943b Isobutane, E 944 Propane, E 949 Hydrogen, E 1201 Polyvinylpyrrolidone and E 1202 Polyvinylpyrrolidone is added:

E 650 ZINC ACETATE**Synonyms**

Acetic acid, zinc salt, dihydrate

Definition*Chemical name*

Zinc acetate dihydrate

Chemical formula $C_4H_6O_4 \text{ Zn} \cdot 2H_2O$ *Molecular weight*

219,51

*Assay*Content not less than 98 % and not more than 102 % of $C_4H_6O_4 \text{ Zn} \cdot 2H_2O$ *Description*

Colourless crystals or fine, off-white powder

Identification

A. Positive tests for acetate and for zinc

B. pH of a 5 % solution

Between 6,0 and 8,0

Purity

Insoluble matter

Not more than 0,005 %

Chlorides

Not more than 50 mg/kg

Sulphates

Not more than 100 mg/kg

Alkalines and alkaline earths

Not more than 0,2 %

Organic volatile impurities

Passes test

Iron

Not more than 50 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 20 mg/kg

Cadmium

Not more than 5 mg/kg

E 943a BUTANE**Synonyms**

n-Butane

Definition*Chemical name*

Butane

Chemical formula $CH_3CH_2CH_2CH_3$ *Molecular weight*

58,12

Assay

Content not less than 96 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

108,935 kPa at 20 °C

Purity

Methane

Not more than 0,15 % v/v

Ethane

Not more than 0,5 % v/v

Propane

Not more than 1,5 % v/v

Isobutane	Not more than 3,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 943b ISOBUTANE**Synonyms**

2-methyl propane

Definition*Chemical name*

2-methyl propane

Chemical formula $(\text{CH}_3)_2\text{CH CH}_3$ *Molecular weight*

58,12

Assay

Content not less than 94 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

205,465 kPa at 20 °C

Purity

Methane

Not more than 0,15 % v/v

Ethane

Not more than 0,5 % v/v

Propane

Not more than 2,0 % v/v

n-Butane

Not more than 4,0 % v/v

1,3-butadiene

Not more than 0,1 % v/v

Moisture

Not more than 0,005 %

E 944 PROPANE**Definition***Chemical name*

Propane

Chemical formula $\text{CH}_3\text{CH}_2\text{CH}_3$ *Molecular weight*

44,09

Assay

Content not less than 95 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

732,910 kPa at 20 °C

Purity

Methane

Not more than 0,15 % v/v

Ethane

Not more than 1,5 % v/v

Isobutane

Not more than 2,0 % v/v

n-Butane

Not more than 1,0 % v/v

1,3-butadiene

Not more than 0,1 % v/v

Moisture

Not more than 0,005 %

E 949 HYDROGEN**Definition**

<i>Chemical name</i>	Hydrogen
<i>EINECS</i>	215-605-7
<i>Chemical formula</i>	H ₂
<i>Molecular weight</i>	2
<i>Assay</i>	Content not less than 99,9 %
<i>Description</i>	Colourless, odourless, highly flammable gas

Purity

Water	Not more than 0,005 % v/v
Oxygen	Not more than 0,001 % v/v
Nitrogen	Not more than 0,75 % v/v

E 1201 POLYVINYLPIRROLIDONE**Synonyms**

Povidone
PVP
Soluble polyvinylpyrrolidone

Definition

<i>Chemical name</i>	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidiny)-ethylene]
<i>Chemical formula</i>	(C ₆ H ₉ NO) _n
<i>Molecular weight</i>	Not less than 25 000
<i>Assay</i>	Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis
<i>Description</i>	White or nearly white powder

Identification

A. Solubility	Soluble in water and in ethanol. Insoluble in ether
B. pH of a 5 % solution	Between 3,0 and 7,0

Purity

Water	Not more than 5 % (Karl Fischer)
Total ash	Not more than 0,1 %
Aldehyde	Not more than 500 mg/kg (as acetaldehyde)
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Hydrazine	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg

E 1202 POLYVINYLPIRROLIDONE**Synonyms**

Crospovidone
Cross linked polyvidone
Insoluble polyvinylpyrrolidone

Definition

Polyvinylpyrrolidone is a poly-[1-(2-oxo-1-pyrrolidiny)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination

Chemical name

Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidiny)-ethylene]

Chemical formula

$(C_6H_9NO)_n$

Assay

Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis

Description

A white hygroscopic powder with a faint, non-objectionable odour

Identification

A. Solubility

Insoluble in water, ethanol and ether

B. pH of a 1 % suspension in water

Between 5,0 and 8,0

Purity

Water

Not more than 6 % (Karl Fischer)

Sulphated ash

Not more than 0,4 %

Water-soluble matter

Not more than 1 %

Free-N-vinylpyrrolidone

Not more than 10 mg/kg

Free-N,N'-divinyl-imidazolidone

Not more than 2 mg/kg

Lead

Not more than 5 mg/kg'.

COMMISSION DIRECTIVE 2003/95/EC
of 27 October 2003
amending Directive 96/77/EC laying down specific purity criteria on food additives other than
colours and sweeteners
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 ⁽¹⁾, as amended by Directive 94/34/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) 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⁾, as last amended by Directive 2001/5/EC ⁽⁴⁾, lays down a list of substances which may be used as additives other than colours and sweeteners in foodstuffs.
- (2) Commission Directive 96/77/EC ⁽⁵⁾, as last amended by Directive 2002/82/EC ⁽⁶⁾, sets out the purity criteria for the additives mentioned in Directive 95/2/EC.
- (3) The Scientific Committee on Food concluded in its opinion of 6 May 2002 that the presence of ethylene oxide should be brought below the detection limit. Consequently, the relevant criterion of the existing purity criteria set out in Directive 96/77/EC needs to be adapted.
- (4) It is necessary to adapt to technical progress the existing purity criteria for E 251 sodium nitrate and E 459 beta-cyclodextrin.
- (5) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (6) Directive 96/77/EC should therefore be amended accordingly.
- (7) 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 96/77/EC is amended as set out 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 by 1 November 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 shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

Products put on the market or labelled before 1 November 2004 which do not comply with this Directive may be marketed until stocks are exhausted.

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, 27 October 2003.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 55, 24.2.2001, p. 59.

⁽⁵⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁶⁾ OJ L 292, 28.10.2002, p. 1.

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

1. The text concerning E 251 sodium nitrate is replaced by the following:

E 251 SODIUM NITRATE**1. SOLID SODIUM NITRATE****Synonyms**

Chile saltpetre
Cubic or soda nitre

Definition

Chemical name

Sodium nitrate

EINECS

231-554-3

Chemical formula

NaNO₃

Molecular weight

85,00

Assay

Content not less than 99 % after drying

Description

White crystalline, slightly hygroscopic powder

Identification

A. Positive tests for nitrate and for sodium

B. pH of a 5 % solution

Not less than 5,5 and not more than 8,3

Purity

Loss on drying

Not more than 2 % after drying at 105 °C for four hours

Nitrites

Not more than 30 mg/kg expressed as NaNO₂

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 251 SODIUM NITRATE**2. LIQUID SODIUM NITRATE****Definition**

Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoichiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.

Chemical name

Sodium nitrate

EINECS

231-554-3

Chemical formula

NaNO₃

Molecular weight

85,00

Assay

Content between 33,5 % and 40,0 % of NaNO₃

Description

Clear colourless liquid

Identification

A. Positive tests for nitrate and for sodium

B. pH

Not less than 1,5 and not more than 3,5

Purity

Free nitric acid

Not more than 0,01 %

Nitrites

Not more than 10 mg/kg expressed as NaNO₂

Arsenic

Not more than 1 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 0,3 mg/kg

This specification refers to a 35 % aqueous solution.

2. The text concerning E 431 Polyoxyethylene (40) stearate, E 432 Polyoxyethylene sorbitan monolaurate (Polysorbate 20), E 433 Polyoxyethylene sorbitan monooleate (Polysorbate 80), E 434 Polyoxyethylene sorbitan monopalmitate (Polysorbate 40), E 435 Polyoxyethylene sorbitan monostearate (Polysorbate 60) and E 436 Polyoxyethylene sorbitan tristearate (Polysorbate 65) is replaced by the following:

'E 431 POLYOXYETHYLENE (40) STEARATE

Synonyms

Polyoxyl (40) stearate

Definition

polyoxyethylene (40) monostearate

A mixture of the mono- and diesters of edible commercial stearic acid and mixed polyoxyethylene diols (having an average polymer length of about 40 oxyethylene units) together with free polyol

Assay

Content not less than 97,5 % on the anhydrous basis

Description

Cream-coloured flakes or waxy solid at 25 °C with a faint odour

Identification

A. Solubility

Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil

B. Congealing range

39 °C — 44 °C

C. Infrared absorption spectrum

Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water

Not more than 3 % (Karl Fischer method)

Acid value

Not more than 1

Saponification value

Not less than 25 and not more than 35

Hydroxyl value

Not less than 27 and not more than 40

1,4-dioxane

Not more than 5 mg/kg

Ethylene oxide

Not more than 0,2 mg/kg

Ethylene glycols (mono- and di-)

Not more than 0,25 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

E 432 POLYOXYETHYLENE SORBITAN MONOLAUROATE (POLYSORBATE 20)

Synonyms

Polysorbate 20

Polyoxyethylene (20) sorbitan monolaurate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis

Description

A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification

A. Solubility

Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether

B. Infrared absorption spectrum

Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 40 and not more than 50
Hydroxyl value	Not less than 96 and not more than 108
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)**Synonyms**

Polysorbate 80
Polyoxyethylene (20) sorbitan monooleate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis

Description

A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 65 and not more than 80
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)

Synonyms	<p>Polysorbate 40</p> <p>Polyoxyethylene (20) sorbitan monopalmitate</p>
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 41 and not more than 52
Hydroxyl value	Not less than 90 and not more than 107
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)

Synonyms	<p>Polysorbate 60</p> <p>Polyoxyethylene (20) sorbitan monostearate</p>
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 81 and not more than 96
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)**Synonyms**

Polysorbate 65
Polyoxyethylene (20) sorbitan tristearate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay

Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis

Description

A tan-coloured, waxy solid at 25 °C with a faint characteristic odour

Identification

A. Solubility	Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol
B. Congealing range	29 — 33 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity

Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 88 and not more than 98
Hydroxyl value	Not less than 40 and not more than 60
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

3. The text concerning E 459 beta-cyclodextrin is replaced by the following:

'E 459 BETA-CYCLODEXTRIN

Definition

Chemical name

EINECS

Chemical formula

Molecular weight

Assay

Description

Identification

A. Solubility

B. Specific rotation

Purity

Water

Other cyclodextrins

Residual solvents (toluene and trichloroethylene)

Sulphated ash

Arsenic

Lead

Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α -1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cyclodextran transferase (CGTase) obtained from *Bacillus circulans*, *Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch.

Cycloheptaamylose

231-493-2

$(C_6H_{10}O_5)_7$

1135

Content not less than 98,0 % of $(C_6H_{10}O_5)_7$ on an anhydrous basis

Virtually odourless white or almost white crystalline solid

Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol

$[\alpha]_D^{25}$: +160 ° to +164 ° (1 % solution)

Not more than 14 % (Karl Fischer method)

Not more than 2 % on an anhydrous basis

Not more than 1 mg/kg for each solvent

Not more than 0,1 %

Not more than 1 mg/kg

Not more than 1 mg/kg

4. The text concerning Polyethylene glycol 6000 is replaced by the following:

'POLYETHYLENE GLYCOL 6000

Synonyms

Definition

Chemical formula

Molecular weight

Assay

Description

Identification

A. Solubility

B. Melting range

Purity

Viscosity

Hydroxyl value

Sulphated ash

Ethylene oxide

Arsenic

Lead

PEG 6000

Macrogol 6000

Polyethylene glycol 6000 is a mixture of polymers with the general formula $H-(OCH_2-CH_2)_n-OH$ corresponding to an average relative molecular mass of approximately 6 000

$(C_2H_4O)_n \cdot H_2O$ (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140)

5 600 — 7 000

Not less than 90,0 % and not more than 110,0 %

A white or almost white solid with a waxy or paraffin-like appearance

Very soluble in water and in methylene chloride. Practically insoluble in alcohol, in ether and in fatty and mineral oils

Between 55 °C and 61 °C

Between 0,220 and 0,275 kgm⁻¹s⁻¹ at 20 °C

Between 16 and 22

Not more than 0,2 %

Not more than 0,2 mg/kg

Not more than 3 mg/kg

Not more than 5 mg/kg

**COMMISSION DIRECTIVE 2004/45/EC
of 16 April 2004**

amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 96/77/EC ⁽²⁾ of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners sets out the purity criteria for the additives mentioned in 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⁾.
- (2) The Scientific Committee on Food concluded in its opinion of 5 March 2003 that the presence of low molecular weight carrageenan should be kept to a minimum. Consequently, the relevant criterion of the existing purity criteria for E 407 Carrageenan and E 407a (Processed Eucheuma Seaweed) set out in Directive 96/77/EC needs to be adapted.
- (3) It is necessary to adopt specifications for the new additives authorised through Directive 2003/114/EC of the European Parliament and of the Council of 22 December 2003 amending Directive 95/2/EC on food additives other than colours and sweeteners: E 907 Hydrogenated poly-1-decene, E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol.
- (4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) Directive 96/77/EC should therefore 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 96/77/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 1 April 2005 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 shall be accompanied by such 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

Products put on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

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, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, 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 339, 30.12.1996, p. 1. Directive as last amended by Directive 2003/95/EC (OJ L 283, 31.10.2003, p. 71).

⁽³⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/114/EC (OJ L 24, 29.1.2003, p. 58).

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

1. The texts concerning E 407 Carrageenan and E 407a Processed Eucheuma Seaweed are replaced by the following:

'E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from <i>Eucheuma</i> spp.) Iridophycan (from <i>Iridaea</i> spp.) Hypnean (from <i>Hypnea</i> spp.) Furcellaran or Danish agar (from <i>Furcellaria fastigiata</i>) Carrageenan (from <i>Chondrus</i> and <i>Gigartina</i> spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of <i>Gigartinaceae</i> , <i>Solieriaceae</i> , <i>Hypneaceae</i> and <i>Furcellariaceae</i> , families of the class <i>Rhodophyceae</i> (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded
EINECS	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> and <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g'

2. The following text concerning E 907 Hydrogenated poly-1-decene is inserted after E 905 Microcrystalline wax:

'E 907 HYDROGENATED POLY-1-DECENE

Synonyms	Hydrogenated polydec-1-ene Hydrogenated poly-alpha-olefin
Definition	
Chemical formula	$C_{10n}H_{20n+2}$ where $n = 3 - 6$
Molecular weight	560 (average)
Assay	Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution: C ₃₀ : 13 — 37 % C ₄₀ : 35 — 70 % C ₅₀ : 9 — 25 % C ₆₀ : 1 — 7 %
Description	Colourless, odourless, viscous liquid
Identification	
A. Solubility	Insoluble in water; slightly soluble in ethanol; soluble in toluene
B. Burning	Burns with a bright flame and a paraffin-like characteristic smell
Purity	
Viscosity	Between $5,7 \times 10^{-6}$ and $6,1 \times 10^{-6} \text{ m}^2\text{s}^{-1}$ at 100 °C
Compounds with carbon number less than 30	Not more than 1,5 %
Readily carbonisable substances	After 10 minutes shaking in a boiling water bath, a tube of sulfuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
Nickel	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg'

3. The following text concerning E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol is added:

'E 1517 GLYCERYL DIACETATE

Synonyms	Diacetin
Definition	Glyceryl diacetate consists predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters
Chemical names	Glyceryl diacetate 1,2,3-propanetriol diacetate
Chemical formula	$C_7H_{12}O_5$
Molecular weight	176,17
Assay	Not less than 94,0 %
Description	Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour
Identification	
A. Solubility	Soluble in water. Miscible with ethanol
B. Positive tests for glycerol and acetate	
C. Specific gravity	d_{20}^{20} : 1,175 — 1,195
D. Boiling range	Between 259 and 261 °C
Purity	
Total ash	Not more than 0,02 %
Acidity	Not more than 0,4 % (as acetic acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 1519 BENZYL ALCOHOL**Synonyms**

Phenylcarbinol
Phenylmethyl alcohol
Benzenemethanol
Alpha-hydroxytoluene

Definition

Chemical names

Benzyl alcohol
Phenylmethanol

Chemical formula

C_7H_8O

Molecular weight

108,14

Assay

Not less than 98,0 %

Description

Colourless, clear liquid with a faint, aromatic odour

Identification

A. Solubility

Soluble in water, ethanol and ether

B. Refractive index

$[n]_D^{20}$: 1,538 – 1,541

C. Specific gravity

d_{25}^{25} : 1,042 — 1,047

D. Positive test for peroxides

Purity

Distillation range

Not less than 95 % v/v distils between 202 and 208 °C

Acid value

Not more than 0,5

Aldehydes

Not more than 0,2 % v/v (as benzaldehyde)

Lead

Not more than 5 mg/kg'

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 2216/2001 of 15 November 2001 amending the rates of the refunds applicable to certain products from the milk sector exported in the form of goods not covered by Annex I to the Treaty

(Official Journal of the European Communities L 300 of 16 November 2001)

On page 30, recital 1:

for: '... 1 July 2001 ...',

read: '... 1 November 2001 ...'.

First Commission Directive 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity

Official Journal L 257 , 10/09/1981 P. 0001 - 0027

Finnish special edition: Chapter 13 Volume 11 P. 0154

Spanish special edition: Chapter 13 Volume 11 P. 0220

Swedish special edition: Chapter 13 Volume 11 P. 0154

Portuguese special edition Chapter 13 Volume 11 P. 0220

FIRST COMMISSION DIRECTIVE of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity (81/712/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Council Directive of 23 October 1962 on the approximation of the laws of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (1), as last amended by Directive 78/144/EEC (2), and in particular Article 11 (2) thereof,

Having regard to Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption (3), as last amended by Directive 79/40/EEC (4), and in particular Article 8 (2) thereof.

Having regard to Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidants authorized for use in foodstuffs intended for human consumption (5), as last amended by Directive 78/143/EEC (6), and in particular Article 5 (2) thereof.

Whereas these provisions lay down that Community methods of analysis shall be established for verifying that these additives satisfy general and specific criteria of purity;

Whereas a first series of methods for which the studies have been completed should now be adopted;

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

The Member States shall prescribe that the analyses necessary for verifying that certain additives used in foodstuffs satisfy the general and specific criteria of (1) OJ No 115, 11.11.1962, p. 2645/62. (2) OJ No L 44, 15.2.1978, p. 20. (3) OJ No 12, 27.1.1964, p. 161/64. (4) OJ No L 13, 19.1.1979, p. 50. (5) OJ No L 157, 18.7.1970, p. 31. (6) OJ No L 44, 15.2.1978, p. 18. purity shall be carried out according to the methods described in Annex II, the scope of which is laid down in Annex I.

Article 2

The Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive not later than 20 February 1983. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 28 July 1981.

For the Commission

Karl-Heinz NARJES

Member of the Commission

ANNEX I SCOPE OF THE COMMUNITY METHODS OF ANALYSIS FOR VERIFYING THAT CERTAIN ADDITIVES USED IN FOODSTUFFS MEET PURITY CRITERIA

I. INTRODUCTION

...

II. COLOURING MATTERS

II.1. Determination of substances extractable with diethyl ether from water-soluble sulphonated organic colouring matters used in foodstuffs using Annex II, method 1.

III. PRESERVATIVES

III.1. Determination of formic acid, formates and of other oxidizable impurities in acetic acid (E 260), potassium acetate (E 261), sodium diacetate (E 262) and calcium acetate (E 263) using Annex II, method 2.

III.2. Determination of non-volatile substances in propionic acid (E 280) using Annex II, method 3.

III.3. Determination of the loss of mass on drying of sodium nitrite (E 250) using Annex II, method 4.

III.4. Limit test for salicylic acid in ethyl p-hydroxybenzoate (E 214), ethyl p-hydroxybenzoate, sodium salt (E 215), n-propyl p-hydroxybenzoate (E 216), n-propyl p-hydroxybenzoate, sodium salt (E 217), methyl p-hydroxybenzoate (E 218) and methyl p-hydroxybenzoate, sodium salt (E 219) using Annex II, method 5.

III.5. Determination of free acetic acid in sodium diacetate (E 262) using Annex II, method 6.

III.6. Determination of sodium acetate in sodium diacetate (E 262) using Annex II, method 7.

III.7. Limit test for determination of aldehydes in sorbic acid (E 200) in sodium, potassium and calcium sorbates (E 201, E 202, E 203) and in propionic acid (E 280) using Annex II, method 8.

IV. ANTIOXIDANTS

IV.1. Determination of the number of peroxide groups of lecithins (E 322) using Annex II, method 9.

IV.2. Determination of toluene-insoluble substances in lecithins (E 322) using Annex II, method 10.

IV.3. Limit test for reducing substances in sodium, potassium and calcium lactates (E 325, E 326 and E 327) using Annex II, method 11.

IV.4. Determination of volatile acids in orthophosphoric acid (E 338) using Annex II, method 12.

IV.5. Limit test for nitrates in orthophosphoric acid (E 338) using Annex II, method 13.

IV.6. Determination of water-insoluble substances in mono-, di- and tri-sodium orthophosphate and mono-, di- and tri-potassium orthophosphates (E 339(i), E 339(ii), E 339(iii), E 340(i), E 340(ii), E 340(iii)) using Annex II, method 14.

V. GENERAL

V.1. Determination of pH in food additives using Annex II, method 15.

ANNEX II

METHODS OF ANALYSIS RELATING TO THE CRITERIA OF PURITY OF FOOD ADDITIVES

INTRODUCTION

1. Preparation of the analysis sample 1.1. General

The mass of the laboratory sample intended for analysis must normally be 50 g unless a larger quantity is required for a specific determination.

1.2. Sample preparation

The sample shall be made homogeneous prior to analysis.

1.3. Preservation

The prepared sample shall always be kept in an air-tight and moisture-tight container and stored so that deterioration is prevented.

2. Reagents 2.1. Water 2.1.1. Wherever mention is made of water for solution, dilution or washing purposes, distilled water, or demineralized water of at least equivalent purity, is intended.

2.1.2. Wherever reference is made to "solution" or "dilution" without further indication of a reagent, an aqueous solution is intended.

2.2. Chemicals

All chemicals shall be of analytical reagent quality except where otherwise specified.

3. Equipment 3.1. List of equipment

The list of equipment contains only those items with a specialized use and items with a particular specification.

3.2. Analytical balance

Analytical balance means a balance with a sensitivity of 0.1 mg or greater.

4. Expression of results 4.1. Results The result stated in the official analysis report shall be the mean value of at least two determinations the repeatability of which is satisfactory.

4.2. Calculation of percentage

Unless otherwise stated the results shall be expressed as a percentage by mass of the original sample as received at the laboratory.

4.3. Number of significant figures

The number of significant figures in the result so expressed shall be governed by the precision of the method.

METHOD 1 DETERMINATION OF SUBSTANCES EXTRACTABLE WITH DIETHYL ETHER FROM WATER-SOLUBLE SULPHONATED ORGANIC COLOURING MATTERS INTENDED FOR FOODSTUFFS

1. Scope and field of application

The method determines substances extractable with diethyl ether in water soluble sulphonated organic colouring matters which have not been mixed with any support.

2. Definition

Substances extractable with diethyl ether : the content of material as determined by the method specified.

3. Principle

Extract the colouring matter with diethyl ether and weigh the extracted residue after evaporation of the ether.

4. Reagents 4.1. Diethyl ether, dry, peroxide-free (dried with the aid of freshly calcined calcium chloride).

5. Apparatus 5.1. Soxhlet apparatus with flask.

5.2. Desiccator, containing freshly activated silica gel or equivalent desiccant with a water content indicator.

5.3. Analytical balance.

5.4. Oven, thermostatically controlled at 85 ± 2 °C.

6. Procedure

Accurately weigh, to the nearest 10 mg, about 10 g of the sample of the colouring matter on a piece of filter paper. Fold the paper, put it into a paper thimble and close the latter with some fat-free cotton wool. Extract for six hours with diethyl ether (4.1) in a Soxhlet extraction apparatus (5.1). Evaporate the ether at as low a temperature as possible. Place the Soxhlet flask, which has been previously weighed, with the residue in the oven (5.4) at 85 ± 2 °C for 20 minutes to dry. Transfer the flask to a desiccator (5.2), cover with a loose-fitting lid and allow to cool. Weigh the flask and residue.

Repeat the drying and weighing until two successive weighings differ by less than 0.75 mg. Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

7. Expression of results 7.1. Formula and method of calculation

The content of substances extractable with ether, as a percentage of the sample, is given by:
>PIC FILE= "T0020608">

where:

m₁ = mass in grams of the residue after evaporation,

m₀ = initial mass in grams of the sample taken.

7.2. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 20 mg per 100 g of sample.

METHOD 2 DETERMINATION OF FORMIC ACID, FORMATES AND OTHER OXIDIZABLE IMPURITIES IN ACETIC ACID (E 260), POTASSIUM ACETATE (E 261), SODIUM DIACETATE (E 262) AND CALCIUM ACETATE (E 263)

1. Scope and field of application

The method determines formic acid, formates and other oxidizable impurities, expressed as formic acid in: - acetic acid (E 260),

- potassium acetate (E 261),

- sodium diacetate (E 262),

- calcium acetate (E 263).

2. Definition

Formic acid, formates and other oxidizable impurities content : the content of formic acid, formates and other oxidizable impurities as determined by the method specified.

3. Principle

The solution of the sample is treated with excess of standard potassium permanganate in alkaline conditions to form manganese dioxide. The manganese dioxide and excess potassium permanganate are determined iodometrically in acid conditions and the concentration of oxidizable impurities calculated and expressed as formic acid.

4. Reagents >PIC FILE= "T0020908">

5. Apparatus 5.1. Water bath, boiling.

5.2. Analytical balance.

6. Procedure

If the test sample is the free acid, accurately weigh, to the nearest 10 mg, about 10 g of the sample and dilute with 70 ml of water and add a solution containing 10 g of anhydrous sodium carbonate (4.3) in 30 ml of water. If the sample is a salt, accurately weigh, to the nearest 10 mg, about 10 g of the sample and dissolve in 100 ml of water. Add 1 g anhydrous sodium carbonate (4.3) and shake to dissolve. Add 20 ml of 0.702 mol/l potassium permanganate (4.2) and heat on a boiling water bath for 15 minutes. Cool the mixture. Add 50 ml of dilute sulphuric acid (4.6) and 0.75 g of potassium iodide (4.1). Swirl the mixture until all precipitated manganese dioxide has redissolved. Titrate with 0.71 mol/l sodium thiosulphate (4.4) until the solution becomes pale yellow in colour. Add a few drops of starch solution (4.5) and continue the titration until the solution becomes colourless.

7. Expression of results 7.1. Formula and method of calculation

The percentage of formic acid, formates and of other oxidizable impurities, expressed as formic acid, is given by: >PIC FILE= "T0020609">

where:

a = molarity of potassium permanganate,

b = molarity of sodium thiosulphate,

m₀ = initial mass in grams of the sample taken,

V = volume in millilitres of 0.71 mol/l sodium thiosulphate used in the titration.

7.2. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 5 mg per 100 g of sample.

8. Notes 8.1. A volume of 11.73 ml of 0.71 mol/l sodium thiosulphate is equivalent to 0.72 % formic acid in a 10 g sample.

8.2. If there is no formate present, the volume required will be 20 ml, but if there is more than 0.727 % (m/m) of formic acid present, there will be insufficient excess of potassium permanganate and a fixed minimum volume of 8 ml will be obtained. In this case repeat the determination using a smaller sample weight.

METHOD 3 DETERMINATION OF NON-VOLATILE SUBSTANCES IN PROPIONIC ACID (E 280)

1. Scope and field of application

The method determines non-volatile substances in propionic acid (E 280).

2. Definition

The content of non-volatile material in propionic acid : the content of non-volatile material as determined by the method specified.

3. Principle

The sample is evaporated and then dried at 103 ± 2 °C and the residue determined gravimetrically.

4. Apparatus 4.1. Evaporation vessel, silica or platinum and of sufficient size to contain 100 g of sample.

4.2. Oven, electrically heated, thermostatically controlled at 103 ± 2 °C.

4.3. Analytical balance.

4.4. Water bath, boiling.

4.5. Desiccator, containing freshly activated silica gel or equivalent desiccant with water content indicator.

5. Procedure

Weigh, to the nearest 0.01 g, 100 g of the sample of propionic acid into a previously dried and weighed vessel (4.1). Evaporate over a boiling water bath in a fume cupboard (4.4). When all the propionic acid has evaporated, place in an oven (4.2) at 103 ± 2 °C for one hour. Place in a desiccator and allow to cool and then weigh. Repeat the heating, cooling and weighing operations until the difference between two successive weighings is less than 0.05 mg. Should an increase in mass occur the lowest recorded reading will be used in the calculation.

6. Expression of results 6.1. Formula and method of calculation

The non-volatile matter content, calculated as a percentage of the sample, is given by: $\text{PIC} = \frac{m_1}{m_0} \times 100$

where:

m_1 = mass in grams of the residue after evaporation,

m_0 = mass in grams of the sample taken.

6.2. Repeatability

The difference between the results of two determinations, carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 5 mg per 100 g of sample.

METHOD 4 DETERMINATION OF THE LOSS OF MASS ON DRYING OF SODIUM NITRITE (E 250)

1. Scope and field of application

The method determines the loss of mass on drying of sodium nitrite (E 250).

2. Definition

The moisture content of sodium nitrite ; the loss of mass on drying as determined by the method specified.

3. Principle

The loss of mass on drying is obtained by heating in an oven at 103 ± 2 °C, weighing and calculation of the loss in mass.

4. Apparatus 4.1. Oven, electrically heated, thermostatically controlled at 103 ± 2 °C.

4.2. Weighing dish, flat-bottomed, glass, of diameter 60 to 80 mm and depth at least 25 mm, with loose-fitting lid.

4.3. Desiccator, containing freshly activated silica gel or equivalent desiccant with water content indicator.

4.4. Analytical balance.

5. Procedure

Remove the lid from the weighing dish (4.2) and heat dish and lid in the oven (4.1) at 103 ± 2 °C for one hour. Replace the lid and place the dish (4.2) with its lid in the desiccator (4.3) and allow to cool to room temperature. Weigh the covered dish (4.2) to the nearest 10 mg.

Accurately weigh, to the nearest 10 mg, approximately 10 g of sample into the covered dish. Remove the lid and place both dish and lid in the oven (4.1) for one hour at 103 ± 2 °C. Replace the lid and allow the covered dish to cool to room temperature in the desiccator (4.3). Weigh it to the nearest 10 mg. Repeat the heating, cooling and weighing until the difference between two successive weights is less than 10 mg. Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

6. Expression of results 6.1. Formula and method of calculation

The loss of mass on drying, calculated as a percentage by mass of the sample, is given by: >PIC
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where:

m1 = mass in grams of the dish,

m2 = mass in grams of the dish and sample before drying,

m3 = mass in grams of the dish and sample after drying.

6.2. Repeatability

The difference between the results of two determinations, carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 100 mg per 100 g of sample.

METHOD 5 LIMIT TEST FOR SALICYLIC ACID IN ETHYL p-HYDROXYBENZOATE (E 214), ETHYL-p-HYDROXYBENZOATE, SODIUM SALT (E 215), n-PROPYL p-HYDROXYBENZOATE (E 216), n-PROPYL p-HYDROXYBENZOATE, SODIUM SALT (E 217), METHYL p-HYDROXYBENZOATE (E 218), METHYL p-HYDROXYBENZOATE, SODIUM SALT (E 219)

1. Scope and field of application

The method detects salicylic acid in ethyl p-hydroxybenzoate (E 214), n-propyl p-hydroxybenzoate (E 216), and methyl p-hydroxybenzoate (E 218) and in their sodium salts (E 215, E 217 and E 219).

2. Definition

The detection of the limit test concentration of salicylic acid : the limit test result as determined by the method specified.

3. Principle

A violet colouration is produced from the reaction of ammonium iron (III) sulphate with a solution of the sample. Its intensity is compared with that produced by a reference solution.

4. Reagents 4.1. Ammonium iron (III) sulphate solution, 0.72 % m/v. Prepare by dissolving 0.72 g of ammonium iron (III) sulphate dodecahydrate in 50 ml of water, add 10 ml of nitric acid, 10 % v/v, and dilute to 100 ml with water.

4.2. Ethanol, 95 % v/v.

4.3. Salicylic acid solution, 0.71 g/l.

4.4. Sulphuric acid, 1 mol/l.

5. Apparatus 5.1. Nessler cylinders, graduated at 50 ml. Total volume approximately 60 ml.

6. Procedure 6.1. Ethyl, n-propyl and methyl p-hydroxybenzoate samples 6.1.1. Weigh, to the nearest 1 mg, 0.71 g of the sample and dissolve in 10 ml of 95 % v/v ethanol (4.2). Transfer the solution to a graduated Nessler cylinder (5.1) and dilute to 50 ml with water. Stir and add 1 ml of ammonium iron (III) sulphate solution (4.1) while stirring. Allow to stand for one minute.

6.1.2. Prepare a comparison solution at the same time by repeating 6.1.1, but replacing the 0.71 g of sample by 1 ml of salicylic acid solution (4.3).

6.1.3. Compare the colouring in the sample solution with that appearing in the comparison solution.

6.2. Sodium salts of ethyl, n-propyl and methyl p-hydroxybenzoate samples 6.2.1. Repeat 6.1.1 acidifying to pH 5 using 1 mol/l sulphuric acid (4.4) before dilution to 50 ml.

6.2.2. Repeat 6.1.2.

6.2.3. Repeat 6.1.3.

7. Expression of results 7.1. Limit test interpretation

If the reddish-violet colour appearing in the sample solution tube is more intense than that appearing in the comparison solution tube, the test is positive and the sample contains more than 0.71 % salicylic acid.

7.2. Sensitivity

The limit of detection of the test is 30 mg of salicylic acid per 100 g of sample.

7.3. Observations

The results of two limit tests carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

METHOD 6 DETERMINATION OF FREE ACETIC ACID IN SODIUM DIACETATE (E 262)

1. Scope and field of application

The method determines acetic acid in sodium diacetate (E 262).

2. Definition

The acetic acid content : the content of acetic acid as determined by the method specified.

3. Principle

Direct titration of the acetic acid in the sample using standard sodium hydroxide solution and phenolphthalein indicator.

4. Reagents 4.1. Phenolphthalein solution 1 % (m/v) in ethanol.

4.2. Sodium hydroxide, 1 mol/l.

5. Apparatus 5.1. Analytical balance.

6. Procedure

Weigh, to the nearest 1 mg, about 3 g of the test sample and dissolve in about 50 ml of water. Add two or three drops of phenolphthalein indicator solution (4.1) and titrate with 1 mol/l sodium hydroxide (4.2) until a red tint persists for five seconds.

7. Expression of results 7.1. Formula and method of calculation

The acetic acid content, as a percentage of the sample mass, is given by: $\text{PIC FILE} = \frac{V \times N \times 100}{m}$

where:

V = volume in millilitres of sodium hydroxide (4.2) required,

c = concentration of the sodium hydroxide solution in mol/l,

m_0 = initial mass in grams of the sample taken.

7.2. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 500 mg per 100 g of sample.

8. Comment

A volume of 20 ml is obtained when 3 g of a sample containing 40 % acetic acid is titrated with 1 mol/l sodium hydroxide.

METHOD 7 DETERMINATION OF SODIUM ACETATE IN SODIUM DIACETATE (E 262)

1. Scope and field of application

The method determines sodium acetate and water, expressed as sodium acetate, in sodium diacetate (E 262).

2. Definition

Sodium acetate content : the content of sodium acetate and water expressed as sodium acetate as determined by the method specified.

3. Principle

The sample is dissolved in glacial acetic acid, before titration, with standard perchloric acid, using crystal violet as indicator.

4. Reagents >PIC FILE= "T0020613">

>PIC FILE= "T0020614">

5. Apparatus 5.1. Analytical balance.

6. Procedure

Weigh, to the nearest 0.75 mg, about 0.72 g of the sample and dissolve in 50 ml of glacial acetic acid (4.1). Add a few drops of crystal violet indicator solution (4.2) and titrate to a pale green end-point, using standard 0.71 mol/l perchloric acid (4.5).

7. Expression of results 7.1. Formula and method of calculation

The sodium acetate content, as defined in section 2 (definition), expressed as a percentage by weight of the sample, is given by the following formula: >PIC FILE= "T0020615">

where:

V = volume in millilitres of the standard perchloric acid (4.5) used,

c = molarity of the perchloric acid solution (4.5),

m_0 = initial mass in grams of the sample taken.

7.2. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 1.75 g per 100 g of sample.

8. Observations

The reagents used in this method are toxic and explosive and need careful handling.

METHOD 8 LIMIT TEST FOR ALDEHYDES IN SORBIC ACID (E 200), SODIUM, POTASSIUM AND CALCIUM SORBATES (E 201, E 202, E 203) AND PROPIONIC ACID (E 280)

1. Scope and field of application

The method detects aldehydes, expressed as formaldehyde, in: - sorbic acid (E 200),

- sodium, potassium and calcium sorbates (E 201, E 202, E 203),

- propionic acid (E 280).

2. Definition

The detection of the limit test concentration of aldehydes : the limit test result as determined by the method specified.

3. Principle

The aldehydes in the test solution, and the formaldehyde in a comparison solution, react with Schiff's reagent to produce red coloured complexes, the intensities of which are compared.

4. Reagents 4.1. Formaldehyde standard solution (0.701 mg/ml) : prepared by dilution of concentrated formaldehyde solution (400 mg/ml).

4.2. Schiff's reagent.

5. Procedure 5.1. Weigh, to the nearest 1 mg, about 1 g of the sample, add to 100 ml of water and shake. Filter the solution if necessary and treat 1 ml of filtrate or sample solution with 1 ml of Schiff's reagent (4.2). At the same time, treat 1 ml of formaldehyde comparison solution (4.1) with 1 ml of Schiff's reagent (4.2).

5.2. Compare the colour in the sample solution with that appearing in the comparison solution.

6. Expression of results 6.1. Limit test interpretation

If the red colour appearing in the sample solution tube is more intense than that appearing in the comparison solution tube, the test is positive and the sample contains more than 0.71 % aldehydes, expressed as formaldehyde.

6.2. Sensitivity

The limit of detection of this test is 30 mg of formaldehyde per 100 g of sample.

6.3. Observations

The result of two limit tests when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

METHOD 9 DETERMINATION OF THE PEROXIDE NUMBER IN LECITHINS (E 322)

1. Scope and field of application

The method determines the peroxide number in lecithins (E 322).

2. Definition

Peroxide number of lecithins : the result obtained as determined by the method specified.

3. Principle

Oxidation of potassium iodide by the peroxides of lecithin and titration of the iodine liberated using standard sodium thiosulphate solution.

4. Reagents 4.1. Acetic acid glacial.

4.2. Chloroform.

4.3. Potassium iodide.

4.4. Sodium thiosulphate, 0.71 mol/l or 0.701 mol/l.

4.5. Starch solution (approximately 1 % m/v).

5. Apparatus 5.1. Analytical balance.

5.2. Apparatus, as shown in the figure, consisting of: 5.2.1. round-bottomed flask, 100 ml;

5.2.2. reflux condenser;

5.2.3. glass tube, 250 mm long and 22 mm internal diameter, fitted with ground glass joints;

5.2.4. micro beaker (external dimension of 20 mm diameter and 35 to 50 mm height).

6. Procedures 6.1. Place 10 ml of glacial acetic acid (4.1) and 10 ml of chloroform (4.2) in the 100 ml flask (5.2.1). Fit the glass tube (5.2.3) and reflux condenser (5.2.2) and gently boil the mixture for two minutes to expel all dissolved air. Dissolve 1 g of potassium iodide (4.3) in 1.73 ml of water and add this solution to the mixture in the flask (5.2.1) taking care that the boiling is not interrupted.

If a yellow colour appears at this stage the determination must be rejected and repeated using fresh reagents.

6.2. Accurately weigh, to the nearest 1 mg, about 1 g of the sample and, after a further two minutes of boiling, add the weighed sample to the contents of the flask (5.2.1) again taking care that the boiling remains continuous. For this purpose the sample should be contained in a micro-beaker (5.2.4) which may be lowered through the glass tube (5.2.3) with a glass rod, the bottom of which has been suitably shaped as shown in the diagram. The condenser (5.2.2) may be removed for a short time. Continue boiling for three to four minutes. Stop heating and immediately disconnect the condenser (5.2.2). Quickly add 50 ml of water through the glass tube (5.2.3). Remove the glass tube (5.2.3) and cool the flask (5.2.1) to room temperature under the water tap. Titrate with sodium thiosulphate (0.71 mol/l or 0.701 mol/l) (4.4) until the aqueous layer becomes pale yellow. Add 1 ml of starch solution (4.5) and continue the titration until the blue colour is discharged. Shake the flask (5.2.1) well during the titration to ensure the complete extraction of iodine from the non-aqueous layer.

6.3. Obtain a blank titration value by repeating the complete procedure 6.1 and 6.2, but without adding the sample.

7. Expression of results 7.1. Formula and method of calculation

The peroxide number in the sample, in milliequivalents per kilogram, is given by: >PIC FILE="T0020616">

where:

V1 = volume in millilitres of thiosulphate solution required for the titration of the sample (6.2),

V2 = volume in millilitres of thiosulphate solution required for the titration of the blank (6.3),

a = concentration of sodium thiosulphate solution in mol/l,

m0 = initial mass in grams of the sample taken.

7.2. Repeatability

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.75 (expressed as a peroxide number in milliequivalents per kilogram of sample).

8. Notes 8.1. The choice of the concentration of the sodium thiosulphate used depends on the anticipated titration value. If less than 0.75 ml of 0.71 mol/l sodium thiosulphate is required, repeat the determination using 0.701 mol/l sodium thiosulphate.

8.2. The determination should not be carried out in strong light.

>PIC FILE= "T0020617">

METHOD 10 DETERMINATION OF TOLUENE-INSOLUBLE MATTER IN LECITHINS (E 322)

1. Scope and field of application

The method determines the toluene-insoluble matter in lecithins (E 322).

2. Definition

The toluene-insoluble matter content : the content of toluene-insoluble matter as determined by the method specified.

3. Principle

The sample is dissolved in toluene, filtered, and the residue dried and weighed.

4. Reagents 4.1. Toluene.

5. Apparatus 5.1. Sintered glass crucible, 30 ml capacity, G 3 or equivalent porosity.

5.2. Drying oven, electrically heated and thermostatically controlled at 103 ± 2 °C.

5.3. Water bath, operating at a temperature not exceeding 60 °C.

5.4. Desiccator, containing freshly activated silica gel or equivalent desiccant with a water content indicator.

5.5. Conical flask of 500 ml.

5.6. Vacuum pump.

5.7. Analytical balance.

6. Procedure 6.1. Dry a 30 ml sintered glass crucible (5.1) in an oven at 103 ± 2 °C (5.2). Transfer the crucible to desiccator (5.4), allow to cool and then weigh.

6.2. Thoroughly mix the sample of lecithins, if necessary after warming in a water bath (5.3). Weigh, to the nearest 1 mg, about 10 g of the sample into a conical flask (5.5). Add 100 ml of toluene (4.1) and swirl the mixture until all the lecithin has apparently dissolved. Filter the solution through the sintered glass crucible (5.1). Wash the conical flask (5.5) with 25 ml of toluene (4.1) and pass the washings through the crucible (5.1). Repeat this process with another 25 ml of toluene (4.1). Remove excess toluene from the crucible (5.1) by suction.

6.3. Dry the crucible (5.1) in the drying oven (5.2) at 103 ± 2 °C for two hours. Place in desiccator (5.4) and allow to cool. Weigh the crucible and residue when cool.

6.4. Repeat 6.3 until the difference in weight between two successive weighings is less than 0.75 mg.

Should an increase in mass occur, the lowest recorded reading will be used in the calculation.

7. Expression of results 7.1. Formula and method of calculation

The content of toluene insoluble substances is given by: >PIC FILE= "T0020618">

where:

m_1 = mass in grams of the empty crucible (6.1),

m_2 = mass in grams of the crucible and residues (6.4),

m_0 = initial mass in grams of the sample taken.

7.2. Repeatability

The difference between the results of two determinations carried out in simultaneous or rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 30 mg per 100 g of sample.

METHOD 11 LIMIT TEST FOR REDUCING SUBSTANCES IN SODIUM, POTASSIUM AND CALCIUM LACTATES (E 325, E 326, E 327)

1. Scope and field of application

The test detects qualitatively reducing substances in: - sodium lactate (E 325),
- potassium lactate (E 326),
- calcium lactate (E 327).

2. Definition

The detection of the limit test concentration of reducing substances : the limit test result as determined by the method specified.

3. Principle

Fehling's solution is reduced by substances capable of exhibiting reducing action. Such substances will normally be reducing sugars.

4. Reagents 4.1. Fehling's solution A : 6 793 g of copper sulphate pentahydrate is dissolved in water and made up 100 ml with water.

4.2. Fehling's solution B : 34 76 g of potassium sodium tartrate and 10 g of sodium hydroxide are dissolved in water and made up to 100 ml with water.

5. Procedures

Weigh, to the nearest 1 mg, about 1 g of the sample and dissolve in 10 ml of warm water. Add 2 ml of Fehling's solution A (4.1) and 2 ml of Fehling's solution B (4.2) and then boil the mixture for one minute and observe whether a colour change occurs. The precipitation of calcium sulphate, which sometimes occurs, does not interfere.

6. Expression of results 6.1. Limit test interpretation

If there is a colour change after boiling (5), the test is positive and the presence of reducing substances is indicated.

6.2. Sensitivity

The limit of detection for reducing substances reacting is 100 mg glucose per 100 g of sample.

6.3. Observations 6.3.1. The results of two limit tests carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

6.3.2. All of the Fehling solutions react if 2 % glucose is present in the sample.

METHOD 12 DETERMINATION OF VOLATILE ACIDS IN ORTHOPHOSPHORIC ACIDS (E 338)

1. Scope and field of application

The method determines volatile acids, expressed as acetic acid, in orthophosphoric acid (E 338).

2. Definition

Volatile acid content : the content of volatile acids, expressed as acetic acid, as determined by the method specified.

3. Principle

Water is added to the sample and the solution is distilled. The distillate is titrated against standard sodium hydroxide solution and the acidity calculated and expressed as acetic acid.

4. Reagents 4.1. Phenolphthalein solution, 1 % (m/v) in ethanol.

4.2. Sodium hydroxide, 0.701 mol/l.

5. Apparatus 5.1. Distillation apparatus including a spray trap.

6. Procedure

Weigh, to the nearest 50 mg, about 60 g of the sample and place the weighed sample and 75 ml of freshly boiled cooled water in the distillation flask fitted with the spray trap (5.1). Mix and then distil about 50 ml.

Titrate the distillate with standard 0.701 mol/l sodium hydroxide (4.2) using phenolphthalein (4.1) as indicator. Continue the titration until the first red tint in the solution persists for 10 seconds.

7. Expression of results 7.1. Formula and method of calculation

The content of volatile acids, expressed as milligrams per kilogram of acetic acid, is given by:
>PIC FILE= "T0020619">

where:

V = volume in millilitres of 0.701 mol/l sodium hydroxide solution used for neutralization,

m₀ = mass in grams of the orthophosphoric acid sample.

7.2. Repeatability

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 1 mg per 100 g of sample.

METHOD 13 LIMIT TEST FOR NITRATE IN ORTHOPHOSPHORIC ACID (E 338)

1. Scope and field of application

This method detects nitrates in orthophosphoric acid (E 338).

2. Definition

The detection of the limit test concentration of nitrate, expressed as sodium nitrate ; the limit test result as determined by the method specified.

3. Principle

The sample is added to indigo carmine solution in a concentrated sulphuric acid medium. The blue colouration present is discharged by oxidizing agents including nitrates.

4. Reagents >PIC FILE= "T0020911">

5. Procedure

Measure 2 ml of the sample and dilute to 10 ml with the sodium chloride solution (4.2). Add 0.71 ml of carmine indigo solution (4.1) and then slowly add 10 ml of concentrated sulphuric acid (4.3), cooling during the addition. Note whether the blue colouration of the solution persists for five minutes.

6. Expression of results 6.1. Limit test interpretation

If the blue colouration is discharged within five minutes the test is positive and the content of oxidizing agents, expressed as sodium nitrate, is greater than 5 mg/kg.

6.2. Observations 6.2.1. Carry out a blank test.

6.2.2. The results of two limit tests when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall be identical.

6.2.3. Indigo carmine solution should not be used if it has been prepared for more than 60 days.

6.2.4. If a positive result is obtained the sample may contain nitrates and other oxidizing agents and the test must be repeated using ISO Method 3709 (1976) "Phosphoric acid for industrial use (including foodstuffs) - determination of oxides of nitrogen content - 3,4-xylenol spectrophotometric method".

METHOD 14 DETERMINATION OF WATER-INSOLUBLE SUBSTANCES PRESENT IN MONO-, DI- AND TRI-SODIUM ORTHOPHOSPHATES AND MONO-, DI- AND TRI-POTASSIUM ORTHOPHOSPHATES (E 339(i), E 339(ii), E 339(iii), E 340(i), E 340(ii) AND E 340(iii))

1. Scope and field of application

The method determines water-insoluble matter in: - mono-sodium orthophosphate (E 339(i)),

- di-sodium orthophosphate (E 339(ii)),

- tri-sodium orthophosphate (E 339(iii)),

- mono-potassium orthophosphate (E 340(i)),

- di-potassium orthophosphate (E 340(ii)),

- tri-potassium orthophosphate (E 340(iii)).

2. Definition

Water insoluble matter : the content of water-insoluble matter as determined by the method specified.

3. Principle

The sample is dissolved in water and filtered through a suitable porcelain crucible. After washing and drying the residue is weighed and calculated as water-insoluble matter.

4. Apparatus 4.1. Sintered porcelain crucible, porosity G 3 or equivalent.

4.2. Desiccator, containing freshly activated silica gel with a water content indicator, or equivalent desiccant.

4.3. Oven, thermostatically controlled at 103 ± 2 °C.

4.4. Polypropylene beaker, 400 ml.

4.5. Water bath, boiling.

5. Procedure

Weigh, to the nearest 10 mg, about 10 g of the sample of phosphate and dissolve in 100 ml of hot water by bringing to the boil in a polypropylene beaker (4.4) and maintaining on a hot water bath (4.5) for 15 minutes. Filter the solution through a previously cleaned, dried and weighed crucible (4.1). Wash the insoluble residue with hot water. Place the crucible with residue in the oven (4.3) and dry at 103 ± 2 °C for two hours.

Place the crucible in the desiccator and allow to cool and weigh the crucible.

Repeat the drying, cooling and weighing until the difference in weight of two successive weighings is less than 0.75 mg. Should an increase in mass occur the lowest recorded reading will be used in the calculation.

6. Expression of results 6.1. Formula and method of calculation

The content of water-insoluble matter in the sample is given by: >PIC FILE= "T0020620">

where:

m_1 = mass in grams of the residue after drying,

m_0 = mass in grams of the sample taken.

6.2. Repeatability

The difference between the results of two determinations carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 10 mg per 100 g of sample.

METHOD 15 DETERMINATION OF THE pH OF FOOD ADDITIVES

1. Scope and field of application

The method outlines general instructions on how to determine the pH of food additives.

2. Definition

The pH of a food additive : the pH value as determined by the method specified.

3. Principle

The pH value of an aqueous solution of the dissolved or slurried sample is conventionally determined using a glass electrode, reference electrode and pH meter.

4. Reagents 4.1. Calibrate the instrument using the following buffer solutions: 4.1.1. Buffer solution pH 6.788 at 20 °C, consisting of equal volume 0.705 mol/l potassium dihydrogen phosphate (KH_2PO_4) and 0.705 mol/l disodium hydrogen ortho phosphate dyhydrate ($\text{Na}_2\text{HPO}_4 \cdot 7\text{H}_2\text{O}$).

4.1.2. Buffer solution pH 4 at 20 °C, consisting of 0.705 mol/l potassium hydrogen phthalate ($\text{C}_8\text{H}_5\text{KO}_4$).

4.1.3. Buffer solution pH 9.722 at 20 °C, consisting of 0.705 mol/l sodium borate ($\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$).

4.2. Saturated or 3 mol/l potassium chloride solution, or other suitable solution prescribed by the electrode manufacturer, to fill the reference electrode.

4.3. Distilled water, carbon dioxide-free, having a pH between 5 and 6.

5. Apparatus 5.1. pH meter, with an accuracy within 0.01 pH units.

5.2. Electrodes, either a combined glass electrode or single glass and reference electrodes together with suitable clamps to hold the electrodes.

5.3. Magnetic stirrer, with heater element.

5.4. Thermometer, calibrated over the range 0 to 100 °C.

6. Procedure 6.1. Standardization of the pH meter

The glass electrodes must be set using the instructions given by the manufacturer. The pH reading from the electrodes must be regularly checked by comparison with buffer solutions of known pH.

Electrodes should be washed with water and then gently wiped with a soft tissue or should be rinsed with water and then twice with the next sample/standard solution before being placed in the next sample/standard solution to be used.

If the sample to be considered has an acid pH, the buffer solutions used to check the pH reading should be those of pH 4 (4.1.2) and pH 6.788 (4.1.1). If the sample to be analyzed has an alkaline pH, the buffer solutions to be used to check the pH reading should be those of pH 9.722 (4.1.3) and pH 6.788 (4.1.1).

6.2. Measurement of the sample solution

The concentration of sample to be used or the sample preparation procedure to be adopted is as prescribed in the appropriate Community food additive Directive.

Prepare the sample solution as directed using distilled water (4.3) and then adjust to 20 °C while stirring. Stop the stirring, place the glass electrodes in the solution and after two minutes note the pH on the pH meter (5.1).

7. Expression of results 7.1. Repeatability

The difference between the results of two determinations when carried out simultaneously or in rapid succession on the same sample, by the same analyst, under the same conditions, shall not exceed 0.705 pH unit.

8. Note

This method is only applicable to those pH requirements in Community food additives Directives where the food additive is dissolved or slurried in water.

31995L0031

Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs

Official Journal L 178 , 28/07/1995 P. 0001 - 0019

COMMISSION DIRECTIVE 95/31/EC

of 5 July 1995

laying down specific criteria of purity concerning sweeteners for use in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), as amended by Directive 94/34/EC (2), and in particular Article 3 (3) (a) thereof,

After consultation of the Scientific Committee on Food,

Whereas it is necessary to establish purity criteria for all sweeteners mentioned in European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (3);

Whereas it is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the Codex Alimentarius and the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food with a view to full evaluation with emphasis on the purity criteria;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Purity criteria mentioned under Article 3 (3) (a) of Directive 89/107/EEC for sweeteners mentioned in Directive 94/35/EC are set out in the Annex.

2. The purity criteria for E 420 (i), E 420 (ii) and E 421 mentioned in the Annex to this Directive supersede the purity criteria for the said substances mentioned in the Annex to Council Directive 78/663/EEC (4).

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1996. 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 procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

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, 5 July 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 27.

(2) OJ No L 237, 10. 9. 1994, p. 1.

(3) OJ No L 237, 10. 9. 1994, p. 3.

(4) OJ No L 223, 14. 8. 1978, p. 7.

ANNEX

>TABLE>

31998L0066

Commission Directive 98/66/EC of 4 September 1998 amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (Text with EEA relevance)

Official Journal L 257 , 19/09/1998 P. 0035 - 0036

COMMISSION DIRECTIVE 98/66/EC of 4 September 1998 amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 (1), as amended by European Parliament and Council Directive 94/34/EC (2), and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (3), as amended by Directive 96/83/EC (4), lists those substances which may be used as sweeteners in foodstuffs;

Whereas Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs (5) sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC;

Whereas it is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/31/EC for isomalt (E 953); whereas it is consequently necessary to adapt that Directive;

Whereas it is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the Codex Alimentarius by the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

Whereas food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, shall be submitted for evaluation by the Scientific Committee on Food with a view to full evaluation with emphasis on the purity criteria;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

In the Annex to Directive 95/31/EC, the text concerning E 953 - isomalt is replaced by the text in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive before 1 July 1999. They shall immediately 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 procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the 20th 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, 4 September 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 40, 11. 2. 1989, p. 27.

(2) OJ L 237, 10. 9. 1994, p. 1.

(3) OJ L 237, 10. 9. 1994, p. 3.

(4) OJ L 48, 19. 2. 1997, p. 16.

(5) OJ L 178, 28. 7. 1995, p. 1.

ANNEX

>TABLE>

32000L0051

Commission Directive 2000/51/EC of 26 July 2000 amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (Text with EEA relevance)

Official Journal L 198 , 04/08/2000 P. 0041 - 0043

Commission Directive 2000/51/EC

of 26 July 2000

amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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(1), as amended by European Parliament and Council Directive 94/34/EC(2), and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs(3), as amended by Directive 96/83/EC(4), lists those substances which may be used as sweeteners in foodstuffs.

(2) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs(5), as amended by Directive 98/66/EC(6), sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC.

(3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/31/EC for mannitol (E 421) and maltitol syrup (E 965(ii)). It is consequently necessary to adapt that Directive.

(4) It is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the Codex Alimentarius by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(5) 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

In the Annex to Directive 95/31/EC, the text concerning (E 421) mannitol and (E 965 (ii)) maltitol syrup shall be replaced by the text 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 by 30 June 2001 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

For the Commission

David Byrne

Member of the Commission

(1) OJ L 40, 11.2.1989, p. 27.

(2) OJ L 237, 10.9.1994, p. 1.

(3) OJ L 237, 10.9.1994, p. 3.

(4) OJ L 48, 19.2.1997, p. 16.

(5) OJ L 178, 28.7.1995, p. 1.

(6) OJ L 257, 19.9.1998, p. 35.

ANNEX

"E 421 MANNITOL

>TABLE>"

"E 965(ii) SYRUP MALTITOL

>TABLE>"

COMMISSION DIRECTIVE 2001/52/EC
of 3 July 2001
amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use
in foodstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 ⁽¹⁾, as amended by Directive 94/34/EC ⁽²⁾ of the European Parliament and of the Council, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽³⁾, as amended by Directive 96/83/EC ⁽⁴⁾, lists those substances which may be used as sweeteners in foodstuffs.
- (2) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽⁵⁾, as last amended by Directive 2000/51/EC ⁽⁶⁾, sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC.
- (3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/31/EC for mannitol (E 421) and acesulfame K (E 950).
- (4) It is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the *Codex alimentarius* by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) It is consequently necessary to adapt Directive 95/31/EC.
- (6) 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

In the Annex to Directive 95/31/EC, the text concerning E 421 mannitol and E 950 acesulfame K shall be replaced by the text 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 by 30 June 2002 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 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, 3 July 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 237, 10.9.1994, p. 3.

⁽⁴⁾ OJ L 48, 19.2.1997, p. 16.

⁽⁵⁾ OJ L 178, 28.7.1995, p. 1.

⁽⁶⁾ OJ L 198, 4.8.2000, p. 41.

ANNEX

E 950 ACESULFAME K**Synonyms**

Acesulfame potassium, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one, 2,2-dioxide

Definition

Chemical name	6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
Einecs	259-715-3
Chemical formula	$C_4H_4KNO_4S$
Molecular weight	201,24
Assay	Content not less than 99 % of $C_4H_4KNO_4S$ on the anhydrous basis

Description

Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose

Identification

A. Solubility	Very soluble in water, very slightly soluble in ethanol
B. Ultra violet absorption	Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
C. Positive test for potassium	Passes test (test the residue obtained by igniting 2 g of the sample)
D. Precipitation test	Add a few drops of a 10 % solution of sodium cobaltinitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced

Purity

Loss on drying	Not more than 1 % (105 °C, two hours)
Organic impurities	Passes test for 20 mg/kg of UV active components
Fluoride	Not more than 3 mg /kg
Lead	Not more than 1 mg/kg

E 421 MANNITOL**1. Mannitol****Synonyms**

D-mannitol

Definition

Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose

Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	$C_6H_{14}O_6$
Molecular weight	182,2
Assay	Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis

Description

White, odourless, crystalline powder

Identification

A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C
C. Thin layer chromatography	Passes test
D. Specific rotation	$[\alpha]^{20}_D$: + 23° to + 25° (borate solution)
E. pH	Between 5 and 8
	Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

Purity

Loss on drying	Not more than 0,3 % (105 °C, four hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

2. Mannitol manufactured by fermentation**Synonyms**

D-mannitol

DefinitionManufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii*

Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	C ₆ H ₁₄ O ₆
Molecular weight	182,2
Assay	Not less than 99 % on the dried basis

Description

White, odourless crystalline powder

Identification

A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C
C. Thin layer chromatography	passes test
D. Specific rotation	[α] _D ²⁰ : + 23° to + 25° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

Purity

Arabitol	Not more than 0,3 %
Loss on drying	Not more than 0,3 % (105 °C, four hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Lead	Not more than 1 mg/kg
Aerobic mesophilic bacteria	Not more than 10 ³ /g
Coliforms	Absent in 10 g
<i>Salmonella</i>	Absent in 10 g
<i>E. coli</i>	Absent in 10 g
<i>Staphylococcus aureus</i>	Absent in 10 g
<i>Pseudomonas aeruginosa</i>	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g'

COMMISSION DIRECTIVE 2004/46/EC
of 16 April 2004
amending Directive 95/31/EC as regards E 955 sucralose and E 962 salt of aspartame-acesulfame
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽²⁾ sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽³⁾.
- (2) It is necessary to establish purity criteria for E 955 sucralose and E 962 salt of aspartame-acesulfame.
- (3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (4) Directive 95/31/EC should therefore be amended accordingly.
- (5) 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 95/31/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 1 April 2005 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 shall be accompanied by such 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, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, 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 178, 28.7.1995, p. 1. Directive as last amended by Directive 2001/52/EC (OJ L 190, 12.7.2001, p. 18).

⁽³⁾ OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2003/115/EC of the European Parliament and of the Council (OJ L 24, 29.1.2004, p. 65).

ANNEX

In the Annex, the following text is inserted:

E955 E 955 SUCRALOSE

Synonyms	4,1',6'-trichlorogalactosucrose
Definition	
Chemical name	1,6-Dichloro-1,6-dideoxy-b-D-fructofuranosyl-4-chloro-4-deoxy-a-D-galactopyranoside
Einecs	259-952-2
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.
Description	White to off-white, practically odourless crystalline powder.
Identification	
A. pH of a 10 % solution	Not less than 5,0 and not more than 7,0
B. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
C. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard.
D. Thin-layer chromatography	The main spot in the test solution has the same R _f value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol.
E. Specific rotation	$[\alpha]^{20}_D$: + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution)
Purity	
Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Lead	Not more than 1 mg/kg
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %

E962 E 962 SALT OF ASPARTAME-ACESULFAME

Synonyms	Aspartame-acesulfame Aspartame-acesulfame salt
Definition	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.
Chemical name	6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-a-aspartic acid
Chemical formula	$C_{18}H_{23}O_9N_3S$
Molecular weight	457,46
Assay	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37,0 % acesulfame (acid form on a dry basis)

Description

A white, odourless, crystalline powder.

Identification

A. Solubility

Sparingly soluble in water; slightly soluble in ethanol.

B. Transmittance

The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022.

C. Specific rotation

$[\alpha]^{20D}$: +14,5° to +16,5°

Determine at a concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame.

Purity

Loss on drying

Not more than 0,5 % (105 °C, 4 h)

5-Benzyl-3,6-dioxo-2-piperazineacetic acid

Not more than 0,5 %

Lead

Not more than 1 mg/kg'

31995L0045

Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs

Official Journal L 226 , 22/09/1995 P. 0001 - 0045

COMMISSION DIRECTIVE 95/45/EC

of 26 July 1995

laying down specific purity criteria concerning colours for use in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), as last amended by Directive 94/34/EC (2), and in particular Article 3 (3) (a) thereof,

After consulting the Scientific Committee for Food,

Whereas it is necessary to establish purity criteria for all colours mentioned in European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (3);

Whereas it is necessary to revise the purity criteria for colours mentioned in the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (4), as last amended by Directive 85/7/EEC (5);

Whereas it is necessary to take into account the specifications and analytical techniques for colours as set out in the Codex Alimentarius and the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

Whereas food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, shall be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;

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

The purity criteria referred to in Article 3 (3) (a) of Directive 89/107/EEC for colours mentioned in Directive 94/36/EC are set out in the Annex hereto.

Article 8 and Annex III to the Directive of 23 October 1962 are hereby deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1996. They shall immediately inform the Commission thereof.

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.

2. Products put on the market or labelled before 1 July 1996 which do not comply with this Directive may, however, be marketed until stocks are exhausted.

Article 3

This Directive shall enter into force on the third 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, 26 July 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 40, 11. 2. 1989, p. 27.

(2) OJ No L 237, 10. 9. 1994, p. 1.

(3) OJ No L 237, 10. 9. 1994, p. 13.

(4) OJ No 115, 11. 11. 1962, p. 2645/62.

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

ANNEX

A. General specifications for aluminium lakes of colours

>TABLE>

B. SPECIFIC CRITERIA OF PURITY

>TABLE>

31999L0075

Commission Directive 1999/75/EC of 22 July 1999 amending Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs (Text with EEA relevance)

Official Journal L 206 , 05/08/1999 P. 0019 - 0021

COMMISSION DIRECTIVE 1999/75/EC

of 22 July 1999

amending Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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(1), as amended by European Parliament and Council Directive 94/34/EC(2), and in particular Article 3(3)(a) thereof;

After consulting the Scientific Committee for Food,

(1) Whereas European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs(3), lists those substances which may be used as colours in foodstuffs;

(2) Whereas Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs(4) sets out the purity criteria for the colours mentioned in Directive 94/36/EC;

(3) Whereas it is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E160a (i)); whereas it is consequently necessary to adapt this Directive;

(4) Whereas it is appropriate to take into account the specifications and analytical techniques for colours as set out in the Codex Alimentarius and the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

(5) 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 95/45/EC is hereby amended as follows:

In the Annex part B the chapter concerning E 160a (i) Mixed Carotenes is replaced by the text of 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 before 1.7.2000. They shall immediately 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 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

1. This Directive is addressed to the Member States.

Done at Brussels, 22 July 1999.

For the Commission

Karel VAN MIERT

Member of the Commission

(1) OJ L 40, 11.2.1989, p. 27.

(2) OJ L 237, 10.9.1994, p. 1.

(3) OJ L 237, 10.9.1994, p. 13.

(4) OJ L 226, 22.9.1995, p. 1.

ANNEX

"E 160a (i) mixed carotenes

1. PLANT CAROTENES

>TABLE>

2. ALGAL CAROTENES

>TABLE>"

COMMISSION DIRECTIVE 2001/50/EC
of 3 July 2001
amending Directive 95/45/EC laying down specific purity criteria concerning colours for use in
foodstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/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 ⁽¹⁾, as amended by Directive 94/34/EC of the European Parliament and of the Council ⁽²⁾ and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee for Food,

Whereas:

- (1) Council Directive 94/36/EC of the European Parliament and of Council of 30 June 1994 on colours for use in foodstuffs ⁽³⁾ lists those substances which may be used as colours in foodstuffs.
- (2) Commission Directive 94/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs ⁽⁴⁾, as amended by Directive 1999/75/EC ⁽⁵⁾, sets out the purity criteria for the colours mentioned in Directive 94/36/EC.
- (3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E160a(i)) and beta-carotene (E160a(ii)).
- (4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) It is consequently necessary to adapt Directive 95/45/EC.
- (6) 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

In part B of the Annex to Directive 95/45/EC, the text concerning mixed carotenes (E160a(i)) and beta-carotene (E160a(ii)) is replaced by the text of 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 before 30 June 2002. They shall immediately 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 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, 3 July 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 237, 10.9.1994, p. 13.

⁽⁴⁾ OJ L 226, 22.9.1995, p. 1.

⁽⁵⁾ OJ L 206, 5.8.1999, p. 19.

ANNEX

'E 160 a (i) MIXED CAROTENES**1. Plant carotenes****Synonyms**

CI food orange 5

Definition

Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle

The main colouring principle consists of carotenoids of which β -carotene accounts for the major part. α , γ -carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material

Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (*), dichloromethane and carbon dioxide

Class

Carotenoid

Colour index No

75130

Einecs

230-636-6

Chemical formula

 β -carotene: $C_{40}H_{56}$

Molecular weight

 β -carotene: 536,88

Assay

Content of carotenes (calculated as β -carotene) is not less than 5 %. For products obtained by extraction of vegetables oils: not less than 0,2 % in edible fats

$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry

Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm

Purity

Solvent residues

Acetone

Methyl ethyl ketone

Methanol

Propan-2-ol

Hexane

Ethanol

Not more than 50 mg/kg, singly or in combination

Dichloromethane

Not more than 10 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

2. Algal carotenes**Synonyms**

CI food orange 5

Definition

Mixed carotenes may also be produced from natural strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. β -carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29

The main colouring principle consists of carotenoids of which β -carotene accounts for the major part. α -carotene, lutein, zeaxanthin and β -cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material

Class	Carotenoid
Colour Index No	75130
Chemical formula	β -Carotene: $C_{40}H_{56}$
Molecular weight	β -Carotene: 536,88
Assay	Content of carotenes (calculated as β -carotene) is not less than 20 % $E_{1\text{ cm}}^{1\%}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry	Maximum in cyclohexane at 448 nm to 457 nm and 474 nm to 486 nm
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Purity

Natural tocopherols in edible oil	Not more than 0,3 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 160 a (ii) BETA-CAROTENE**1. Beta-carotene**

Synonyms	CI food orange 5
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Definition	These specifications apply predominantly to all trans isomer of β -carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios
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Class	Carotenoid
Colour index No	40800
Einecs	230-636-6
Chemical names	β -carotene, β,β -carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as β -carotene) $E_{1\text{ cm}}^{1\%}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane

Description	Red to brownish-red crystals or crystalline powder
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Identification

A. Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm
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Purity

Sulphated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than β -carotene: not more than 3,0 % of total colouring matters
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

2. Beta-carotene from *Blakeslea trispora***Synonyms**

CI food orange 5

Definition

Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (-) of natural strains of the fungus *Blakeslea trispora*. The β -carotene is extracted from the biomass with ethyl acetate and crystallised. The crystallised product consists mainly of trans β -carotene. Because of the natural process approximately 3 % of the product consists of mixed carotenoids, which is specific for the product

Class

Carotenoid

Colour Index No

40800

Einecs

230-636-6

Chemical names

 β -carotene, β,β -carotene

Chemical formula

 $C_{40}H_{56}$

Molecular weight

536,88

Assay

Not less than 96 % total colouring matters (expressed as β -carotene) $E_{1\%}^{1\text{ cm}}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane**Description**

Red to brownish-red crystals or crystalline powder

Identification

A. Spectrometry

Maximum in cyclohexane at 453 nm to 456 nm

Purity

Solvent residues

Ethyl acetate

Ethanol

Not more than 0,8 %, singly or in combination

Sulphated ash

Not more than 0,2 %

Subsidiary colouring matters

Carotenoids other than β -carotene: not more than 3,0 % of total colouring matters

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Aflatoxin B1

Absent

Mycotoxins:

T2

Ochratoxin

Zearalenone

Absent

Microbiology:

Moulds

Not more than 100/g

Yeasts

Not more than 100/g

Salmonella

Absent in 25 g

Escherichia coli

Absent in 5 g

(*) Benzene not more than 0,05 % v/v.

CORRIGENDA**Corrigendum to Commission Directive 2001/50/EC of 3 July 2001 amending Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs**

(Official Journal of the European Communities L 190 of 12 July 2001)

On page 14, in the first recital, first and second lines:

for: 'Council Directive 94/36/EC of the European Parliament and of Council'

read: 'Directive 94/36/EC of the European Parliament and of the Council';

in the second recital, first line:

for: 'Commission Directive 94/45/EC'

read: 'Commission Directive 95/45/EC'.

COMMISSION DIRECTIVE 2004/47/EC**of 16 April 2004****amending Directive 95/45/EC as regards mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii))****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee for Food,

Whereas:

- (1) Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs⁽²⁾ sets out the purity criteria for the colours mentioned in Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs⁽³⁾.
- (2) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)).
- (3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (4) Directive 95/45/EC should therefore be amended accordingly.
- (5) 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 95/45/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 1 April 2005 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 shall be accompanied by such 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

Products on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

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, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, 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 226, 22.9.1995, p. 1. Directive as last amended by Directive 2001/50/EC (OJ L 190, 12.7.2001, p. 14).

⁽³⁾ OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX

In the Annex, the text concerning mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)) is replaced by the following:

E 160 a (i) MIXED CAROTENES**1. Plant carotenes****Synonyms**

CI Food Orange 5

Definition

Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (*), dichloromethane and carbon dioxide.

Class

Carotenoid

Colour index No

75130

EINECS

230-636-6

Chemical formula

Beta-carotene: $C_{40}H_{56}$

Molecular weight

Beta-carotene: 536,88

Assay

Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetable oils: not less than 0,2 % in edible fats

$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry

Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm

Purity

Solvent residues

Acetone

Methyl ethyl ketone

Methanol

Propan-2-ol

Hexane

Ethanol

Not more than 50 mg/kg, singly or in combination

Dichloromethane

Not more than 10 mg/kg

Lead

Not more than 5 mg/kg

(*) Benzene not more than 0,05 % v/v.

2. Algal carotenes

Synonyms	CI Food Orange 5
Definition	<p>Mixed carotenes may also be produced from natural strains of the algae <i>Dunaliella salina</i>, grown in large saline lakes located in Whyalla, South Australia. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29.</p> <p>The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.</p>
Class	Carotenoid
Colour index No	75130
Chemical formula	Beta-carotene: $C_{40}H_{56}$
Molecular weight	Beta-carotene: 536,88
Assay	<p>Content of carotenes (calculated as beta-carotene) is not less than 20 %.</p> <p>$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane</p>
Identification	
A. Spectrometry	Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm
Purity	
Natural tocopherols in edible oil	Not more than 0,3 %
Lead	Not more than 5 mg/kg

E 160 a (ii) BETA-CAROTENE**1. Beta-carotene**

Synonyms	CI Food Orange 5
Definition	These specifications apply predominantly to all trans isomers of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.
Class	Carotenoid
Colour index No	40800
EINECS	230-636-6
Chemical names	Beta-carotene, beta,beta-carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	<p>Not less than 96 % total colouring matters (expressed as beta-carotene)</p> <p>$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane</p>
Description	Red to brownish-red crystals or crystalline powder
Identification	
A. Spectrometry	Maximum in cyclohexane at 453 to 456 nm
Purity	
Sulfated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters
Lead	Not more than 2 mg/kg

2. Beta-carotene from *Blakeslea trispora*

Synonyms

CI Food Orange 5

Definition

Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (-) of natural strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate, or isobutyl acetate followed by isopropyl alcohol, and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process, approximately 3 % of the product consists of mixed carotenoids, which is specific for the product.

Class

Carotenoid

Colour index No

40800

EINECS

230-636-6

Chemical names

Beta-carotene, beta,beta-carotene

Chemical formula

$C_{40}H_{56}$

Molecular weight

536,88

Assay

Not less than 96 % total colouring matters (expressed as beta-carotene)

$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Description

Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)

Identification

A. Spectrometry

Maximum in cyclohexane at 453 nm to 456 nm

Purity

Solvent residues

Ethyl acetate

Ethanol

} Not more than 0,8 %, singly or in combination

Isobutyl acetate: Not more than 1,0 %

Isopropyl alcohol: Not more than 0,1 %

Sulfated ash

Not more than 0,2 %

Subsidiary colouring matters

Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters

Lead

Not more than 2 mg/kg

Mycotoxins:

Aflatoxin B1

Absent

Trichothecene (T2)

Absent

Ochratoxin

Absent

Zearalenone

Absent

Microbiology:

Moulds

Not more than 100/g

Yeasts

Not more than 100/g

Salmonella

Absent in 25 g

Escherichia coli

Absent in 5 g

COMMISSION DECISION
of 27 March 2002
suspending the placing on the market and import of jelly confectionery containing the food
additive E 425 konjac

(notified under document number C(2002) 1283)

(Text with EEA relevance)

(2002/247/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾, and in particular Article 53(1) thereof,

Whereas:

- (1) Under Article 53(1) of Regulation (EC) No 178/2002 the Commission can suspend the placing on the market or use of a food that is likely to constitute a serious risk to human health, when such risk cannot be contained satisfactorily by means of measures taken by the Member States concerned.
- (2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽²⁾ authorises in its Annex IV the use of the food additive E 425 konjac in foodstuffs under certain conditions.
- (3) Several Member States and third countries have taken measures to temporarily prohibit the placing on the market of jelly mini-cups containing E 425 konjac because they have caused the death of several children in third countries through choking. The Commission has been informed of these measures.
- (4) Some manufacturers of jelly mini-cups recognise the risk to human health by affixing a warning on the food package, highlighting the risk for children and elderly.
- (5) The Commission has examined the information given by the Member States together with the Standing Committee on the Food Chain and Animal Health.
- (6) On the basis of the information provided by the Member States who adopted measures at national level, it can be concluded that jelly mini-cups containing E 425 konjac constitute a life-threatening risk. In addition to their shape and size, the chemical and physical

properties of konjac are the cause for jelly mini-cups to constitute a serious risk to human health.

- (7) In the present case, warning through labelling is not sufficient to protect human health, especially with regard to children.
- (8) Community-wide measures are necessary to provide adequate protection of human health, due to the disparity of the measures taken by some Member States and the fact that other Member States have not taken any measures at all.
- (9) It is necessary to suspend the placing on the market of jelly mini-cups containing konjac and the use of konjac in jelly mini-cups and imports of jelly mini-cups containing konjac in order to protect human health. In addition, any other jelly confectionery containing konjac and the use of konjac in any such products should be suspended, as they may present the same risk as jelly mini-cups.
- (10) The Commission will propose to the European Parliament and to the Council an amendment to Directive 95/2/EC on food additives other than colours and sweeteners in order to modify the authorisation for the use of E 425 konjac in line with this Decision.
- (11) The Commission will examine whether there is a need to take further action to address the risk of choking that may exist from the general use of gelling agents in jelly confectionery, and will come forward, if necessary, with appropriate proposals.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

1. The placing on the market of jelly confectionery, including jelly mini-cups, containing E 425: Konjac: (i) Konjac gum (ii) Konjac glucomannane is suspended.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 61, 18.3.1995, p. 1.

2. The use of E 425: Konjac: (i) Konjac gum (ii) Konjac glucomannane in jelly confectionery, including jelly mini-cups, is suspended.
3. The import of jelly confectionery, including jelly mini-cups, containing E 425: Konjac: (i) Konjac gum (ii) Konjac glucomannane is suspended.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 27 March 2002.

For the Commission

David BYRNE

Member of the Commission

COMMISSION DECISION

of 13 April 2004

suspending the placing on the market and import of jelly mini-cups containing the food additives E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417 and/or E 418

(notified under document number C(2004) 1401)

(Text with EEA relevance)

(2004/374/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾, as amended by Regulation (EC) No 1642/2003 ⁽²⁾, and in particular Article 53(1) thereof,

Whereas:

- (1) Under Article 53(1) of Regulation (EC) No 178/2002 the Commission can suspend the placing on the market or use of a food that is likely to constitute a serious risk to human health, when such risk cannot be contained satisfactorily by means of measures taken by the Member States concerned.
- (2) 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⁾, as last amended by Regulation (EC) No 1882/2003 ⁽⁴⁾, authorises the use of the food additives E 400 alginic acid, E 401 sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 405 propane 1,2-diol alginate, E 406 agar, E 407 carrageenan, E 407a processed eucheama seaweed, E 410 locust bean gum, E 412 guar gum, E 413 tragacanth, E 414 acacia gum, E 415 xanthan gum, E 417 tara gum and/or E 418 gellan gum in foodstuffs under certain conditions.
- (3) Several Member States have taken measures to temporarily prohibit the placing on the market or import of jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cup or mini-capsule to project the confectionery into the mouth and containing additives derived from seaweed and/or certain gums, hereafter designated as jelly mini-cups. The concerned Member States have taken these measures as these jelly mini-cups combine several risk factors due

to their consistence, shape, size and manner of ingestion, giving rise to a risk that they remain blocked in the throat and provoke choking. The Commission has been informed of these measures.

- (4) The Commission has examined the information given by the Member States together with the Standing Committee on the Food Chain and Animal Health.
- (5) On the basis of the information provided by the Member States who adopted measures at national level, it can be concluded that jelly mini-cups containing additives derived from seaweed and/or certain gums constitute a life-threatening risk. Even if the shape, size and manner of ingestion are the main cause, the risk also originates from the chemical and physical properties of these additives which contribute to the cause for jelly mini-cups to constitute a serious risk to human health.
- (6) In the present case, warning through labelling would not be sufficient to protect human health, especially with regard to children.
- (7) Community-wide measures are necessary to provide adequate protection of human health, due to the disparity of the measures taken by some Member States and the fact that other Member States have not taken any measures at all.
- (8) It is necessary to suspend the placing on the market of jelly mini-cups containing one or more of the food additives E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417 and/or E 418 and the use of these additives in jelly mini-cups and imports of jelly mini-cups containing these additives in order to protect human health.
- (9) The Commission will consult the European Food Safety Authority on this matter as it is of public health relevance and, on the basis of the scientific opinion of the Authority, it will review the present decision and examine whether there is a need to propose to the European Parliament and to the Council an amendment to Directive 95/2/EC.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 245, 29.9.2003, p. 4.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 284, 31.10.2003, p. 1.

- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of this Decision, jelly mini-cups means jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cup or mini-capsule to project the confectionery into the mouth and containing food additives derived from seaweed and/or certain gums.

Article 2

1. The placing on the market of jelly mini-cups containing E 400 alginic acid, E 401 sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 405 propane 1,2-diol alginate, E 406 agar, E 407 carrageenan, E 407a processed eucheima seaweed, E 410 locust bean gum, E 412 guar gum, E 413 tragacanth, E 414 acacia gum, E 415 xanthan gum, E 417 tara gum and/or E 418 gellan gum is suspended.

2. The use of E 400 alginic acid, E 401 sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 405 propane 1,2-diol alginate, E 406 agar, E 407 carrageenan, E 407a processed eucheima seaweed, E 410 locust bean gum, E 412 guar gum, E 413 tragacanth, E 414 acacia gum, E 415 xanthan gum, E 417 tara gum and/or E 418 gellan gum in jelly mini-cups is suspended.

3. The import of jelly mini-cups containing E 400 alginic acid, E 401 sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 405 propane 1,2-diol alginate, E 406 agar, E 407 carrageenan, E 407a processed eucheima seaweed, E 410 locust bean gum, E 412 guar gum, E 413 tragacanth, E 414 acacia gum, E 415 xanthan gum, E 417 tara gum and/or E 418 gellan gum is suspended.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission