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

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REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients

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) in the light of the joint text approved by the Conciliation Committee on 9 December 1996,

(1) Whereas differences between national laws relating to novel foods or food ingredients may hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the functioning of the internal market;

(2) Whereas, in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community; whereas in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for;

(3) Whereas food additives, flavourings for use in foodstuffs and extraction solvents are covered by other Community legislation and should therefore be excluded from the scope of this Regulation;

(4) Whereas appropriate arrangements should be made for the placing on the market of novel foods and novel food ingredients derived from plant varieties subject to Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (4) and Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (5);

(5) Whereas risks to the environment may be associated with novel foods or novel food ingredients which contain or consist of genetically modified organisms; whereas Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (6) stipulates that, for such products, an environmental risk assessment must always be undertaken to ensure environmental safety; whereas, in order to establish a unified Community system for assessment of such products, provision must be made under this Regulation for a specific environmental risk assessment, which in accordance with the procedure provided for in Article 10 of Directive 90/220/EEC must be similar to that laid down in that Directive, but must also include the assessment of the suitability of the product to be used as a food or food ingredient;

(6) Whereas the Scientific Committee for Food set up by Decision 74/234/EEC (7) should be consulted on any question relating to this Regulation which may have an effect on public health;

(7) Whereas Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (8) and Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (9) apply to novel foods or food ingredients;

(8) Whereas, without prejudice to the other requirements in Community legislation relating to the labelling of foodstuffs, additional specific requirements on labelling should be laid down; whereas these requirements must be subject to precise provisions in order to ensure that the necessary information is available to the consumer; whereas defined population groups associated with well established practices regarding food should be informed when the presence in a novel food of material which is not present in the existing equivalent foodstuff gives rise to ethical concerns as regards those groups; whereas foods and food ingredients which contain genetically modified organisms and which are placed on the market must be safe for human health; whereas this assurance is provided for through compliance with the authorization procedure contained in Directive 90/220/EEC and/or by the single assessment procedure laid down in this Regulation; whereas insofar as an organism is defined by Community law, with respect to labelling, information to the consumer on the presence of an organism which has been genetically modified constitutes an additional requirement applicable to the foods and food ingredients referred to in this Regulation;

(9) Whereas, in respect of foods and food ingredients which are intended to be placed on the market to be supplied to the final consumer, and which may contain both genetically modified and conventional produce, and without prejudice to the other labelling requirements of this Regulation, information for the consumer on the possibility that genetically modified organisms may be present in the foods and food ingredients concerned is deemed - by way of exception, in particular as regards bulk consignments - to fulfil the requirements of Article 8;

(10) Whereas nothing shall prevent a supplier from informing the consumer on the labelling of a food or food ingredient that the product in question is not a novel food within the meaning of this Regulation or that the techniques used to obtain novel foods indicated in Article 1 (2) were not used in the production of that food or food ingredient;

(11) Whereas, under this Regulation, 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 Decision 69/414/EEC (10);

(12) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994 (11),

HAVE ADOPTED THIS REGULATION:

Article 1

1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

3. Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls within the scope of paragraph 2 of this Article.

Article 2

1. This Regulation shall not apply to:

(a) food additives falling within the scope of 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 (12);

(b) flavourings for use in foodstuffs, falling within the scope 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 (13);

(c) extraction solvents used in the production of foodstuffs, falling within the scope of 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 (14).

2. The exclusions from the scope of this Regulation referred to in paragraph 1, indents (a) to (c) shall only apply for so long as the safety levels laid down in Directives 89/107/EEC, 88/388/EEC and 88/344/EEC correspond to the safety level of this Regulation.

3. With due regard for Article 11 the Commission shall ensure that the safety levels laid down in the above Directives, as well as in the implementing measures for these Directives and this Regulation, correspond to the safety level of this Regulation.

Article 3

1. Foods and food ingredients falling within the scope of this Regulation must not:

- present a danger for the consumer,

- mislead the consumer,

- differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

2. For the purpose of placing the foods and food ingredients falling within the scope of this Regulation on the market within the Community, the procedures laid down in Articles 4, 6, 7 and 8 shall apply on the basis of the criteria defined in paragraph 1 of this Article and the other relevant factors referred to in those Articles.

However, in the case of foods or food ingredients referred to in this Regulation derived from plant varieties subject to Directives 70/457/EEC and 70/458/EEC, the authorization decision referred to in Article 7 of this Regulation shall be taken in accordance with the procedures provided for in those Directives, provided they take account of the assessment principles laid

down in this Regulation and the criteria set out in paragraph 1 of this Article, with the exception of the provisions relating to the labelling of such foods or food ingredients, which shall be established, pursuant to Article 8, in accordance with the procedure laid down in Article 13.

3. Paragraph 2 shall not apply to the foods and food ingredients referred to in Article 1 (2) (b) where the genetically modified organism used in the production of the food or food ingredient has been placed on the market in accordance with this Regulation.

4. By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4 (3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under this paragraph.

Article 4

1. The person responsible for placing on the Community market (hereinafter 'the applicant`) shall submit a request to the Member State in which the product is to be placed on the market for the first time. At the same time, he shall forward a copy of the request to the Commission.

2. An initial assessment as provided for in Article 6 shall be carried out.

Following the procedure referred to in Article 6 (4), the Member State referred to in paragraph 1 shall inform the applicant without delay:

- that he may place the food or food ingredient on the market, where the additional assessment referred to in Article 6 (3) is not required, and that no reasoned objection has been presented in accordance with Article 6 (4), or

- that, in accordance with Article 7, an authorization decision is required.

3. Each Member State shall notify to the Commission the name and address of the food assessment bodies responsible in its territory for preparing the initial assessment reports referred to in Article 6 (2).

4. Before the date of entry into force of this Regulation, the Commission shall publish recommendations concerning the scientific aspects of:

- the information necessary to support an application and the presentation of such information,

- the preparation of the initial assessment reports provided for in Article 6.

5. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 5

In the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3 (4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the 'C` series of the Official Journal of the European Communities.

With respect to labelling, the provisions of Article 8 shall apply.

Article 6

1. The request referred to in Article 4 (1) shall contain the necessary information, including a copy of the studies which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Article 3 (1), as well as an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier.

2. Upon receipt of the request, the Member State referred to in Article 4 (1) shall ensure that an initial assessment is carried out. To that end, it shall notify the Commission of the name of the competent food assessment body responsible for preparing the initial assessment report, or ask the Commission to arrange with another Member State for one of the competent food assessment bodies referred to in Article 4 (3) to prepare such a report.

The Commission shall forward to the Member States without delay a copy of the summary provided by the applicant and the name of the competent body responsible for carrying out the initial assessment.

3. The initial assessment report shall be drawn up within a period of three months from receipt of a request meeting the conditions laid down in paragraph 1, in accordance with the recommendations referred to in Article 4 (4), and shall decide whether or not the food or food ingredient requires additional assessment in accordance with Article 7.

4. The Member State concerned shall without delay forward the report of the competent food assessment body to the Commission, which shall forward it to the other Member States. Within a period of 60 days from the date of circulation of the report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing of the food or food ingredient concerned. The comments or objections may also concern the presentation or labelling of the food or food ingredient.

Comments or objections shall be forwarded to the Commission, which shall circulate them to Member States within the period of 60 days referred to in the first subparagraph.

The applicant shall, where a Member State so requests, provide a copy of any pertinent information appearing in the request.

Article 7

1. Where an additional assessment is required in accordance with Article 6 (3) or an objection is raised in accordance with Article 6 (4), an authorization decision shall be taken in accordance with the procedure laid down in Article 13.

2. The decision shall define the scope of the authorization and shall establish, where appropriate:

- the conditions of use of the food or food ingredient,

- the designation of the food or food ingredient, and its specification,

- specific labelling requirements as referred to in Article 8.

3. The Commission shall without delay inform the applicant of the decision taken. Decisions shall be published in the Official Journal of the European Communities.

Article 8

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

- composition,

- nutritional value or nutritional effects,

- intended use of the food,

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.

A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;

(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1 of Directive 90/220/EEC.

2. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary in order to ensure that consumers are adequately informed of the nature of the food or food ingredient.

3. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 9

1. Where a food or food ingredient falling within the scope of this Regulation contains or consists of a genetically modified organism within the meaning of Article 2 (1) and (2) of Directive 90/220/EEC, the information required in the request for placing on the market referred to in Article 6 (1) shall be accompanied by:

- a copy of the written consent, if any, from the competent authority, to the deliberate release of the genetically modified organisms for research and development purposes provided for in Article 6 (4) of Directive 90/220/EEC, together with the results of the release(s) with respect to any risk to human health and the environment;

- the complete technical dossier supplying the relevant information requested in Article 11 of Directive 90/220/EEC and the environmental risk assessment based on this information, the results of any studies carried out for the purposes of research and development or, where appropriate, the decision authorizing the placing on the market provided for in part C of Directive 90/220/EEC.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to foods or food ingredients which contain or consist of genetically modified organisms.

2. In the case of foods or food ingredients falling within the scope of this Regulation containing or consisting of genetically modified organisms, the decision referred to in Article 7 shall

respect the environmental safety requirements laid down by Directive 90/220/EEC to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Commission or the Member States with the bodies set up by the Community or the Member States in accordance with Directive 90/220/EEC.

Article 10

Detailed rules for the protection of the information provided by the applicant shall be adopted in accordance with the procedure laid down in Article 13.

Article 11

The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health.

Article 12

1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.

Article 13

1. Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, hereinafter referred to as the 'Committee`.

2. Matters shall be referred to the Committee by the Chairman 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 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 14

1. No later than five years from the date of entry into force of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any suitable proposal.

2. Notwithstanding the review provided for in paragraph 1, the Commission shall monitor the application of this Regulation and its impact on health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 15

This Regulation shall enter into force 90 days following its publication in the Official Journal of the European Communities.

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

Done at Brussels, 27 January 1997.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

G. ZALM

(1) OJ No C 190, 29. 7. 1992, p. 3

and OJ No C 16, 19. 1. 1994, p. 10.

(2) OJ No C 108, 19. 4. 1993, p. 8.

(3) Opinion of the European Parliament of 27 October 1993 (OJ No C 315, 22. 11. 1993, p. 139). Council Common Position of 23 October 1995 (OJ No C 320, 30. 11. 1995, p. 1) and Decision of the European Parliament of 12 March 1996 (OJ No C 96, 1. 4. 1996, p. 26). Decision of the Council of 19 December 1996 and Decision of the European Parliament of 16 January 1997.

(4) OJ No L 225, 12. 10. 1970, p. 1. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

(5) OJ No L 225, 12. 10. 1970, p. 7. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

(6) OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

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

(8) OJ No L 186, 30. 6. 1989, p. 23. Directive as last amended by Directive 93/99/EEC (OJ No L 290, 24. 11. 1993, p. 14).

(9) OJ No L 290, 24. 11. 1993, p. 14.

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

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

(12) 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).

(13) OJ No L 184, 15. 7. 1988, p. 61. Directive as last amended by Directive 91/71/EEC (OJ No L 42, 15. 2. 1991, p. 25).

(14) OJ No L 157, 24. 6. 1988, p. 28. Directive as last amended by Directive 92/115/EEC (OJ No L 409, 31. 12. 1992, p. 31).

COMMISSION STATEMENT - AD ARTICLE 2

The Commission confirms that should it appear, in the light of experience, that there are gaps in the system of protection of public health provided for by the existing legal framework, in particular in respect of processing aids, it will formulate appropriate proposals in order to fill those gaps.

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(Acts whose publication is obligatory)

REGULATION (EC) No 1882/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 September 2003

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

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

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

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

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

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

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

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

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

HAVE ADOPTED THIS REGULATION:

Article 1

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

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[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	*For the Council*
The President	*The President*
P. COX	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 apprised, 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.

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(*) 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 apprised, 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.

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(*) Council Decision 1999/468/EC of 28 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.

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([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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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

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[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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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

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([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.

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(*) Council Decision 1999/468/EC of 28 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).'

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([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.

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

([2]) OJ L 49, 21.2.1989, p. 26.

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

Article 14

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

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

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

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

Article 7 is replaced by the following:

'*Article 7*

1. A Committee on Statistical Confidentiality, hereinafter referred to as "the Committee", is hereby set up.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 9 is replaced by the following:

'*Article 9*

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

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

2. The Committee shall adopt its rules of procedure.

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

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

Articles 12 and 13 are replaced by the following:

'*Article 12*

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

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

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

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

2. The Committee shall adopt its rules of procedure.

Article 13

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

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

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

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

Article 30 is replaced by the following:

'*Article 30*

1. The Commission shall be assisted by the Committee on the statistics relating to the trading of goods between Member States, hereinafter referred to as "the Committee".

2. The provisions required for the implementation of this Regulation shall be adopted according to the procedure laid down in paragraph 3.

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

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

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

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

Articles 9 and 10 are replaced by the following:

'*Article 9*

Committee

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

2. The procedures for implementing this Regulation, including the measures for adjustment to technical progress concerning collection of data and the processing of the results, shall be laid down by the Commission in accordance with the procedure laid down in Article 10.

3. The Committee shall adopt its rules of procedure.

Article 10

Procedure

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

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

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

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

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

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

Article 6 is replaced by the following:

'*Article 6*

1. The Commission shall be assisted by a committee.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 15 is replaced by the following:

'*Article 15*

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

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

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

— a similar level of responsibility and activity.

3. The Commission shall be assisted by a committee.

The Committee shall adopt its rules of procedure.

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

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

[1] OJ L 377, 31.12.1991, p. 48.

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

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

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

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

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

Article 10 is replaced by the following:

'*Article 10*

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

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

The Committee shall adopt its rules of procedure.

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

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

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

(a) the determination, where appropriate, of the conditions relating to the documentation and labelling of mixtures and preparations of substances in category 2 of Annex I as provided for in Article 2;

(b) the amendment of the Annexes to this Directive, in cases where the tables of the Annex to the United Nations Convention are amended;

(c) the amendment of the thresholds specified in Annex II.

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

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

Article 7 is replaced by the following:

'*Article 7*

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

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

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 13 is replaced by the following:

'*Article 13*

1. The Commission shall be assisted by a committee.

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

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

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

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

4. The Committee shall adopt its rules of procedure.

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

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

Article 9 is replaced by the following:

'*Article 9*

Procedure

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

[1] OJ L 121, 15.5.1993, p. 20.

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

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 6 is replaced by the following:

'*Article 6*

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

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

2. The Committee shall adopt its rules of procedure.

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

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

Article 21 is replaced by the following:

'*Article 21*

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

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

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

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

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

Article 31 is replaced by the following:

'*Article 31*

1. The Commission shall be assisted by a committee.

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

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

([3]) OJ L 281, 23.11.1995, p. 31.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 12 is replaced by the following:

'*Article 12*

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

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

2. The Committee shall adopt its rules of procedure.

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

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

Article 13 is replaced by the following:

'*Article 13*

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

([1]) OJ L 291, 6.12.1995, p. 32.

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

([3]) OJ L 235, 17.9.1996, p. 31.

Article 12 is replaced by the following:

'*Article 12*

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 7 is replaced by the following:

'*Article 7*

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

Article 17(3) is replaced by the following:

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

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

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

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

Article 27 is replaced by the following:

'*Article 27*

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

([1]) OJ L 108, 1.5.1996, p. 1.

([2]) OJ L 163, 2.7.1996, p. 1.

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

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

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

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

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

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

The Standing Committee shall adopt its rules of procedure.

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

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

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

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

Article 10 is replaced by the following:

'*Article 10*

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

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

[1] OJ L 52, 22.2.1997, p. 1.

[2] OJ L 123, 24.4.1998, p. 1.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

(a) Article 8 is replaced by the following:

'*Article 8*

1. The Commission shall be assisted by a committee.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

Article 12 is replaced by the following:

'*Article 12*

1. The Commission shall be assisted by a committee.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

[1] OJ L 213, 30.7.1998, p. 1.

[2] OJ L 330, 5.12.1998, p. 32.

[3] OJ L 354, 30.12.1998, p. 5.

Article 8 is replaced by the following:

'*Article 8*

1. The Commission shall be assisted by the geographically-determined committee competent for development (hereinafter referred to as "the Committee").

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

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

3. As regards the points referred to in paragraph 2, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

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

Article 4 is replaced by the following:

'*Article 4*

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

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

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

3. The Committee shall adopt its rules of procedure.

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

([1]) OJ L 146, 11.6.1999, p. 33.

([2]) OJ L 117, 5.5.1999, p. 39.

ANNEX III

REGULATORY PROCEDURE

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

1) Council Directive 75/442/EEC of 15 July 1975 on waste [1].

Article 18 is replaced by the following:

'Article 18

1. The Commission shall be assisted by a committee.

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

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

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

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

The Committee shall adopt its rules of procedure.

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

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

Article 8 is replaced by the following:

'Article 8

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

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

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

Article 12 is replaced by the following:

'Article 12

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

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

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

3. The Committee shall adopt its rules of procedure.

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

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

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

Articles 13 and 14 are replaced by the following:

'Article 13

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

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

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

3. The Committee shall adopt its rules of procedure.

Article 14

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

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

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

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

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

Article 4 is replaced by the following:

'Article 4

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

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

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

[3] OJ L 372, 31.12.1985, p. 50.

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

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

3. The Committee shall adopt its rules of procedure.

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(*) 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.

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(*) Council Decision 1999/468/EC of 28 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".

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[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.

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(*) 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).'

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([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.

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(*) Council Decision 1999/468/EC of 28 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.

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

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([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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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

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([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.

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(*) Council Decision 1999/468/EC of 28 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.

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([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).'

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([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.

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(*) Council Decision 1999/468/EC of 28 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).'

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[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 CO_2 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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) 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).'

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[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.

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(*) 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.

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(*) 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.

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([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.

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(*) Council Decision 1999/468/EC of 28 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".

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[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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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[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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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

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([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.

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(*) Council Decision 1999/468/EC of 28 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].

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[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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) 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).'

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([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).'

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([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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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.

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[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.

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(*) Council Decision 1999/468/EC of 28 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.

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(*) Council Decision 1999/468/EC of 28 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 CO_2 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).'

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([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.

CORRIGENDA

Corrigendum to Council Regulation (EC) No 48/1999 of 18 December 1998 fixing, for certain fish stocks and groups of fish stocks, the total allowable catches for 1999 and certain conditions under which they may be fished

(Official Journal of the European Communities L 13 of 18 January 1999)

This corrigendum shall cancel and replace the corresponding part of the corrigendum published in *Official Journal of the European Communities* L 126 of 20 May 1999, page 22.

On page 4 in Article 12(2), second line:

for: '... carry on board only towed nets...',

read: '... carry on board towed nets...'.

31997H0618

97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (Text with EEA relevance)

Official Journal L 253 , 16/09/1997 P. 0001 - 0036

COMMISSION RECOMMENDATION of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (Text with EEA relevance) (97/618/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1), and in particular Article 4 (4) thereof,

Whereas, in order to protect public health, it is necessary that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community;

Whereas recommendations concerning the scientific aspects of the information necessary to support an application for the placing on the market of a novel food or a novel food ingredient will facilitate the task of economic operators in preparing such an application; whereas recommendations concerning the presentation of such information and concerning the preparation of initial assessment reports by the competent food assessment bodies of the Member States will facilitate the evaluation of such applications;

Whereas the Scientific Committee for Food has made recommendations on the information necessary to support such applications, the presentation of that information and the preparation of initial assessment reports on those applications;

Whereas experience in the assessment of novel foods and novel food ingredients is at present limited; whereas therefore any recommendations in this area must be kept under constant review to take account of new scientific information and the work of the relevant international organizations;

Whereas the Member States have been consulted on this Recommendation within the framework of the Standing Committee for Foodstuffs,

HEREBY RECOMMENDS THAT:

1. When preparing applications for the placing on the market of novel foods and novel food ingredients, economic operators should follow the recommendations concerning the scientific aspects of the information necessary to support such applications set out in the Annex, Part I.

2. Economic operators should ensure that the information necessary to support applications referred to in point 1 is presented in accordance with the recommendations set out in the Annex, Part II.

3. Member States should ensure that the initial assessment reports drawn up by their competent food assessment bodies pursuant to Article 6 (2) of Regulation (EC) No 258/97 are prepared in accordance with the recommendations set out in the Annex, Part III.

Done at Brussels, 29 July 1997.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 43, 14. 2. 1997, p. 1.

ANNEX

PART I RECOMMENDATIONS CONCERNING THE SCIENTIFIC ASPECTS OF INFORMATION NECESSARY TO SUPPORT APPLICATIONS FOR THE PLACING ON THE MARKET OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS

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I. INTRODUCTION

Whenever changes are made to the way in which a food is put on the market, produced or processed or uses non-traditional ingredients, the implications for consumer safety and nutritional value will require consideration. Information will be needed on any issue relating to both these aspects. At present, the issue of food safety in relation to novel foods is under consideration world-wide. The World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD), and other national and international bodies have addressed both general and specific aspects relevant to the wholesomeness of novel foods. A number of reports outline the philosophies and developments in this field (see references).

As part of the development of Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients the European Commission has asked the Scientific Committee for Food (SCF) to develop recommendations concerning the scientific aspects of

I. the information necessary to support an application for the placing on the market of novel foods and novel food ingredients;

II. the presentation of such information;

III. the preparation of the initial assessment reports.

This report covers task I.

2. CATEGORIES OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS IDENTIFIED IN REGULATION (EC) No 258/97

According to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1), Regulation (EC) No 258/97 will apply to the placing on the market of foods or food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Council Directive 90/220/EEC (2);

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and which have a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or the level of undesirable substances.

The Regulation does not apply to: food additives falling within the scope of Council Directive 89/107/EEC (3); flavourings for use in foodstuffs falling within the scope of Council Directive 88/388/EEC (4); or extraction solvents used in the production of foodstuffs falling within the scope of Council Directive 88/344/EEC (5).

3. KEY ISSUES FOR THE ASSESSMENT OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS (NF)

3.1 General considerations

Foods are usually complex mixtures of macro- and microconstituents which provide energy and nutrients and contribute to the well-being of humans. They have traditionally been regarded as natural, beneficial and necessary products whose safety and nutritional value need not be questioned. Regulatory approaches to food safety have reflected this attitude and have focused on food additives, processing aids and contaminants of natural or industrial origin. Thus, foods have not hitherto been systematically subjected to nutritional or toxicological evaluation, except in rare cases where acute toxic effects have been reported in humans (e.g. solanine, cyanogenic glycosides) or in those cases where animal studies or human experiences have suggested adverse effects from raw food materials (e.g. raw soya flour). This is not to imply that nutritional evaluation of individual foods and of whole diets has not been performed, but that such nutritional evaluations have not been used as a basis for a safety assessment of individual foods. On the other hand, food additives are not permitted in food unless they have been subjected to exhaustive toxicological evaluation.

Various foods are known to contain toxic compounds, including mutagens and carcinogens. Some chronic diseases in humans have a dietary element in their etiology. Although it is agreed that some adverse effects of the diet on health are related to the pattern of nutrient intake, the exact mechanisms involved are not known. It is possible that some ill health is due to chronic exposure to constituents of traditional foods. Until recently little attention has been given to this aspect or to the possible role of modifiers of toxic effects (e.g. anticarcinogens) naturally present in foods.

The assessment of the wholesomeness of foods including foods and food ingredients (NF) presents a number of scientific challenges. Conventional toxicological evaluation methods cannot be applied to foods, because foods present particular difficulties not encountered with the testing of food additives and contaminants in vivo and in vitro. For example, the amount of food to be incorporated in the diet for animal feeding studies without perturbing its nutritional balance makes the use of conventional safety factors inappropriate for risk assessment and management for any product intended for use as a food or a major food ingredient. Furthermore, traditional metabolic and pharmacokinetic studies are not directly applicable to complex chemical mixtures like foods. The use of mutagenicity and other in vitro tests for foods requires special techniques and cautious interpretation of the results.

Therefore, alternative approaches for the testing and assessment of the wholesomeness of foods and major food ingredients are needed. The ultimate strategy for combined nutritional-toxicological testing will extend from initial tests in vitro and in vivo studies in animal models to studies in humans if needed.

3.2 Genetically Modified Organisms (GMO)

Council Directives 90/219/EEC (6) and 90/220/EEC as amended by Commission Directive 94/15/EC (7) set out the information requirements for the safety of the contained use of genetically modified microorganisms (GMM) and the safety of the deliberate release of genetically modified organisms (GMO), respectively. The requirements in these directives are also relevant to GMO covered by Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients and fulfil basic information requirements needed for the safety assessment of NF. The present recommendations specifically focus on those aspects relevant to human food safety issues.

3.3 Substantial equivalence

The concept of 'substantial equivalence` has been introduced by WHO and OECD with particular reference to foods produced by modern biotechnology. In the terminology of the OECD, the concept of substantial equivalence embodies the idea that existing organisms used as foods or as food sources can serve as a basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new. If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart.

The application of the principle of substantial equivalence can be extended to the evaluation of foods from novel sources and processes. Substantially equivalent NF are thus comparable, in terms of safety, to their conventional counterpart. Substantial equivalence may be established either for the whole food or food component including the introduced 'new` change, or it might be established for the food or food component except for the specific 'new` change introduced. If a NF has not been found to be substantially equivalent to an existing food or food component, this does not imply that it is unsafe. It just indicates that such a NF should be evaluated on the basis of its unique composition and properties.

The establishment of substantial equivalence is an analytical exercise in the assessment of the relative wholesomeness of a NF compared to an existing food or food component. It contains a dynamic element, as the continuing modification of a food requires that the basis of comparison will evolve in a way that the most recent NF is compared with an appropriate former NF and not necessarily with the most traditional counterpart.

The comparison may be a simple task or be very lengthy depending upon experience with and the nature of the NF under consideration. The technical approach to establishing substantial equivalence will differ between whole animals, plants, microorganisms, chemical food ingredients and novel processes and is addressed in more detail under the different classes later in these recommendations.

3.4 Compositional analysis

Analytical studies of the composition of the NF are of crucial importance not only for the establishment of substantial equivalence but also as a prerequisite for nutritional and toxicological assessments. Methods applied have to be standardized and validated to ensure quality and consistency of the data. The analyses and data presented should be based upon sound scientific principles and should be tailored to the nature of the NF. Investigations should focus especially on the determination of the content of critical nutrients (both macro- and micronutrients) and any critical toxicants and anti-nutritional factors which might be either inherently present or process derived.

3.5 Intake

The consumption pattern may show a major change when an NF is included in the diet and thus affects human nutritional status. As it may not be possible to predict such events, a surveillance programme should accompany the marketing of an NF. Such a programme should encompass information on changes in the conditions for processing and preparation as well as effects of possible replacement of other foods or food components of dietary importance. If surveillance reveals changes in those factors which raise concerns regarding wholesomeness, a reappraisal of the acceptability of the NF would be required.

3.6 Nutritional considerations affecting toxicological testing in animals

In the overall evaluation it is of crucial importance to interprete carefully any adverse effects seen in animal studies and to distinguish between toxic effects and those due to nutritional imbalance in the experimental diet. Thus, nutritional and toxicological aspects have to be closely integrated in the assessment of NF. Thorough knowledge of the nutritional properties of the NF (e.g. energy value, protein content, and bioavailability of micronutrients) is needed as a prerequisite of the toxicological testing programme. In designing animal feeding studies, the maximum level of dietary incorporation achievable without causing nutritional imbalance should be the highest dose level, while the lowest dose level should be comparable to its anticipated role in the human diet.

If the predicted usage levels and consumer intakes are likely to be high, the application of the traditionally calculated safety factors employed in safety assessment may create difficulties in designing conventional animal feeding studies with adequate dietary incorporation levels to ensure clearance for use in humans at the anticipated consumption levels. To compensate for the inability of employing reasonably adequate safety factors any subchronic or chronic animal feeding studies require supplementation by absorption and metabolism studies in animals and eventually in humans.

A holistic scientific interpretation of the overall wholesomeness assessment data on a case-by-case basis can provide the acceptable justification for the use of safety factors for NF lower than those traditionally used in safety assessment.

3.7 Toxicological requirements

In principle, the toxicological requirements for NF need to be considered on a case-by-case basis. In establishing the need for the provision of toxicological data three scenarios may be considered:

(1) substantial equivalence can be established to an accepted traditional food or food ingredient, in which case no further testing is needed;

(2) substantial equivalence can be established except for a single or few specific traits of the NF, in which case any further assessment of safety should focus specifically on these traits;

(3) neither partial nor total substantial equivalence can be established; in this case, the wholesomeness of the whole novel food or macronutrient has to be assessed using an appropriate combined nutritional-toxicological approach.

If substantial equivalence to a traditional counterpart cannot be established the wholesomeness assessment has to take into account not only knowledge of the identity, chemical structure and physico-chemical properties of the NF but also aspects such as source, composition, potential intake based on the proposed use in the general diet, the potential exposure of particularly vulnerable population groups, and the likely effects of processing. The greater the predicted dietary exposure the more extensive the required toxicological testing programme will have to be.

3.8 Implications of NF to human nutrition

The overall assessment must consider nutritional implications both at expected customary (normal) intakes and at maximum levels of consumption. This evaluation will be guided by a thorough appraisal of relevant literature, compositional analyses, comparisons to consider substantial equivalence, and, if needed, data from investigations in animal models. If an NF is expected to have an important role in the diet then appropriate human nutritional assessment data are needed. Attention should be paid to the particular physiological characteristics and metabolic requirements of groups such as infants, children, pregnant and lactating women, the elderly, and those with chronic diseases (e.g. diabetes mellitus and malabsorption).

Information will be needed on long term as well as on short term effects of eating the NF. The appropriate information should be derived by combined nutritional and safety post-market surveillance, but additionally consideration should be given to addressing these effects by specific concerns about nutritional quality (e.g. the long term effect of fat replacers on the metabolism of fat soluble vitamins).

3.9 Novel microorganisms used in food

Microorganisms may be used as producers of foods, food ingredients or food additives. Many have a long tradition of safe use in food fermentations. They may be killed in the fermented product or consumed alive with it.

By definition, microorganisms with no traditional use in food production in Europe cannot have a substantially equivalent counterpart in Europe and will therefore need to be assessed. Relevant criteria are: containment (e.g. limited to fermentor, remaining alive in food or killed during processing); potential for colonization of the mammalian gut; potential for toxigenicity as well as pathogenicity in mammals; and whether genetic engineering was applied or not. If genetic modification is employed, the considerations on potential transfer of genetic material from GMM as described in 5.VII become relevant.

The safety assessment of a GMM should consider the origin of the newly introduced material, e.g. vectors, regulatory elements, foreign genes including target and marker genes. Two cases have to be considered:

- the homologous system (self cloning), where all genetic elements involved are derived from strains within the same taxonomic species,

- the heterologous system, where the donor organism of the genetic elements belongs to a taxonomic species other than that of the recipient.

Generally, the segregational and horizontal stability of the constructs are of interest. For self-cloned organisms the concept of substantial equivalence might be applicable in most cases. In heterologous systems both the safety of the gene product in relation to its effects on the food and the effect of the new trait on the properties of the microorganism in the food and, after ingestion, in the gut need to be assessed. The implication of horizontal gene transfer in the gut should be analyzed and evaluated.

3.10 Allergenic potential

The potential occurrence of allergic reactions to novel proteins or other constituents of NF should be explored. As a general principle of assessment, the immunological reactivity of individuals who react to the traditional food counterpart should be tested in vitro and in vivo

against the NF. The latter approach may raise ethical issues which must be taken into account. If the novel protein is expressed by genes drived from a source known to be associated with food allergy, sera of people with confirmed allergies to that source can be subjected to specific immunological tests, e.g. Western Blotting or radioallergosorbent test (RAST). If in vitro tests are negative, in vivo skin prick tests or clinically supervised double blind placebo controlled challenges in these people may be performed. All studies should comply with relevant elements and ethical principles of guidelines on good clinical practice and good laboratory practice.

A number of factors can serve as indicators of the potential allergenicity of novel proteins, such as sequence epitope homology with known allergens, heat stability, sensitivity to pH, digestibility by gastrointestinal proteases, detectable amounts in plasma, and molecular weight. Additional evidence might emerge from pre-marketing human results and reports of workers' sensitizations.

New approaches are needed to assess the potential allergenicity of NF in humans. In the present state of knowledge, the allergenicity of a novel food from a GM source should include consideration of the allergenic potential of the donor and of the recipient organism.

3.11 Assessment of marker genes

Marker genes are used as 'tags` to identify and to select those cells of plants or microorganisms which have been transformed successfully by genetic modification. Normally they are not supposed to play a role of their own in the final product or NF. The marker genes, presently used most frequently in plants, are those conferring resistance to antibiotics or increased tolerance to herbicides. Others confer heavy metal tolerance or phenotypic and biochemical selection. The requirements for evaluating the safety of marker genes are basically similar to those applicable to the safety evaluation of any other foreign genes.

The assessment in plants needs to consider:

- the marker gene itself and the product it encodes,

- the methods for analyzing and quantifying the marker gene and its expression products in the food,

- the potential toxicological and/or nutritional effects related to the function of the marker gene,

- the potential for horizontal gene transfer to gut microorganisms.

The use of marker genes in microorganisms, especially those genes conferring antibiotic resistance, has to be assessed in relation to the host organism, the biological containment established by the genetic construct, the possibility of colonization of the human gut by these GMO, and the relationship between the efficacy of antimicrobials and the acquired resistance.

It can be foreseen that a list of approved marker genes can be developed based upon an evaluation of their primary effects on the host organism. Their secondary effects on the host will depend on, among other factors, the insertion site in the host DNA and will need an assessment on a case-by-case basis, although there is no reason to suppose that the potential for secondary effects is greater for marker genes than for any other inserted genes.

4. SCIENTIFIC CLASSIFICATION OF NOVEL FOODS FOR THE ASSESSMENT OF WHOLESOMENESS

Foods and food ingredients which fall within the scope of Regulation (EC) No 258/97 on Novel Foods and Food Ingredients are very diverse (see Section 2). To facilitate safety and nutritional evaluation, six classes of NF have been identified. These differ in complexity and in the issues that need to be addressed.

For the purpose of these recommendations, the term 'plants` covers also seaweed. The term 'animals` includes fish and shellfish, and the term 'microorganism` encompasses bacteria, fungi

(including yeasts), and micro-algae (viruses and plasmids are outside the scope of these guidelines).

Class 1 Pure chemicals or simple mixtures from non-GM sources

This class comprises foods and food components that are single chemically defined substances or mixtures of these which are not obtained from plants, animals or microorganisms that have been genetically modified. Two sub-classes can be identified:

1.1 the source of the NF has a history of food use in the Community;

1.2 the source of the NF has no history of food use in the Community.

Class 2 Complex NF from non-GM source

This class comprises complex NF which are not, or are derived from sources which have not, been genetically modified. Intact plants, animals and microorganisms used as foods as well as food components (e.g. complex carbohydrates, fats, proteins or those substances collectively described as dietary fibre) are included. Two sub-classes can be identified:

2.1 the source of the NF has a history of food use in the Community;

2.2 the source of the NF has no history of food use in the Community.

Class 3 GM plants and their products

GM plants can be consumed directly as unprocessed foods or after having been processed into foods and food ingredients including pure chemicals. This class of NF includes all such foods and food ingredients. Two sub-classes can be identified:

3.1 the host plant used for the genetic modification has a history of use as food or as a source of food in the Community under comparable conditions of preparation and intake;

3.2 the host plant used for the genetic modification has no history of use as food or as a source of food in the Community under comparable conditions of preparation and intake.

Class 4 GM animals and their products

GM animals can be consumed directly as unprocessed foods or after having been processed into foods and food ingredients including pure chemicals. Products directly produced by GM animals (e.g. eggs, milk) can be consumed either processed or unprocessed. This class of NF includes all such foods and food ingredients. Two sub-classes can be identified:

4.1 the host animal used for the genetic modification has a history of use as food or as a source of food in the Community under comparable conditions of preparation and intake;

4.2 the host animal used for the genetic modification has no history of use as food or as a source of food in the Community under comparable conditions of preparation and intake.

Class 5 GM microorganisms and their products

Living GM microorganisms may be used in food production or in the production of food ingredients. This class includes all NF which are, or are produced using, GM microorganisms whether or not there are any living cells in the NF as consumed: Two sub-classes can be identified:

5.1 the host microorganism used for the genetic modification has a history of use as food or as a source of food in the Community under comparable conditions of preparation and intake;

5.2 the host microorganism used for the genetic modification has no history of use as food or as a source of food in the Community under comparable conditions of preparation and intake.

Class 6 Foods produced using a novel process

This class comprises foods and food ingredients which have been subjected to a process not currently used in food production. Novel processes for food production may encompass for example new types of heat processing, non-thermal preservation methods, new processes to chill or freeze products, to dehydrate products, and the application of new processes catalyzed by enzymes. According to the scope of Regulation (EC) No 258/97, the resulting product is only considered to be an NF, if the process results in changes in the chemical composition or structure of the food or food ingredient, which affect its nutritional value, metabolism or level of undesirable substances.

The association between the described classes and the categorization in Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients is outlined in Table I.

5. IDENTIFICATION OF ESSENTIAL INFORMATION FOR ASSESSMENT OF WHOLESOMENESS

In this section structured schemes are provided to identify the types of information that are likely to be required to establish the safety of particular classes of NF. It is recognized that no formalistic approach can cover adequately all NF, and these schemes are therefore provided for guidance only. If other information is available or relevant for the assessment, it should be submitted. However, if it is proposed to omit certain information from a dossier requested in any of the schemes, the scientific justification for this should be given. The results of any investigations relevant to safety assessment which have been carried out must be reported.

In the assessment of NF the focus is the novelty per se. Chemical or microbiological contaminants of NF not specifically related to the novelty are not addressed in these recommendations. Similarly, the presence of microbial toxins and microbial or viral infective agents is not considered unless this is a consequence of the novelty.

The identification of essential information for assessment is guided by the division into six classes described in chapter 4. After allocating an NF to a class or sub-class, the attached Table II can be used to determine which of the structured schemes I-XIII should be consulted to provide the information required to support its safety and nutritional evaluation.

In the following, the information requested in each particular structured scheme is specified in more detail:

I. Specification of the NF

Specification of the origin and the composition of the NF is needed to ensure the identity of the product tested/evaluated and the product to be marketed. In the design of the specification, parameters most relevant to characterize the product from a safety and nutritional point of view should be considered.

Such parameters include species and taxon, as well as chemical composition relating particularly to nutritional properties and possible antinutritional/toxicological concerns. Taxonomic identity should be established according to referenced and internationally accepted principles and deviation from such principles should be explained.

Information on the availability of specified reference material should be submitted.

II. Effect of the production process applied to the NF

In principle, this scheme applies to all NF which have been processed during production. The description of the technical details has to be sufficiently detailed (i) to permit a distinction between novel and existing processes, and (ii) to predict whether the potential of the process to introduce physical, chemical and/or biological changes in the food might have an impact on essential nutritional, toxicological and microbiological parameters of the final product.

The assessment of new technologies needs to address any organic and inorganic residues or contaminants derived from apparatus and equipments or from chemical, physical or biological aids used in the novel process. Critical aspects of the production process in relation to NF are

those which ensure that the final products of the described process comply with the specifications given under scheme I.

Hygienic parameters are not included in the assessment of NFs but are covered by Directive 93/43/EEC (8).

The assessment will focus on the food product resulting from the novel process on a case-by-case basis. The ultimate aim of assessment will be the evaluation of the process in a wider sense without the need for actually testing and assessing each conceivable food/process combination. This implies a broader strategy in which representatives of relevant food classes, processed by the novel food process, should be compared either to untreated counterparts or to counterparts which have been processed in a related traditional manner.

III. History of the organism used as the source of the NF

The novelty of food plants, food animals or food microorganisms in relation to these guidelines is defined by their novelty in the European food supply. If species/taxons of plants, animals or microorganisms have had no generally recognised use in the diet of any of the Community countries according to national dietary records, the species/taxon is considered new, and a full description is needed to assess its future role in the European food supply. This should include information on the past and present use of the plant, animal or microorganism and its products in the food supply in other parts of the world. Such information should also include:

- past and present methods to obtain raw materials and food, e.g. by raising, harvesting, slaughtering, and capture,

- procedures for fermentation and preparation,

- description of transport and storage conditions, and

- its traditional role in the diet at locations outside the Community.

IV. Effect of the genetic modification on the properties of the host organism

The information gathered through this scheme focuses on the effects of the genetic modification on the properties of the GMO compared to the host organism. It differentiates between intended and unintended effects. In the latter case, special attention should be given to any nutritional, toxicological, and microbiological impact on the foods.

GM plants

The principles for evaluating GM plants and their products are similar to those valid for non-GM plants and their products. The safety evaluation of a GM plant may be a simpler task than the evaluation of a novel non-GM plant, if the non-modified organism is a traditional food plant and the alteration has occurred by means of a precisely defined process of genetic modification. In this case, the safety assessment can focus on the results of the genetic modification.

Where the genetic modification results in a new phenotype, the compositional consequences of this modification should be defined and tested. If, for example, a genetically modified plant is so designed as to express a naturally occurring insecticide, encoded by a gene derived from another organism, and has therefore become resistant to certain insect pests, then the toxicological profile of the introduced insecticidal component needs to be determined. The safety of this modification of the chemical composition can be evaluated by standard toxicological procedures; it should include an assessment of the potential allergenicity. In addition, secondary effects (positional effects) have to be taken into consideration. These effects of the insertional event, e.g. the insertional mutation itself or a genomic rearrangement will influence the overall outcome of the genetic modification. A knowledge of the normal toxin production in the plant and the effect on it of various growth and culturing conditions to which the GM plant is subjected, as well as knowledge whether the new gene product appears in the final food, is essential. The same reasoning applies to nutritionally important components especially in food plants.

Essential steps of the safety evaluation are therefore:

- characterization of the parent food organism,

- characterization at the molecular level of the nature of the genetic modification including insertional position, copy number and biochemical expression level,

- establishment, as far as possible, of substantial equivalence between the parent food organism and its new derivative through chemical and phenotypic analysis,

- if substantial equivalence cannot be established, conventional safety studies on specific chemicals occurring in the food due to the phenotypic changes involving either the new product of the new gene or the safety of inherent natural toxins now present in altered amounts. The potential allergenicity of the new components also needs to be addressed.

GM animals

The general principles established for the safety evaluation of GM plants apply also to GM animals. The safety assessment will initially address the establishment of substantial equivalence between the parent organism and the GM organism focussing on primary and secondary effects of the genetic modification process. For example if the modification is directed towards changing the globulins in cow's milk to a more 'human` type, the new globulins have to be assessed. Another example may be a fish genetically modified to produce an antifreeze protein. The safety of this chemical modification can be evaluated by conventional toxicological strategies and should also include an assessment of the allergenicity aspects.

GM microorganisms

In compliance with the provisions set out for GM plants and GM animals, the parent microorganism, which is the subject of genetic modification has a priori to be recognized either as a microorganism with a tradition in food fermentation in the Community, as a non-pathogenic, biologically advantageous human intestinal commensal, or as a traditionally used production organism for foods, including food additives and technical aids, to simplify the evaluation procedure. In other cases, not only the genetic modification but also the parent microorganism needs to be assessed as being novel.

V. Genetic stability of the GMO used as NF source

The question of genetic stability relates to the structural and local maintenance of the introduced genetic material and to the gene expression in the GMO.

VI. Specificity of expression of novel genetic material

This scheme relates to the factors involved in regulation of gene expression, for instance organ/tissue specificity, conditions of repression and activation.

VII. Transfer of genetic material from GMO

Based on current knowledge, considerations of gene transfer from GMO in the human gut focus on microorganisms. Horizontal gene transfer among microorganisms is well established and has therefore to be considered in food safety assessments. One aspect of biological containment is the possible transfer of genetic material from GM microorganisms to the human gut microflora. There are different possibilities for addressing this aspect in an experimental setting, e.g. animal or in vitro gut models.

In assessing the food safety consequences of gene transfer, the nature of the gene and its product, the frequency of the transfer, and the level of expression in transformed gut microorganisms should be taken into account. Transfer of genes from plants to microorganisms is a theoretical possibility; the consequences of such an event should be considered.

VIII. Ability of the GMM to survive in and colonise the human gut

The genetic modification might facilitate survival during passage through the intestines and colonization of the human gut. Antagonistic and synergistic effects on the composition of the intestinal flora may occur and have an influence on human health. Therefore, experimental data are required on the respective properties of the GMO.

For living GMM in food, attention should particularly focus on their capability to survive in and colonize the gastrointestinal tract and to maintain their genomic stability. For this assessment in vitro and in vivo gut models mimicking the human situation as closely as possible may be needed. Aspects relating to pathogenicity and gastrointestinal immunity need special consideration.

IX. Anticipated intake/extent of use of the NF

Projections of anticipated intakes are needed to evaluate the dietary and nutritional significance of NF. This assessment will naturally draw upon information on the nature of the NF and its anticipated uses based upon its properties e.g. as a fat replacer.

X. Information from previous human exposure to the NF or its source

Documentation on previous use of the NF source in the Community or the NF source and/or the NF in other parts of the world is important to establish a baseline for assessment. However, history of food use outside the Community is not of itself a guarantee that the NF can be safely consumed in the Community. The information should deal with such aspects, where traditional handling and preparation of the plant, animal or microorganism prevent misuse or adverse short and long term health effects, for example those due to inherent antinutritional/toxic factors. In many cases, necessary precautions are reflected in the corresponding regional and cultural habits.

XI. Nutritional information on the NF

The overall assessment should, as indicated above, include a systematic review of the NF's composition, preparation and role which it is expected to have in the diet. Such an assessment with a review of relevant published material would enable an appraisal of substantial equivalence to a traditional food or food component.

If substantial equivalence cannot be established, appropriate preliminary assessments should be made in animal models to establish some aspects of nutritional quality but full nutritional assessment needs to be done in human subjects. Such studies should be based on well defined hypotheses with clear nutritional and metabolic outcomes relevant to the NF, to its dietary context, and to the anticipated consumer group.

Nutritional consequences should be assessed at normal and maximum levels of consumption, and the nutrient compositional data should take into account the effects of storage, further processing and cooking. The effect of antinutritional factors (e.g. inhibiting mineral absorption or bioavailability) on the nutritional value of the whole diet should also be assessed.

The numbers involved in study groups should ensure that the study has adequate statistical power. All studies should comply with relevant elements and ethical principles of guidelines on good clinical practice and good laboratory practice.

In some circumstances it is envisaged that plans should be provided for post-market surveillance for possible long term effects of the NF.

XII. Microbiological information on the NF

In addition to toxicological and nutritional safety, wholesomeness of an NF embraces microbiological safety. Generally, the intentionally used source organism for the NF has to be recognised as a non-pathogenic, non-toxigenic microorganism of known genetic stability which does not affect the desirable properties of the normal intestinal flora. The examination of an NF should include a characterization of the microorganisms present and the analysis of their metabolites.

XIII. Toxicological information on the NF

This scheme covers the set of toxicological information needed to assess the NF. The range of scenarios can extend from foods for which substantial equivalence can be established to foods for which substantial equivalence cannot be established and which, therefore, require an appropriate nutritional-toxicological testing program.

If substantial equivalence to a traditional counterpart cannot be established, the safety assessment based on a case-by-case evaluation must consider the following elements:

- consideration of the possible toxicity of the analytically identified individual chemical components,

- toxicity studies in vitro and in vivo including mutagenicity studies, reproduction and teratogenicity studies as well as long term feeding studies, following a tiered approach on a case-by-case basis,

- studies on potential allergenicity.

In the case of novel microconstituents and isolated novel food components, which differ by identifiable characteristics from traditional foods, or of defined novel products obtained from genetically modified organisms, it is possible to restrict testing to only those products or substances rather than the whole NF. In some cases, the testing of the novel property would have only marginal nutritional implications for laboratory animals so that the traditional toxicological approach can be applied for establishing safety.

Most of the defined chemical substances can probably be tested for their safety similarly to food additives by utilizing conventional methods of safety evaluation as described in the SCF Report No 10. This implies the use of conventional toxicological testing procedures applied in a tiered sequence. This would involve initial mutagenicity studies and an appropriate feeding study in a rodent species with an exhaustive investigation of all relevant toxicological parameters. Furthermore, if warranted by structural or exposure considerations, additional investigations should be undertaken covering all the usual toxicological endpoints including metabolism, toxicokinetics, chronic toxicity/carcinogenicity, reproductive function, teratogenicity, and possibly neurotoxicity and immunotoxicity.

Novel macroconstituents, or NF which are not substantially equivalent to traditional counterparts, will require a testing programme depending on the toxicological concerns raised. In general, this programme should include at least a 90 day feeding study in a rodent species, whereby special attention is paid to the choice of doses and the avoidance of problems of nutritional imbalance. These constraints may require a different way of conducting toxicological studies and interpreting their results (see 3.6).

The potential for mutagenicity needs investigation. Any in vitro mutagenicity studies will need to cover the usual major endpoints. Special technical problems may be encountered in testing novel macroconstituents in in vitro mutagenicity test systems, particularly because of effects of the NF or its constituents on the growth medium, the test cells or the test organisms, unrelated to mutagenicity. There may be cases where feeding studies in a second species and an investigation of effects on the composition of the intestinal flora are needed. Also chronic toxicity/carcinogenicity studies may be necessary. The allergenic potential needs also to be investigated.

6. REVIEW OF RECOMMENDATIONS

The area of novel foods is developing rapidly. The science and technology are making enormous advances and many countries and international organisations are elaborating procedures and guidelines for the safety assessment of novel foods. The SCF will review these recommendations in the light of experience gained in their application and new scientific developments in the field.

7. REFERENCES

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17. Report of a WHO Workshop: The application of the principles of substantial equivalence to the safety evaluation of foods or food components from plants derived by modern biotechnology. WHO, Geneva, 1995

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19. Engel, K.-H., Takeoka, G.R., Teranishi, R. (eds.) Genetically Modified Foods. Safety Aspects. American Chemical Society Symposium Series 605, Washington, DC, 1995

20. The Safety Assessment of Novel Food. Guidelines prepared by ILSI Europe Novel Food Task Force, 1995

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22. Health Effects of Marker Genes in Genetically Engineered Food Plants. TemaNord: 530, The Nordic Council of Ministers, Copenhagen, 1996

8. GLOSSARY

This glossary is intended to explain the way in which various terms are used by the SCF in its recommendations rather than to provide precise scientific definitions.

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PART II RECOMMENDATIONS CONCERNING THE SCIENTIFIC ASPECTS OF THE PRESENTATION OF INFORMATION NECESSARY TO SUPPORT APPLICATIONS FOR THE PLACING ON THE MARKET OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS

INTRODUCTION

In Part 1 of the SCF Recommendations on the Assessment of Novel Foods recommendations concerning the scientific aspects of information necessary to support applications for the placing on the market of novel foods and novel food ingredients (NF) have been presented. In this part recommendations concerning the scientific aspects of the presentation of such information are summarized. Such a uniform structure of applications will facilitate their scientific evaluation.

GENERAL SCHEME

It has been emphasised in the first part of the recommendations that no formalistic approach can adequately cover all NF. Thus, the schemes developed are not to be considered as a rigid checklist but are provided for guidance only. Nevertheless, the underlying philosophy and the major principles of the recommendations should be reflected in an application for placing NF on the market. The following box illustrates the logic flow.

>START OF GRAPHIC>

General description of the NF including technical data and categorization according to Regulation (EC) No 258/97

/

Allocation of the NF to one of the SCF classes/sub-classes

/

Identification of essential information requirements

/

Consultation of structured schemes (decision trees) and provision of data required

/

Evaluation and conclusion by the applicant>END OF GRAPHIC>

The information package submitted by the applicant should be presented in the order and under the headings described below:

1. Administrative data

This section should include information on the name and address of the applicant, of the manufacturer of the NF and of the person responsible for the dossier.

2. General description

In order to ensure that the food or food ingredient intended to be placed on the market falls within the scope of Regulation (EC) No 258/97 on novel foods and novel food ingredients, data should be provided to enable a categorization according to Article 1 (2) of Regulation (EC) No 258/97.

To facilitate the assessment procedure the SCF has reclassified the diverse categories defined by the legislation according to their similarities in terms of safety considerations. Six major classes and corresponding sub-classes are defined in chapter 4 of the SCF Recommendations on the Assessment of Novel Food, Part I (later referred to as Part I). The NF should be allocated to one of these classes/sub-classes (see also Table I, Part I); the scientific justification for this allocation should be given.

3. Identification of essential information requirements

Table II, Part I should be used to determine which of Schemes I-XIII are essential to provide data permitting a safety and nutritional evaluation of the NF.

4. Consultation of structured schemes (decision trees)

The structured Schemes I-XIII elaborated in Part I should be consulted regarding the data to be assembled. The schemes lead through a decision-tree-like set of questions and will assist in deciding whether the data available to the applicant are sufficient or if further information has to be sought and reappraised.

The logic of the schemes should be followed in the dossier. For each box the information leading to either 'yes` or 'no` should be provided in detail. If it is proposed to omit certain information requested in any of the schemes, the scientific justification should be given. If other information is available or considered to be relevant for the assessment, it should be submitted.

5. Evaluation and conclusion by the applicant

Conclusions drawn by the applicant after having evaluated the total information assembled should be presented covering the key issues relevant to the NF (see chapter 3 of Part I).

6. Summary by the applicant

A summary has to be provided that is suitable for further circulation to the Member States as foreseen in Article 6 (2) of Regulation (EC) No 258/97.

PART III RECOMMENDATIONS CONCERNING THE SCIENTIFIC ASPECTS OF THE PREPARATION OF THE INITIAL ASSESSMENT REPORTS ON APPLICATIONS FOR THE PLACING ON THE MARKET OF NOVEL FOODS AND NOVEL FOOD INGREDIENTS

INTRODUCTION

Regulation (EC) No 258/97 on novel foods and novel food ingredients stipulates in Article 4 that a person responsible for placing such a product on the Community market submit a request for this action to the Member State in which the product is to be marketed for the first time. According to the provisions of Article 6 the Member State must then prepare an initial assessment report.

Part I of the SCF Recommendations on the Assessment of Novel Foods presents recommendations concerning the scientific aspects of information necessary to support applications for the placing on the market of novel foods and novel food ingredients (NF). Part II summarises recommendations concerning the scientific aspects of the presentation of such information.

Some experience in assessing the safety of novel foods has been gained by applying the procedures of various national and international bodies and authorities. For practical purposes it is necessary to achieve comparability between assessments by different national authorities and also uniformity in the reports of their scientific appraisals. Details of the requirements for particular types of NF are provided in Part I and elsewhere, e.g. with regard to products produced by genetic modifications (1), or other novel sources of protein (2). Specific recommendations for safety testing have not been made for each class of NF and it is not possible to do so in the current state of knowledge. The use of a case-by-case approach ensures that novel risks are adequately addressed. Part III is intended to provide guidance for this task and therefore contains recommendations concerning the scientific aspects of the preparation of the initial assessment reports by the competent authorities of the Member States.

STRUCTURE OF THE INITIAL ASSESSMENT REPORT

The general considerations underlying the assessment of NF have been set out in Part I, e.g. Section 3.1. Initial assessment reports are confined to the human food safety of NF. Their preparation should proceed in the following three phases:

1. Check of the completeness of the application and its presentation in accordance with Part II;

2. Appraisal of appropriateness of interpretations and evaluations by the applicant of the data submitted;

3. Assessment of the data submitted, executive summary, conclusions and recommendations.

1. Check of the completeness of the application and its presentation in accordance with Part II

The initial assessment report must provide a statement that the submission contains the appropriate administrative and technical details presented in the order laid down in Part II, sections 1 and 2, as well as the information set out in Part I, sections 5 and 5.1. If the data submitted differ from those requested in Part II or are not presented in the order required, the applicant's explanation should be reviewed.

2. Appraisal of appropriateness of interpretations and evaluations by the applicant on the data submitted

The adequacy of the data and of the arguments relating to their interpretation and evaluation by the applicant should be assessed and an opinion provided. In the event of disagreements in

the interpretations and evaluations between the national assessing authorities and the applicants the pertinent reasons should be fully described in the assessment report.

2.1 Substantial equivalence

For assessment purposes the comparison of the final product with one having an acceptable standard of safety furnishes an important element. Therefore, the initial assessment report should include the competent authority's opinion regarding the applicant's claims concerning substantial equivalence.

2.1.1 Substantial equivalence to a traditional counterpart is claimed

For guidance the relevant discussion in Part I, section 3.3 should be consulted. If substantial equivalence to a traditional counterpart has been established, the NF can be regarded as wholesome and as toxicologically and nutritionally acceptable for use in the overall diet in a manner comparable to its counterpart or as replacement of its counterpart. When judging the comparability of the NF to its counter part, the limits of known and measurable natural diversity of any conventional counterpart should be taken into account.

2.1.2 Substantial equivalence except for one or more defined traits is claimed

If substantial equivalence except for one or more defined traits has been established, the assessment should focus on these traits. These should be evaluated on a case-by-case basis and may in certain cases require data, matching those needed for the safety evaluation of food additives.

2.1.3 Substantial equivalence is not claimed

If substantial equivalence to a traditional food or food ingredient is not claimed, the NF will require extensive testing details of which are outlined in Part I.

2.2 Special considerations

For foods that are substantially equivalent to existing foods no further data need to be evaluated. Other NF require further consideration. This may be targeted at specific defined traits or at the whole NF. The information provided in the application will need to be assessed in the light of the origin, method of production and complexity of the NF, and its role in the diet of the population at large and particular sub-groups.

2.2.1 Nutritional assessment

Special attention should be paid to the expected consumption level of the NF and its potential nutritional impact (see Part I, e.g. sections 3.8 and 5.XI). It should be checked, for example, that the effects of the consumption of the NF on the total dietary intakes of nutrients, for which PRI's (population reference intakes) or an 'acceptable range of intakes` have been established, have been assessed within specific population groups.

The competent authority should evaluate the documentation on animal models and human metabolic studies, including clinical observations. Long term as well as short term effects of the NF on human nutrition have to be considered. Attention should be paid to the occurrence of unexpected adverse interferences with other dietary constituents and to changes in relevant biomarkers.

2.2.2 Assessment of novel microorganisms for food use

For NF which are or which contain live microorganisms, scrutiny by the authority should confirm, that the application contains adequate data on their safety in use. Even with microorganisms the data submitted should allow them to be categorised according to the principle of substantial equivalence (see also Part I).

2.2.3 Assessment of toxicity and allergenicity

The evaluation will need to address - as appropriate - data on toxicity and allergenicity regarding defined traits of the NF or the entire NF. The information necessary to assess the wholesomeness of NF has been discussed in Part I, e.g. sections 3.7, 3.10 and 5.XIII. The application should be scrutinized for the adequacy of the data presented and an opinion on the data should be formulated.

2.2.4 Novel Processes

Products of novel processes should be evaluated on the basis of the concept of substantial equivalence (see also Part I and II).

3. Assessment of the data submitted, executive summary, conclusions and recommendations

The assessment report should include an opinion on the adequacy and completeness of the data provided. The competent authority should prepare an executive summary. The assessment report should be accompanied by a statement on its conclusions and recommendations including any conditions for marketing. In addition, benefits claimed by the applicant as well as pitfalls should be described and discussed briefly.

4. References

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2. PAG/UNU Guidelines. D. Jonas Paper.

(1) OJ L 43, 14. 2. 1997, p. 1.

(2) OJ L 117, 8. 5. 1990, p. 15.

(3) OJ L 40, 11. 2. 1989, p. 27.

(4) OJ L 184, 15. 7. 1988, p. 61.

(5) OJ L 157, 24. 6. 1988, p. 28.

(6) OJ L 117, 8. 5. 1990, p. 1.

(7) OJ L 103, 22. 4. 1994, p. 20.

(8) OJ L 175, 19. 7. 1993, p. 1.

COMMISSION REGULATION (EC) No 1852/2001

of 20 September 2001

laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 4(5) and Article 10 thereof,

Whereas:

(1) Experience has shown the need for detailed rules for the protection of the information provided by applicants to ensure the smooth functioning of the assessment of applications under Regulation (EC) No 258/97.

(2) These rules should ensure the confidentiality of information relating to the manufacturing process where the disclosure of such information might harm the competitive position of the applicant in a disproportionate manner.

(3) In order to improve transparency in the operation of the procedures established by Article 4 of Regulation (EC) No 258/97, certain information about products being assessed under that Article, and about the outcome of the assessment should be made available to the public. That information should be made available by the Commission on the Internet.

(4) Such rules should be consistent with the new legislative framework laid down in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2].

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

1. The Commission, the national authorities of the Member States and the food assessment bodies referred to in Article 4(3) of Regulation (EC) No 258/97 shall not divulge information identified as confidential pursuant to paragraph 3, except for information that must be made public if circumstances so require in order to protect human health.

2. The applicant may indicate the information submitted by him pursuant to Regulation (EC) No 258/97 relating to the manufacturing process that should be kept confidential because its disclosure might harm his competitive position. Verifiable justification must be given in such cases.

3. The competent authority of the Member, which has received the application, shall determine, after consultation with the applicant, which information relating to the manufacturing process shall be kept confidential and shall inform the applicant, the competent food assessment body and the Commission of its decision.

4. The Commission shall ensure that the Member States are informed of any decision communicated to it pursuant to paragraph 3.

Article 2

1. When the initial assessment of the request is carried out pursuant to Article 4(1) of Regulation (EC) No 258/97, the Commission shall make the following information available to the public:

(a) name and address of the applicant;

(b) description allowing the identification of the food or food ingredient;

(c) intended use of the food or food ingredient;

(d) summary of the dossier, except for those parts for which the confidential character has been determined in accordance with Article 1(3);

(e) date of receipt of a complete request.

2. The Commission shall make the initial assessment report available to the public, except for any information identified as confidential pursuant to Article 1(3), in the following way:

(a) when there are no objections pursuant to Article 6(4) of Regulation (EC) No 258/97. the initial assessment report shall he made available to the public after the expiry of the period of 60 days referred to in that Article and after the time necessary for the information of the applicant;

(b) when, pursuant to Article 7 of Regulation (EC) No 258/97, an authorisation decision is required, the initial assessment report shall wherever possible be made available to the public at the same time the opinion of the Scientific Committee for Food is given or, if no such opinion is required, at the time that the decision is published in the *Official Journal of the European Communities*.

Article 3

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

[1] OJ L 43, 14.2.1997, p. 1.
[2] OJ L 106, 17.4.2001, p. 1.

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

Done at Brussels, 20 September 2001.

For the Commission
David BYRNE
Member of the Commission

32000D0195

2000/195/EC: Commission Decision of 22 February 2000 authorising the placing on the market of 'phospholipides from egg yolk' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2000) 2) (Only the French text is authentic)

Official Journal L 061 , 08/03/2000 P. 0012 - 0013

COMMISSION DECISION

of 22 February 2000

authorising the placing on the market of "phospholipides from egg yolk" as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2000) 2)

(Only the French text is authentic)

(2000/195/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients(1), and in particular Article 7 thereof,

Having regard to the request submitted by Belovo to the Belgian competent authorities on 23 January 1998 for placing "phospholipides from egg yolk" on the market as a novel food or novel food ingredient,

Having regard to the initial assessment report drawn up by the Belgian competent authorities, which the Commission forwarded to all Member States on 29 October 1998,

Whereas:

(1) Within the 60 day-period laid down in Article 6(4) of the Regulation, reasoned objections were raised in accordance with that provision. In accordance with Article 7 of the Regulation, a decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(2) The Scientific Committee for Food has been consulted on this matter in accordance with Article 11 of the Regulation. On 17 June 1999, the Scientific Committee for Food delivered its opinion that there is no reason to believe that the placing on the market of phospholipides purified and concentrated using a new process will have any adverse effect on public health and that the product is safe for human consumption.

(3) Food additives falling within the scope 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(2), are excluded from the scope of Regulation (EC) No 258/97. This Decision does therefore not constitute authorisation to use phospholipides from egg yolk as a food additive.

(4) It has therefore been demonstrated that the product complies with the criteria laid down in Article 3(1) of the Regulation.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Phospholipides from egg yolk purified to 85 % and 100 % may be placed on the Community market as novel foods or novel food ingredients.

Article 2

This Decision is addressed to Belovo, Industrial area 1, 6600 Bastogne, Belgium.

Done at Brussels, 22 February 2000.

For the Commission

Erkki LIIKANEN

Member of the Commission

(1) OJ L 43, 14.2.1997, p. 1.

(2) OJ L 40, 11.2.1989, p. 27.

32000D0196

2000/196/EC: Commission Decision of 22 February 2000 refusing the placing on the market of Stevia rebaudiana Bertoni: plants and dried leaves as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2000) 77) (Only the Dutch text is authentic)

Official Journal L 061 , 08/03/2000 P. 0014 - 0014

COMMISSION DECISION

of 22 February 2000

refusing the placing on the market of Stevia rebaudiana Bertoni: plants and dried leaves as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2000) 77)

(Only the Dutch text is authentic)

(2000/196/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients(1), and in particular Article 7 thereof,

Having regard to the request submitted by Professor J. Geuns of the KUL Laboratory of Plant Physiology to the Belgian competent authorities on 5 November 1997 for placing Stevia rebaudiana Bertoni: plants and dried leaves on the market as a novel food or novel food ingredient,

Having regard to the initial assessment report drawn up by the Belgian competent authorities, which the Commission forwarded to all Member States on 18 August 1998,

Whereas:

(1) The initial assessment report drawn up by the Belgian competent authorities concluded that, based on the information provided, the product should not receive an authorisation to be placed on the market.

(2) The applicant, in reaction to the initial assessment report, had provided supplementary documentation to the Commission, who brought this information to the attention of the Member States and the Scientific Committee for Food.

(3) An additional assessment was carried out in accordance with Article 7 of the Regulation. The Scientific Committee for Food adopted an opinion on 17 June 1999 which essentially confirmed the initial assessment report.

(4) Stevia rebaudiana Bertoni: plants and dried leaves, are a novel food in the sense of Regulation (EC) No 258/97. It has not been demonstrated that the product complies with the criteria laid down in Article 3(1) of the Regulation, it shall not be placed on the market in the Community.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Stevia rebaudiana Bertoni: plants and dried leaves may not be placed on the Community market as food or food ingredient.

Article 2

This Decision is addressed to Professor J. Geuns, KUL, Laboratory of Plant Physiology, Kardinaal Mercierlaan 92, 3001 Heverlee, Belgium.

Done at Brussels, 22 February 2000.

For the Commission

Erkki LIIKANEN

Member of the Commission

(1) OJ L 43, 14.2.1997, p. 1.

COMMISSION DECISION

of 24 July 2000

on authorising the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2000) 2121)

(Only the English text is authentic)

(2000/500/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 [1] of the European Parliament and of the Council of 27 January 1997, and in particular Article 7 thereof,

Having regard to the request by Unilever to the competent authorities of the Netherlands of 22 May 1998 for placing 'yellow fat spreads with added phytosterol-esters' on the market as a novel food or novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the Netherlands, which the Commission forwarded to all Member States on 28 December 1998,

Whereas:

(1) Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections were raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(2) The Scientific Committee for Food has been consulted on this matter in accordance with Article 11 of the Regulation. On 6 April 2000, the Scientific Committee for Food delivered its opinion that the 'yellow fat spreads with added phytosterol-esters' (maximum 8 % w/w phytosterol equivalent to 14 % w/w phytosterol esters) that are the subject of this application are safe for human consumption.

(3) The marketing of the product will be focused on people who try to lower their blood cholesterol levels.

(4) Patients on cholesterol-lowering medication should only consume the product under medical supervision.

(5) A reduction in plasma Beta-carotene will be relevant for people whose vitamin A status is not optimal, in particular pregnant and lactating women as well as younger children. Therefore information about the Beta-carotene lowering effect of the product should be provided to the consumer, together with appropriate dietary advice regarding the regular consumption of fruits and vegetables.

(6) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Yellow fat spreads with added phytosterol esters as specified in the Annex, hereinafter called the products, may be placed on the market in the Community as novel foods or novel food ingredients.

The addressee shall ensure that the products meet the requirements of Article 2.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply:

(a) The product shall be labelled as: margarine (or vegetable fat spread) with plant sterol esters, in conformity with Council Regulation (EC) No 2991/94.

(b) The content of plant sterol esters shall be declared on the list of ingredients.

(c) There shall be a statement that the product is for people who want to lower their blood cholesterol levels.

(d) There shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision.

(e) There shall be an easily visible and legible statement that the product may not be nutritionally appropriate for certain sections of the population (pregnant and breast-feeding women and children under the age of five years).

(f) Advice shall be given that the product should be used as part of a healthy diet, including regular consumption of fruit and vegetables (to help maintain carotenoid levels).

[1] OJ L 43, 14.2.1997, p. 1.

Article 3

Unilever shall establish a surveillance programme accompanying the marketing of the product. This programme should encompass, in particular, information on individual intakes of the product. This programme shall be submitted for approval by the Commission prior to the placing on the market of the product.

The data collected should be made available to the Commission and Member States in order to estimate the extent to which the product is reaching its target group, people who try to control their elevated blood cholesterol, and to estimate exposures to phytosterols from this source in other population groups.

Article 4

This Decision is addressed to Unilever (UK) Central Resources Limited, Unilever House, Blackfriars, London, United Kingdom.

Done at Brussels, 24 July 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Specifications of yellow fat spread with added phytosterol esters

1. The margarine/vegetable oil spread may contain up to 8 % w/w of added phytosterols (equivalent to 14 % w/w phytosterol-esters).
2. The composition of the phytosterols is specified in the table below:

Table 1: Composition of phytosterols

Component	Minimum	Maximum
Campesterol	10 %	40 %
Stigmasterol	6 %	30 %
β-Sitosterol	30 %	65 %
Other	0 %	5 %

COMMISSION DECISION

of 19 December 2000

on refusing the placing on the market of 'Nangai nuts (*Canarium indicum* L.)' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2000) 3888)

(Only the French text is authentic)

(2001/17/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients [1], and in particular Article 7 thereof,

Having regard to the request submitted by Mr Y. Jobert on behalf of Pacific Nuts Ltd, PO Box 429, Santo, Vanuatu to the French competent authorities on 9 December 1998 for placing 'Nangai nuts (*Canarium indicum* L.)' on the market as a novel food or novel food ingredient,

Whereas:

(1) The initial assessment report drawn up by the French competent authorities concluded, based on the information provided that the product is safe for human consumption and could therefore be authorised.

(2) The initial assessment report was forwarded by the Commission to all Member States on 7 April 1999.

(3) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections were nevertheless raised by other Member States so that an authorisation decision is required, to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(4) An additional assessment was carried out in accordance with Article 7 of the Regulation. The Scientific Committee for Food adopted an opinion on 8 March 2000, which stated that data necessary for the assessment of the safety of the product are lacking. Therefore the product should not be authorised.

(5) The applicant was given the opportunity to provide additional information.

(6) Information that 'Nangai nuts' (or synonymously 'Kenari nuts') were consumed in the Netherlands to a significant degree was examined by the Dutch authorities who could not find such nuts. Thus it was confirmed that 'Nangai nuts' have not been consumed in the Community to a significant degree before Regulation (EC) No 258/97 entered into force. Accordingly Nangai nuts should be considered as a novel food within the meaning of Regulation (EC) No 258/97.

(7) As it has not been demonstrated that the product complies with the criteria laid down in Article 3(1) of the Regulation, it should not be placed on the market in the Community.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

'Nangai nuts (*Canarium indicum* L.)' may not be placed on the Community market as a food or a food ingredient.

Article 2

This Decision is addressed to Mr Y. Jobert, La Meillade No 65, F-34150 Montpeyroux, acting on behalf of Pacific Nuts Ltd.

Done at Brussels, 19 December 2000.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

COMMISSION DECISION

of 30 January 2001

on authorising the placing on the market of a dextran preparation produced by *Leuconostoc mesenteroides* as a novel food ingredient in bakery products under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2001) 174)

(Only the Dutch text is authentic)

(2001/122/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 [1] of the European Parliament and of the Council of 27 January 1997, and in particular Article 7 thereof,

Having regard to the request by Puracor to the competent authorites of Belgium of 9 April 1999 for placing a dextran preparation produced by the bacterium *Leuconostoc mesenteroides* on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of Belgium, which the Commission forwarded to all Member States on 28 July 1999.

Whereas:

(1) Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections were raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(2) The Scientific Committe for Food has been consulted on this matter in accordance with Article 11 of the Regulation. On 18 October 2000, the Scientific Committee for Food delivered its opinion that the dextran preparation produced by the bacterium *Leuconostoc mesenteroides* that is the subject of this application is safe for human consumption, up to 5 % in bakery products.

(3) Like gluten, soybean flour, malted flour or inactivated sourdough, dextran is an ingredient in bakery products.

(4) Dextran is highly digestible and has similar nutritional properties as starch.

(5) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

The dextran preparation produced by the bacterium *Leuconostoc mesenteroides*, as specified in the Annex, may be placed on the market in the Community as a novel food ingredient in bakery products, under the condition that no more than 5 % by weight of the final bakery product is made up of the dextran preparation.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs that the word 'dextran' will be mentioned in the list of ingredients of the bakery product containing it.

Article 3

This Decision is addressed to Puracor nv/sa, Industrialaan 25, B-1702 Groot Bijgaarden.

Done at Brussels, 30 January 2001.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX

Specifications of a dextran preparation produced by the bacterium, *Leuconostoc mesenteroides*

1. Powdered form:

Carbohydrates	60 % with:
(Dextran: 50 % Mannitol: 0,5 % Fructose: 0,3 % Leucrose: 9,2 %)	
Protein	6,5 %
Lipid	0,5 %
Lactid acid	10 %
Ethanol	traces
Ash	13 %
Moisture	10 %

2. Liquid form:

Carbohydrate	12 % with:
(Dextran: 6,9 % Mannitol: 1,1 % Fructose: 1,9 % Leucrose: 2,2 %)	
Protein	2 %
Lipid	0,1 %
Lactid acid	2 %
Ethanol	0,5 %
Ash	3,4 %
Moisture	80 %

COMMISSION DECISION

of 23 May 2001

authorising the placing on the market of pasteurised fruit-based preparations produced using high-pressure pasteurisation under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2001) 1462)

(Only the French text is authentic)

(2001/424/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Having regard to the request by Groupe Danone to the competent authorities of France of 3 December 1998 for placing pasteurised fruit-based preparations produced by high-pressure pasteurisation on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of France, which the Commission forwarded to all Member State on 16 May 2000.

Whereas:

(1) In their initial assessment report the French competent food assessment body came to the conclusion that high-pressure treatment (8 kbar for 6 minutes at 20°C) may be safely used instead of the specified generally used heat pasteurisation process (85°C for 10 minutes).

(2) Within the 60 days' period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were nevertheless raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(3) At a meeting on 9 October 2000 experts of Groupe Danone were called upon to provide the necessary information in response to the comments and objections raised by Member States. In particular, a technical explanation was given that the high-pressure treatment provides the same level of safety as the generally used heat pasteurisation process with respect to the bacteriological risks and the allergenic potential.

(4) It is therefore considered that the use of high-pressure pasteurisation in the production of fruit preparations is not likely to have an effect on public health so that a decision can be taken without consultation of the Scientific Committee for Food.

(5) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

The fruit preparations pasteurised by high-pressure treatment, as specified in the Annex, may be placed on the market in the Community as a novel food ingredient.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the wording 'pasteurised by high-pressure treatment' is displayed next to the fruit preparations in question as such and in any product in which it is used.

Article 3

This Decision is addressed to Groupe Danone, 7 rue de Téhéran, F-75391 Paris CEDEX 08.

Done at Brussels, 23 May 2001.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX

Specifications for fruit preparations pasteurised by high-pressure treatment

Parameter	Target	Comments
Types of Fruit	apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarine, mango, melon, peach, pear, pineaple, prune, raspberry, rhubarb, strawberry	Fruit used in conventional process
Fruit storage before high-pressure treatment	Minimum 15 days at – 20 °C	Fruit harvested and stored in conjunction with good/hygienic agricultural and manufacturing practices
Fruit added	40 % to 60 % of thawed fruit	Fruit homogenised and added to other ingredients
pH	3,2 to 4,2	
° Brix	7 to 42	Assured by added sugars
a_w	< 0,95	Assured by added sugars
Final storage	60 days maximum at + 5 °C maximum	Equivalent to storage regimen for conventionally processed product.

COMMISSION DECISION

of 30 January 2001

on authorising the placing on the market of a dextran preparation produced by *Leuconostoc mesenteroides* as a novel food ingredient in bakery products under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2001) 174)

(Only the Dutch text is authentic)

(2001/122/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 [1] of the European Parliament and of the Council of 27 January 1997, and in particular Article 7 thereof,

Having regard to the request by Puracor to the competent authorites of Belgium of 9 April 1999 for placing a dextran preparation produced by the bacterium *Leuconostoc mesenteroides* on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of Belgium, which the Commission forwarded to all Member States on 28 July 1999.

Whereas:

(1) Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections were raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(2) The Scientific Committe for Food has been consulted on this matter in accordance with Article 11 of the Regulation. On 18 October 2000, the Scientific Committee for Food delivered its opinion that the dextran preparation produced by the bacterium *Leuconostoc mesenteroides* that is the subject of this application is safe for human consumption, up to 5 % in bakery products.

(3) Like gluten, soybean flour, malted flour or inactivated sourdough, dextran is an ingredient in bakery products.

(4) Dextran is highly digestible and has similar nutritional properties as starch.

(5) On this basis, it is established that the products comply with the criteria laid down in Article 3(1) of the Regulation.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

The dextran preparation produced by the bacterium *Leuconostoc mesenteroides*, as specified in the Annex, may be placed on the market in the Community as a novel food ingredient in bakery products, under the condition that no more than 5 % by weight of the final bakery product is made up of the dextran preparation.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs that the word 'dextran' will be mentioned in the list of ingredients of the bakery product containing it.

Article 3

This Decision is addressed to Puracor nv/sa, Industrialaan 25, B-1702 Groot Bijgaarden.

Done at Brussels, 30 January 2001.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX

Specifications of a dextran preparation produced by the bacterium, *Leuconostoc mesenteroides*

1. Powdered form:

Carbohydrates	60 % with:
(Dextran: 50 % Mannitol: 0,5 % Fructose: 0,3 % Leucrose: 9,2 %)	
Protein	6,5 %
Lipid	0,5 %
Lactid acid	10 %
Ethanol	traces
Ash	13 %
Moisture	10 %

2. Liquid form:

Carbohydrate	12 % with:
(Dextran: 6,9 % Mannitol: 1,1 % Fructose: 1,9 % Leucrose: 2,2 %)	
Protein	2 %
Lipid	0,1 %
Lactid acid	2 %
Ethanol	0,5 %
Ash	3,4 %
Moisture	80 %

COMMISSION DECISION

of 15 February 2002

authorising the placing on the market of coagulated potato proteins and hydrolysates thereof as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2002) 506)

(Only the Dutch text is authentic)

(2002/150/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Having regard to the request by AVEBE ba to the competent authorities of the Netherlands of 25 May 2000 for placing coagulated potato protein and hydrolysates thereof on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the Netherlands,

Whereas:

(1) Whilst protein has been extracted from a number of plants to be used in foods, potato protein had not been on the market in the Community before Regulation (EC) No 258/97 entered into force. Therefore, potato protein requires authorisation according to Article 1(2)(e) of the Regulation.

(2) In their initial assessment report the Netherlands' competent food assessment body came to the conclusion that coagulated potato proteins and hydrolysates thereof are safe for human consumption.

(3) The Commission forwarded the initial assessment report to all Member States on 19 February 2001.

(4) Within the 60-days period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision concerning, in particular, the use of sulphite as an additive and the specification requirements for certain alkaloids.

(5) AVEBE provided additional information in response to the comments and objections raised by Member States, which was discussed with Member States' experts on 17 July 2001.

(6) On the basis of this additional information and the initial assessment report, it is established that coagulated potato protein and hydrolysates thereof comply with the criteria laid down in Article 3(1) of the Regulation.

(7) The use and the labelling of sulphite is governed by 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 [2] and Directive 95/2/EC of 20 February 1995 of the European Parliament and of the Council on food additives other than colours and sweeteners [3].

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Coagulated potato protein and hydrolysates thereof as specified in the Annex, may be placed on the market in the Community as novel food ingredients.

Article 2

The designation 'potato protein' shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

Article 3

This Decision is addressed to AVEBE ba, Prins Hendrikplein 20, 9641 GK Veendam, The Netherlands.

Done at Brussels, 15 February 2002.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 40, 11.2.1989, p. 27.

[3] OJ L 61, 18.3.1995, p. 1.

ANNEX

Specifications of coagulated potato proteins and hydrolysates thereof

Dry substance: not less than 800 mg/g
Protein (N*6,25): not less than 600 mg/g (dry substance)
Ash: not more than 400 mg/g (dry substance)
Glycoalkaloid (total): not more than 150 mg/kg
Lysinoalanine (total): not more than 500 mg/kg
Lysinoalanine (free): not more than 10 mg/kg

COMMISSION DECISION

of 5 June 2003

authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2003) 1789)

(Only the English text is authentic)

(2003/426/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Having regard to the request by Morinda Inc. to the competent authorities of Belgium of 25 April 2000 for placing 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) on the market as a novel food,

Having regard to the initial assessment report drawn up by the competent authorities of Belgium,

Whereas:

(1) In their initial assessment report the Belgian competent food assessment body came to the conclusion that an additional assessment was required.

(2) The Commission forwarded the initial assessment report to all Member States on 18 September 2001.

(3) The Scientific Committee on Food (SCF) was asked to provide an additional assessment on 4 December 2001. The SCF in its opinion of 4 December 2002 considered Tahitian Noni® juice, at the observed levels of intake, as acceptable. The Committee also noted that the data supplied and the information available provided no evidence for special health benefits of 'Noni juice' which go beyond those of other fruit juices.

(4) 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

'Noni juice' (juice of the fruit of *Morinda citrifolia* L.) may be placed on the market in the Community as a novel food ingredient to be used in pasteurised fruit drinks.

Article 2

The term 'Noni juice' or 'juice of *Morinda citrifolia*' shall be displayed on the labelling of the product as such or in the list of ingredients of fruit drinks containing it in accordance with 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 [2].

Article 3

This Decision is addressed to Morinda Inc., 333 W. River Park Drive, Provo, UT 84604, USA.

Done at Brussels, 5 June 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 109, 6.5.2000, p. 29.

COMMISSION DECISION

of 5 June 2003

authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) from the micro-algae *Schizochytrium sp.* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2003) 1790)

(Only the English text is authentic)

(2003/427/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Having regard to the request by Martek Biosciences Corporation, formerly OmegaTech GmbH to the competent authorities of the United Kingdom of 13 February 2001 for placing oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium sp.* on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the United Kingdom,

Whereas:

(1) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that DHA-rich oil from the microalgae *Schizochytrium sp.* is safe for human consumption.

(2) The Commission forwarded the initial assessment report to all Member States on 20 June 2002.

(3) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97, reasoned objections to the marketing of the product were raised in accordance with that provision.

(4) In response to the comments and objections raised, OmegaTech GmbH amended the specifications and the applications of the DHA-rich oil. These amendments were discussed with Member States' experts on 21 October 2002.

(5) On the basis of the initial assessment report, it is established that DHA-rich oil from the microalgae *Schizochytrium sp.* complies with the criteria laid down in Article 3(1) of the Regulation.

(6) 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

DHA-rich oil from the microalgae *Schizochytrium sp.* as specified in Annex 1, may be placed on the market in the Community as a novel food ingredient for the uses and at the maximum levels as listed in Annex 2.

Article 2

The designation 'DHA-rich oil from the microalgae *Schizochytrium sp.*' shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

Article 3

This Decision is addressed to Martek Biosciences Corporation, 6480 Dobbin Road, Columbia, Maryland 21045 USA.

Done at Brussels, 5 June 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX 1

SPECIFICATION OF OIL RICH IN DHA (DOCOSAHEXAENOIC ACID) OBTAINED BY HEXANE EXTRACTION OF MICROALGAE *SCHIZOCHYTRIUM SP.*

Test	Specification
Acid value	Not more than 0,5 mg KOH/g
Peroxide value (PV)	Not more than 5,0 meq/kg oil
Moisture and volatiles	Not more than 0,05 %
Unsaponifiables	Not more than 4,5 %
Trans-fatty acids	Not more than 1 %
DHA content	Not less than 32,0 %

ANNEX 2

USES OF OIL RICH IN DHA (DOCOSAHEXAENOIC ACID) FROM THE MICROALGAE *SCHIZOCHYTRIUM SP.*

Use group	Maximum use level of DHA
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g
Spreadable fat and dressings	600 mg/100 g
Breakfast cereals	500 mg/100 g
Food supplements	200 mg per daily dose as recommended by the manufacturer
Dietary foods for special medical purposes	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction	200 mg/meal replacement

Note: All food products containing DHA-rich oil from *Schizochytrium sp*. should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC).

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 1 December 2003

authorising the placing on the market of salatrims as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2003) 4408)

(Only the Danish text is authentic)

(2003/867/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 28 June 1999 Danisco, formerly Cultor Food Science, submitted to the competent authorities of the United Kingdom a request for placing salatrims on the market in the Community as novel food ingredients.

(2) Salatrims are a group of reduced calorie triacylglycerides developed for use as alternative fats.

(3) The competent authorities of the United Kingdom carried out the initial assessment. The Commission forwarded the initial assessment report to all Member States on 22 November 1999.

(4) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(5) The Scientific Committee on Food was consulted on the matter in accordance with Article 11 of the Regulation. On 13 December 2001, the Scientific Committee on Food delivered its opinion that salatrims are safe for human consumption.

(6) The Scientific Committee on Food noted the only adverse effects of salatrims observed in a number of human tolerance studies were gastro-intestinal complaints at high intakes (i.e. >30 g/day). Such inconveniences caused by gastro-intestinal intolerance are easily and commonly resolved by the individual abstaining from consumption when he or she becomes aware of the problem. It is therefore appropriate to provide a statement on the label which informs the consumer that excessive consumption may lead to gastro-intestinal problems.

(7) The Scientific Committee on Food also noted that no data had been generated on the effect of consumption of foods containing salatrims by children under 16 years, as this population group was unlikely to consume products intended for use mainly by persons aiming to control their weight by choosing an energy restricted diet. Therefore it is appropriate to provide a statement on the label which informs the consumer that products containing salatrims are not for use by children.

(8) The declaration of the energy value of foods and food ingredients is governed by Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs [2].

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 276, 6.10.1990, p. 40.

HAS ADOPTED THIS DECISION:

Article 1

Salatrims as specified in the Annex may be placed on the market in the Community as novel food ingredients for use in bakery products and confectionery.

Article 2

The designation 'reduced energy fat (salatrims)' shall be displayed on the labelling of the product, as such, or in the list of ingredients of foodstuffs containing it.

There shall be a statement that excessive consumption may lead to gastro-intestinal disturbance.

There shall be a statement that the products are not intended for use by children.

Article 3

This Decision is addressed to Danisco A/S, Langebrogade 1, PO Box 17, DK-1001 Copenhagen K, Denmark.

Done at Brussels, 1 December 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

SPECIFICATIONS OF SALATRIMS

Definition:

Salatrim is the internationally recognised ([1]) acronym for (short and long chain acyl triglyceride molecules).

Salatrim is prepared by non-enzymatic inter-esterification of triacetin, tripropionin, tributyrin, or their mixtures with hydrogenated canola, soybean, cottonseed, or sunflower oil.

Description:

Clear, slightly amber liquid to a light coloured waxy solid at room temperature. Free of particulate matter and of foreign or rancid odour.

Glycerol ester distribution:

— Triacylglycerols: > 87 %

— Diacylglycerols: ≤ 10 %

— Monoacylglycerols: ≤ 2 %

Fatty acid composition:

— MOLE % LCFA (long chain fatty acids): 33 to 70 %

— MOLE % SCFA (short chain fatty acids): 30 to 67 %

— Saturated long chain fatty acids: < 70 % by weight

— Trans fatty acids: ≤ 1 %

— Free fatty acids as oleic acid: ≤ 0,5 %

Triacylglycerol profile:

— Triesters (short/long of 0,5 to 2,0): ≥ 90 %

— Triesters (short/long = 0): ≤ 10 %

Unsaponifiable material: ≤ 1 %

Moisture: ≤ 0,3 %

Ash: ≤ 0,1 %

Colour: ≤ 3,5 Red (Lovibond)

Peroxide value: ≤ 2,0 Meq/Kg.

([1]) FAO/WHO Joint Expert Committee on Food Additives (2002) FAO Food and Nutrition Paper 52 Additive 10, page 23.

COMMISSION DECISION

of 31 March 2004

authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2004) 1243)

(Only the English text is authentic)

(2004/333/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 2 November 2001 Archer Daniels Midland Company (ADM) made a request to the competent authorities of the Netherlands for placing phytosterols and phytosterol esters on the market.

(2) On 13 December 2001 the competent authorities of the Netherlands issued their initial assessment report.

(3) In their initial assessment report, the Netherlands' competent food assessment body came to the conclusion that the phytosterols/stanols are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 5 March 2002.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the SCF, in its opinion on an application from ADM for approval of plant sterol-enriched foods of 4 April 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3g.

(7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters [2] ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(8) 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

Foods and food ingredients as described in Annex 1 with added phytosterols/phytostanols as specified in Annex 2, hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3g (in case of one portion per day) or a maximum of 1g (in case of three portions per day) of added phytosterols/phytostanols.

Salad dressings shall be packed as single portions.

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Archer Daniels Midland Company, 4666 Faries Parkway, Decatur, IL. 62526-5666, USA.

Done at Brussels, 31 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX 1

Products referred to in Article 1

Yellow fat spreads, as defined by Council Regulation (EC) No 2991/94 [1], excluding cooking and frying fats and spreads based on butter or other animal fat.

Salad dressings including mayonnaise.

Milk type products such as semi skimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products such as yoghurt, soya drinks, and cheese type products (fat content ≤ 12 g per 100 g), where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein.

ANNEX 2

Specifications of phytosterols and phytostanols for the addition to foods and food ingredients

Definition:

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method):

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

[1] OJ L 316, 9.12.1994, p. 2.

COMMISSION DECISION

of 31 March 2004

authorising the placing on the market of yellow fat spreads, milk type products, yoghurt type products, and spicy sauces with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2004) 1244)

(Only the Finnish text is authentic)

(2004/334/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 24 September 2001 Pharmaconsult Oy Ltd. (formerly MultiBene Health Oy Ltd.) made a request to the competent authorities of Finland for placing phytosterols on the market.

(2) On 17 January 2002 the competent authorities of Finland issued their initial assessment report.

(3) In their initial assessment report, Finland's competent food assessment body came to the conclusion that the phytosterols/stanols are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 5 March 2002.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the SCF, in its opinion on an application from MultiBene for approval of plant sterol-enriched foods of 4 April 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3 g.

(7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters [2] ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(8) 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

Foods and food ingredients as described in Annex 1 with added phytosterols/phytostanols as specified in Annex 2, hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytostanols.

Spicy sauces shall be packed as single portions.

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Pharmaconsult Oy, Riippakoivunkuja 5, FIN — 02130 Espoo.

Done at Brussels, 31 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX 1

Products referred to in Article 1

Yellow fat spreads, as defined by Council Regulation (EC) No 2991/94 [1], excluding cooking and frying fats and spreads based on butter or other animal fat.

Milk type products, such as semi-skimmed and skimmed milk type products and yoghurt type products, where the milk fat has been reduced or partly or fully replaced by vegetable fat.

Spicy sauces

ANNEX 2

Specifications of phytosterols and phytostanols for the addition to foods and food ingredients

Definition:

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method):

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method):

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

[1] OJ L 316, 9.12.1994, p. 2.

COMMISSION DECISION

of 31 March 2004

authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2004) 1245)

(Only the English text is authentic)

(2004/335/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 6 August 2002 Unilever made a request to the competent authorities of the United Kingdom to place phytosterol esters as a novel food ingredient in a range of foods on the market.

(2) On 21 November 2002 the competent authorities of the United Kingdom issued their initial assessment report.

(3) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that these extensions of uses of phytosterol esters are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 11 December 2002.

(5) Within the 60-day period laid down in Article 6 (4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the SCF, in its opinion on applications for approval of a variety of plant sterol enriched foods of 5 March 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3g.

(7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters [2], phytostanols and/or phytostanol esters ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(8) 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

Foods and food ingredients as described in Annex 1 with added phytosterol esters as specified in Annex 2, hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3g (in case of one portion per day) or a maximum of 1g (in case of three portions per day) of added phytosterol esters (calculated as free sterols/stanols).

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Unilever, London Road, Purfleet, Essex RM19 1SD, United Kingdom.

Done at Brussels, 31 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX 1

Products referred to in Article 1

Milk type products, such as semi-skimmed and skimmed milk type products, yoghurt type products, and milk/yoghurt type products where the milk fat has been partly or fully replaced by vegetable fat.

ANNEX 2

Specifications of phytosterols and phytostanols for the addition to foods and food ingredients

Definition:

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method):

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

COMMISSION DECISION

of 31 March 2004

authorising the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2004) 1246)

(Only the Finnish text is authentic)

(2004/336/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 15 May 2001 Teriaka Ltd. made a request to the competent authorities of Finland to place phytosterols on the market as novel food ingredients.

(2) On 31 August the competent authorities of Finland issued their initial assessment report.

(3) In their initial assessment report, Finland's competent food assessment body came to the conclusion that the phytosterols/stanols are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 15 October 2001.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the SCF, in its opinion on applications for approval of a variety of plant sterol enriched foods of 5 March 2003, came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3g.

(7) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters [2] ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(8) 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

Foods and food ingredients as described in Annex 1 with added phytosterols/phytostanols as specified in Annex 2 hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3g (in case of one portion per day) or a maximum of 1g (in case of three portions per day) of added phytosterols/phytostanols.

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 97, 1.4.2004, p. 44.

Article 3

This Decision is addressed to Teriaka Ltd., Siirakuja 3, 01490 Vantaa.

Done at Brussels, 31 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX 1

Products referred to in Article 1

Yellow fat spreads as defined by Council Regulation (EC) No 2991/94 [1], excluding cooking and frying fats and spreads based on butter or other animal fat.

Milk based fruit drinks, yoghurt type products and cheese type products (fat content ≤ 12 g per 100 g) where milk fat and or protein has been partly or fully replaced by vegetable fat and/or protein.

ANNEX 2

Specifications of phytosterols and phytostanols for the addition to foods and food ingredients

Definition:

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method):

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

[1] OJ L 316, 9.12.1994, p. 2.

32004D0657

2004/657/EC: Commission Decision of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2004) 1865)

Official Journal L 300 , 25/09/2004 P. 0048 - 0051

Commission Decision of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2004) 1865) (only the Dutch text is authentic) (2004/657/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients(1), (hereinafter referred to as the Regulation), and in particular Article 7 thereof,

Whereas:

(1) Consent has been granted on 22 April 1998 for the placing on the market of grains of genetically modified maize line Bt11 to be used for feed, processing and importing(2), in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms(3).

(2) Food and food ingredients derived from the original transformant Bt11 and any inbred and hybrid lines derived from it and containing the introduced genes may be placed on the market in the Community following a notification(4) pursuant to Article 5 of Regulation (EC) No 258/97.

(3) On 11 February 1999 , Novartis (in the meantime: Syngenta), submitted a request to the competent authorities of the Netherlands for placing sweet maize from genetically modified maize line Bt11 on the market as a novel food or as a novel food ingredient.

(4) In their initial assessment report of 12 May 2000 , the Netherlands' competent food assessment body came to the conclusion that Bt11 sweet maize is as safe as conventional sweet maize.

(5) The Commission forwarded the initial assessment report to all Member States on 15 June 2000 . Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) On 13 December 2000 , the Commission requested an opinion from the Scientific Committee on Food, in accordance with Article 11 of the Regulation. On 17 April 2002 , the Scientific Committee on Food delivered its opinion that Bt11 sweet maize is as safe for human food use as its conventional counterparts. This opinion focused, as requested by the Commission, on the issues raised in the comments made by Member States' authorities, including molecular characterisation and toxicity studies. The concerns raised in the opinion of the «Agence française de sécurité sanitaire des aliments» (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt11.

(7) The data provided by the applicant and the safety assessment of the product carried out followed the criteria and requirements laid down in the Commission Recommendation

618/97/EC(5) concerning the scientific aspects and the presentation of applications under the Novel Food Regulation. The methodology used for the safety assessment of Bt11 was also in line with the recent guidelines prepared by the Scientific Steering Committee concerning the assessment of GMOs, GM food and GM feed and with the Codex Principles and Guidelines on Foods Derived from Biotechnology.

(8) Article 46(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed(6) provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.

(9) The Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the Bt11 transformation event in sweet maize. The method validated had been developed by the National Veterinary Institute of Norway and INRA, France. The materials needed in the study (GM and non-GM DNA as well as the method-specific reagents) had been provided by Syngenta. The JRC has considered that the method performance was appropriate for its aimed purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been made publicly available.

(10) Reference material for sweet maize from genetically modified maize line Bt11 has been produced by the Joint Research Centre (JRC) of the European Commission.

(11) Sweet maize from genetically modified maize line Bt11 and food containing sweet maize from genetically modified maize line Bt11 as ingredient shall be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and shall be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC(7).

(12) Information on the identification of sweet maize from genetically modified maize line Bt11, including the validated detection method and the reference material, contained in the annex, shall be retrievable from the Register to be established by the Commission in accordance with Article 28 of Regulation (EC) No 1829/2003.

(13) Genetically modified maize Bt11 has been notified to the Biosafety Clearing-House, pursuant to Articles 11(1) and 20(3)(c) of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

(14) The Standing Committee on the Food Chain and Animal Health has not given an opinion; the Commission has therefore submitted a proposal to the Council on 4 February 2004 pursuant to Article 13(4)(b) of Regulation (EC) No 258/97 and in accordance with Article 5, paragraph 4 of the Council Decision 1999/468/EC(8), the Council being required to act within three months.

(15) However, the Council has not acted within the required time limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Sweet maize from genetically modified maize line Bt11 (hereinafter referred to as the product), as designated and specified in the Annex, may be placed on the Community market as a novel food or novel food ingredient.

Article 2

The product shall be labelled as «genetically modified sweet maize» , in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) No 1829/2003.

Article 3

The product and the information included in the Annex shall be entered in the Community register of genetically modified food and feed.

Article 4

This Decision is addressed to Syngenta Seeds BV, Westeinde 62, 1600 AA Enkhuizen, The Netherlands, representing Syngenta Seeds AG, Switzerland. It shall be valid for a period of 10 years.

Done at Brussels, 19 May 2004 .

For the Commission

David Byrne

Member of the Commission

(1) OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(2) Commission Decision 98/292/EC (OJ L 131, 5.5.1998, p. 28).

(3) OJ L 117, 8.5.1990, p. 15. Directive amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

(4) OJ C 181, 26.6.1999, p. 22.

(5) OJ L 253, 16.9.1997, p. 1.

(6) OJ L 268, 18.10.2003, p. 1.

(7) OJ L 268, 18.10.2003, p. 24.

(8) OJ L 184, 17.7.1999, p. 23.

ANNEX

Information to be entered in the Community Register of Genetically Modified Food and Feed

(a) Authorisation holder

: Name

: Syngenta Seeds BV Address

: Westeinde 62, 1600 AA Enkhuizen, The Netherlands On behalf of

: Syngenta Seeds AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland (b) Designation and specification of the product

: Sweet maize, fresh or canned, that is progeny from traditionally crosses of traditionally bred maize with genetically modified maize line Bt11 that contains:

- a synthetic version of the cry IA (b) gene derived from Bacillus thuringiensis kurstaki strain HD1 under the control of a 35S promoter from Cauliflower Mosaic Virus, and IVS 6 intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of Agrobacterium tumefaciens , and

- a synthetic version of the pat gene derived from Streptomyces viridochromogenes under the control of a 35S promoter from Cauliflower Mosaic Virus, an IVS intron from the maize alcholdehydrogenase gene and the nopaline synthase terminator sequence of Agrobacterium tumefaciens .

(c) Labellin

: «Genetically modified sweet maize» (d) Method for detection

: - Event specific real-time quantitative PCR based method for genetically modifiedBt11 sweet maize, published in European Food Research and Technology , Vol. 216/2003, pages 347-354.

- Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), published at http://engl.jrc.it/crl/oj/bt11sm.pdf.

- Reference Material: IRMM-412R, produced by the Joint Research Centre (JRC) of the European Commission.

(e) Unique identifier

: SYN-BT Ø11-1 (f) Information required under Annex II to the Cartagena Protocol

: Biosafety Clearing House, Record ID 1240

(see: http://bch.biodiv.org/Pilot/Record.aspx?RecordID=1240)

(g) Conditions or restrictions on the placing on the market of the product

: Not applicable (h) Post-market monitoring requirements

: Not appropriate

32004D0845(01)

2004/845/EC: Commission Decision of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2004) 4289)

Official Journal L 366 , 11/12/2004 P. 0014 - 0016

Commission Decision

of 12 November 2004

on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2004) 4289)

(Only the English text is authentic)

(2004/845/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 7 September 2000 Novartis (now Forbes Medi-Tech Inc.) made a request to the competent authorities of Belgium to place milk based beverages with added phytosterols on the market as a novel food or a novel food ingredient.

(2) On 30 March 2001 the competent authorities of Belgium issued their initial assessment report.

(3) In their initial assessment report, Belgium's competent food assessment body came to the conclusion that an additional assessment was required.

(4) The Commission forwarded the initial assessment report to all Member States on 27 April 2001.

(5) The Scientific Committee on Food (SCF) in its opinion "General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene" of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes may induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day. Furthermore, the European Food Safety Authority's (EFSA) Panel on Dietetic Products, Nutrition and Allergies in its opinion "on a request from the Commission related to a Novel Food application from Forbes Medi-Tech for approval of plant sterol-containing milk-based beverages" of 25 November 2003 concurred for that application with the conclusions of the SCF, in its opinion on applications for approval of a variety of plant sterol enriched foods of 5 March 2003,

came to the conclusion that the addition of phytosterols is safe, provided that the daily consumption does not exceed 3 g.

(6) Commission Regulation (EC) No 608/2004 [2] concerning the labelling of foods and food ingredients with added phytostanol esters ensures that consumers receive the information necessary in order to avoid excessive intake of added phytosterols/phytostanols.

(7) 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

Foods and food ingredients as described in Annex 1 with added phytosterols/phytostanols as specified in Annex 2 (hereinafter called "the products"), may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can easily be divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytostanols.

The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.

Article 3

This Decision is addressed to Forbes Medi-Tech Inc., 750 West Pender Street, Vancouver BC V6C 2T8, Canada.

Done at Brussels, 12 November 2004.

For the Commission

David Byrne

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 97, 1.4.2004, p. 44.

ANNEX 1

Products referred to in Article 1

Milk type products, such as semi-skimmed and skimmed milk type products, where the milk fat has been partly or fully replaced by vegetable fat.

ANNEX 2

Specifications of phytosterols and phytostanols for the addition to foods and food ingredients

Definition

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method)

< 80 % β-sitosterol

< 35 % β-sitostanol

< 40 % campesterol

< 15 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 3 March 2005

authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2005) 580)

(Only the French and Dutch texts are authentic)

(2005/448/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], (hereinafter referred to as the Regulation), and in particular Article 7 thereof,

Whereas:

(1) On 24 April 2001, Monsanto submitted to the competent authorities of the Netherlands a request, in accordance with Article 4 of the Regulation, for placing on the market foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or as novel food ingredients.

(2) In their initial assessment report of 5 November 2002, the Netherlands' competent food assessment body came to the conclusion that foods and food ingredients derived from maize NK 603 are as safe as foods and food ingredients derived from conventional maize and may be used in the same manner.

(3) The Commission forwarded the initial assessment report to all Member States on 6 January 2003. Within the 60 days period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(4) On 27 August 2003, the Commission requested an opinion from the European Food Safety Authority (EFSA), in accordance with Article 11 of the Regulation. On 25 November 2003, EFSA delivered its opinion that NK 603 maize is as safe as conventional maize and therefore the placing on the market of NK 603 maize for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment [2]. In delivering its opinion, the EFSA considered all specific questions and concerns raised by the Member States.

(5) Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed [3] provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.

[1] OJ L 43, 14. 2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] The EFSA Journal (2003) 9, 1-14.

[3] OJ L 268, 18.10.2003, p. 1.

(6) The Joint Research Centre of the European Commission (JRC) in collaboration with the European Network of GMO Laboratories (ENGL), has validated a method for detection of the NK 603 maize. The JRC has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the NK 603 transformation event in maize. The materials needed in the study had been provided by Monsanto. The JRC has considered that the method performance was appropriate for its aimed purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been made publicly available.

(7) Reference material for maize from genetically modified maize line NK 603 has been produced by the Joint Research Centre (JRC) of the European Commission.

(8) Food and food ingredients from genetically modified maize line NK 603 should be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and should be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([1]).

(9) In accordance with Commission Regulation (EC) No 65/2004 ([2]), a unique identifier has been assigned to the product for the purposes of Regulation (EC) No 1830/2003.

(10) Information, contained in the Annex, on the identification of foods and food ingredients derived from genetically modified maize line NK 603, including the validated detection method and the reference material, should be retrievable from the Register referred to in Article 28 of Regulation (EC) No 1829/2003.

(11) The Standing Committee on the Food Chain and Animal Health has not given an opinion; the Commission has therefore submitted a proposal to the Council on 4 February 2004 pursuant to Article 13(b) of Regulation (EC) No 258/97 and in accordance with Article 5(4) of the Council Decision 1999/468/EC ([3]), the Council being required to act within three months.

(12) However, the Council has not acted within the required time-limit; a Decision should now be adopted by the Commission.

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients derived from genetically modified maize line NK 603 (hereinafter referred to as the products), as designated and specified in the Annex, may be placed on the Community market as novel foods or novel food ingredients.

Article 2

The products shall be labelled as 'genetically modified maize' or 'produced from genetically modified maize' in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) No 1829/2003.

Article 3

The products and the information included in the Annex shall be entered in the Community register of genetically modified food and feed.

Article 4

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, B-1150 Brussels, Belgium, representing the Monsanto Company, United States of America. It shall be valid for a period of 10 years.

Done at Brussels, 3 March 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

([1]) OJ L 268, 18.10.2003, p. 24.
([2]) OJ L 10, 16.1.2004, p. 5.
([3]) OJ L 184, 17.7.1999, p. 23.

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED

(a) **Authorisation holder:**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, B-1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products:**

Foods and food ingredients derived from genetically modified maize (*Zea maize* L.) line NK 603 with increased tolerance to the herbicide glyphosate and from all its crosses with traditionally bred maize lines. Maize line NK 603 contains the following DNA sequences in two intact cassettes:

— A 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene derived from *Agrobacterium spec.* strain CP (CP4 EPSPS), which imparts tolerance to glyphosate, under the regulation of the rice actin 1 gene promoter, terminator sequence from *Agrobacterium tumefaciens* and the chloroplast transit peptide sequence from the *epsps* gene of *Arabidopsis thaliana,*

— A 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene derived from *Agrobacterium spec.* strain CP (CP4 EPSPS), which imparts tolerance to glyphosate, under the regulation of an enhanced 35S promoter derived from cauliflower mosaic virus, terminator sequence from *Agrobacterium tumefaciens* and the chloroplast transit peptide sequence from the *epsps* gene of *Arabidopsis thaliana*.

(c) **Labelling:** 'Genetically modified maize' or 'produced from genetically modified maize'

(d) **Method for detection:**

— Event specific real-time quantitative PCR based method for genetically modified NK 603 maize.

— Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), to be published at http://gmo-crl.jrc.it/statusofdoss.htm.

— Reference Material: IRMM-415 produced by the Joint Research Centre (JRC) of the European Commission.

(e) **Unique identifier:** MON-00603-6

(f) **Information required under Annex II to the Cartagena Protocol:** Not applicable

(g) **Conditions or restrictions on the placing on the market of the product:** Not applicable

(h) **Post market monitoring requirements:** Not appropriate.

COMMISSION

COMMISSION DECISION

of 4 April 2005

authorising the placing on the market of isomaltulose as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2005) 1001)

(Only the Dutch text is authentic)

(2005/457/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 30 October 2003 Cargill Incorporated, acting through Cerestar, made a request to the competent authorities of the United Kingdom to place isomaltulose as a novel food or novel food ingredient on the market.

(2) On 19 March 2004 the competent authorities of the United Kingdom issued their initial assessment report.

(3) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that the proposed uses for isomaltulose are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 15 April 2004.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) At a meeting on 10 December 2004 Member States experts considered the initial assessment report as far as risk assessment was concerned and there was no need for further consultation of the European Food Safety Authority.

(7) As regards the nutrition information included in the labelling and advertising of foods containing isomaltulose, the rules of Council Directive 90/496/EC of 24 September 1990 on nutrition labelling for foodstuffs [2] apply.

(8) On the basis of the initial assessment report, it is established that isomaltulose complies with the criteria laid down in Article 3(1) of the Regulation.

(9) 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

Isomaltulose as specified in the Annex, may be placed on the market in the Community as a novel food or novel food ingredient for use in foodstuffs.

Article 2

The designation 'isomaltulose' shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

In a prominently displayed footnote related to the designation isomaltulose by means of an asterisk (*) the words 'isomaltulose is a source of glucose and fructose' shall be displayed. The words shall have a typeface of at least the same size as the list of ingredients itself.

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51).

Article 3

This Decision is addressed to Cargill Incorporated, c/o Cerestar, Havenstraat 84, B-1800 Vilvoorde.

Done at Brussels, 4 April 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

SPECIFICATIONS OF ISOMALTULOSE

Definition:

A reducing disaccharide that consists of one glucose and one fructose moiety linked by an alpha-1,6-glucosidic bond. It is obtained from sucrose by an enzymatic process. The commercial product is the monohydrate.

Chemical name

6-O-a-D-glucopyranosyl-D-fructofuranose, monohydrate

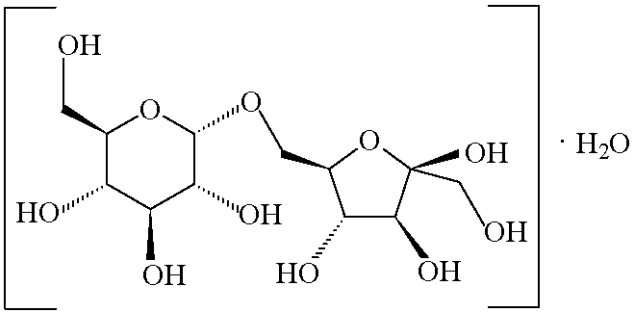
CAS number

13718-94-0

Chemical formula

$C_{12}H_{22}O_{11} \cdot H_2O$

Structural formula



Formula weight

360,3 (monohydrate)

Assay

Not less than 98 % on the dry basis

Description

Virtually odourless, white or almost white crystals with a sweet taste

Loss on drying

Not more than 6,5 % (60 °C, 5 hours)

Lead

Not more than 0,1 mg/kg

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5 ([1]), 'Instrumental methods'.

([1]) Food and Nutrition Paper 5 Rev.2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials. (JECFA) 1991, 322 p. English — ISBN 92-5-102991-1.

I

(Acts whose publication is obligatory)

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed

(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 Articles 37, 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure referred to in Article 251 of the Treaty [4],

Whereas:

(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [5]. This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990 [6] and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [7]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

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[1] OJ C 304 E, 30.10.2001, p. 221.
[2] OJ C 221, 17.9.2002, p. 114.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 43, 14.2.1997, p. 1.
[6] OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.
[7] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by 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]). Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

(10) Experience has shown that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes; therefore such products should only be authorised when fulfilling authorisation criteria for both food and feed.

(11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([2]) provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.

(13) Flavourings falling within the scope 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 ([3]) which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.

(14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([4]) provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.

(15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([5]), provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.

(16) This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore,

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) 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).
([3]) 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).
([4]) 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).
([5]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(18) Article 2 of 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 ([1]) provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

(19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC ([2]) and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms ([3]).

(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([4]) ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.

(24) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for

([1]) OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).
([2]) OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).
([3]) OJ L 6, 11.1.2000, p. 15.

([4]) See page 24 of this Official Journal.

GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.

(29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.

(31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.

(32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

(33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.

(34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC ([1]), 2002/53/EC ([2]) and 2002/55/EC ([3]), which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC ([4]), 66/402/EEC ([5]), 68/193/EEC, 92/33/EEC ([6]), 92/34/EEC ([7]), 2002/54/EC ([8]), 2002/55/EC, 2002/56/EC ([9]) or 2002/57/EC ([10]) which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

([1]) OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).
([2]) OJ L 193, 20.7.2002, p. 1.
([3]) OJ L 193, 20.7.2002, p. 33.
([4]) OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).
([5]) OJ 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.
([6]) OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
([7]) OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.
([8]) OJ L 193, 20.7.2002, p. 12.
([9]) OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).
([10]) OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).

(35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.

(36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

(37) Technological progress and scientific developments should be taken into account when implementing this Regulation.

(38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.

(39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.

(40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.

(41) The measures necessary for the implementation of this Regulation 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 [1].

(42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

(44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.

(45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1

Objective

The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;

[1] OJ L 184, 17.7.1999, p. 23.

(b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;

(c) lay down provisions for the labelling of genetically modified food and feed.

Article 2

Definitions

For the purposes of this Regulation:

1. the definitions of 'food', 'feed', 'final consumer', 'food business' and 'feed business' given in Regulation (EC) No 178/2002 shall apply;

2. the definition of 'traceability', laid down in Regulation (EC) No 1830/2003;

3. 'operator' means the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control;

4. the definitions of 'organism', 'deliberate release' and 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply;

5. 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

6. 'genetically modified food' means food containing, consisting of or produced from GMOs;

7. 'genetically modified feed' means feed containing, consisting of or produced from GMOs;

8. 'genetically modified organism for food use' means a GMO that may be used as food or as a source material for the production of food;

9. 'genetically modified organism for feed use' means a GMO that may be used as feed or as a source material for the production of feed;

10. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

11. 'control sample' means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);

12. 'conventional counterpart' means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;

13. 'ingredient' means 'ingredient' as referred to in Article 6(4) of Directive 2000/13/EC;

14. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

15. 'pre-packaged food' means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

16. 'mass caterer' means 'mass caterer' as referred to in Article 1 of Directive 2000/13/EC.

CHAPTER II

GENETICALLY MODIFIED FOOD

Section 1

Authorisation and supervision

Article 3

Scope

1. This Section shall apply to:

(a) GMOs for food use;

(b) food containing or consisting of GMOs;

(c) food produced from or containing ingredients produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of food falls within the scope of this Section.

Article 4

Requirements

1. Food referred to in Article 3(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

2. No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or

(b) food produced from a GMO as well as foods produced from or containing that food;

(c) an ingredient produced from a GMO as well as food containing that ingredient.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 5

Application for authorisation

1. To obtain the authorisation referred to in Article 4(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the Authority); and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the food, and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);

(d) where applicable, a detailed description of the method of production and manufacturing;

(e) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);

(g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);

(h) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for food use, references to 'food' in paragraph 3 shall be interpreted as referring to food containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject, under other provisions of Community law, to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Article 6

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 5 and examine whether the food complies with the criteria referred to in Article 4(1);

(b) may ask the appropriate food assessment body of a Member State to carry out a safety assessment of the food in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory referred to in Article 32 the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the food, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the food, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the food and/or foods produced from it;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan referred to in Article 5(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 7

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 6(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in the Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 11. The authorised food shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 8

Status of existing products

1. By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions referred to in Regulation (EC) No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 7(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and food containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 9, 10 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure referred to in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 9

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 5(3)(k) and/or monitoring as referred to in Article 5(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 5(2). Articles 5, 6 and 7 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 10

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 7.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

Article 11

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following:

(a) a copy of the authorisation for placing the food on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the food and the risks of the food to the consumer or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 12

Scope

1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:

(a) contain or consist of GMOs; or

(b) are produced from or contain ingredients produced from GMOs.

2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2) in particular in respect of foods containing or consisting of GMOs or in order to take into account advances in science and technology.

Article 13

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods falling within the scope of this Section shall be subject to the following specific labelling requirements:

(a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients;

(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

3. In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

Article 14

Implementing measures

1. Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

2. Specific rules concerning the information to be given by mass caterers providing food to the final consumer may be adopted in accordance with the procedure referred to in Article 35(2).

In order to take into account the specific situation of mass caterers, such rules may provide for adaptation of the requirements of Article 13(1)(e).

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and supervision

Article 15

Scope

1. This Section shall apply to:

(a) GMOs for feed use;

(b) feed containing or consisting of GMOs;

(c) feed produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of feed falls within the scope of this Section.

Article 16

Requirements

1. Feed referred to in Article 15(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the user;

(c) harm or mislead the consumer by impairing the distinctive features of the animal products;

(d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

2. No person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No product referred to in Article 15(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and feed containing or consisting of that GMO as well as feed produced from that GMO; or

(b) feed produced from a GMO as well as feeds produced from or containing that feed.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 17

Application for authorisation

1. To obtain the authorisation referred to in Article 16(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform the Authority without delay; and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority:

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the feed and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;

(d) where applicable, a detailed description of the method of production and manufacturing and intended uses of the feed;

(e) a copy of the studies including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the feed complies with the criteria referred to in Article 16(1), and, in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition [1];

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 25(2)(c), or a proposal for labelling the feed in accordance with Article 25(2)(c) and (3);

(g) either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 25(2)(d);

(h) where appropriate, the conditions for placing the feed on the market, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in the feed produced from it;

(j) samples of the feed and their control samples and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring for the use of the feed for animal consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for feed use, references to 'feed' in paragraph 3 shall be interpreted as referring to feed containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMOs has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject under other provisions of Community law to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

[1] OJ L 126, 13.5.1983, p. 23.

Article 18

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion, the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 17, and examine whether the feed complies with the criteria laid down in Article 16(1);

(b) may ask the appropriate feed assessment body of a Member State to carry out a safety assessment of the feed in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or feed containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC, designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the feed, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the feed, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the feed;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan as referred to in Article 17(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 19

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 18(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 23. The authorised feed shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any feed operator in respect of the feed concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 20

Status of existing products

1. By way of derogation from Article 16(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but which are not referred to in point (a), operators responsible for placing on the market in the Community the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 17(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 19(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure laid down in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to the Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 21

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and the parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 17(3)(k) and/or monitoring as referred to in Article 17(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 17(2). Articles 17, 18 and 19 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the feed. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent Authority of any third country in which the feed is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 22

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 19.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

Article 23

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following particulars and documents:

(a) a copy of the authorisation for placing the feed on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed and the risks of the feed to animals, humans or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 24

Scope

1. This Section shall apply to feed referred to in Article 15(1).

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2), in particular in respect of feed containing or consisting of GMOs, or in order to take into account advances in science and technology.

Article 25

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) shall be subject to the specific labelling requirements laid down below.

2. No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

(a) for the feeds referred to in Article 15(1) (a) and (b), the words 'genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(b) for the feed referred to in Article 15(1)(c), the words 'produced from genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 15(1) such as those indicated hereunder, which is different from its conventional counterpart:

(i) composition;

(ii) nutritional properties;

(iii) intended use;

(iv) implications for the health of certain species or categories of animals;

(d) as specified in the authorisation, any characteristic or property where a feed may give rise to ethical or religious concerns.

3. In addition to the requirements referred to in paragraph 2(a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed falling within the scope of this Section which does not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the feed concerned.

Article 26

Implementing measures

Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

CHAPTER IV

COMMON PROVISIONS

Article 27

Products likely to be used as both food and feed

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.

2. The Authority shall consider whether the application for authorisation should be submitted both as food and feed.

Article 28

Community register

1. The Commission shall establish and maintain a Community register of genetically modified food and feed, hereinafter referred to as 'the Register'.

2. The Register shall be made available to the public.

Article 29

Public access

1. The application for authorisation, supplementary information from the applicant, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public.

2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] when handling applications for access to documents held by the Authority.

3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 30

Confidentiality

1. The applicant may indicate which information submitted under this Regulation it wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.

3. Information relating to the following shall not be considered confidential:

(a) name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;

(b) general description of the GMO and the name and address of the authorisation-holder;

(c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);

(d) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;

(e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;

(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);

(g) information on waste treatment and emergency response.

4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and Member States with all information in its possession.

5. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

6. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

7. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information as to the confidentiality of which the Commission and the applicant disagree.

Article 31

Data protection

The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used.

On the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Article 32

Community reference laboratory

The Community reference laboratory and its duties and tasks shall be those referred to in the Annex.

National reference laboratories may be established in accordance with the procedure referred to in Article 35(2).

Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex.

[1] OJ L 145, 31.5.2001, p. 43.

The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

Detailed rules for implementing this Article, the Annex and any changes to it may be adopted in accordance with the procedure referred to in Article 35(2).

Article 33

Consultation with the European Group on Ethics in Science and New Technologies

1. The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies or any other appropriate body it might establish, with a view to obtaining its opinion on ethical issues.

2. The Commission shall make these opinions available to the public.

Article 34

Emergency measures

Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 35

Committee procedure

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 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.

3. The Committee shall adopt its rules of procedure.

Article 36

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.

Article 37

Repeals

The following Regulations shall be repealed with effect from the date of application of this Regulation:

— Regulation (EC) No 1139/98,

— Regulation (EC) No 49/2000,

— Regulation (EC) No 50/2000.

Article 38

Amendments to Regulation (EC) No 258/97

Regulation (EC) No 258/97 is hereby amended with effect from the date of application of this Regulation as follows:

1. The following provisions shall be deleted:
   — Article 1(2)(a) and (b),
   — Article 3(2), second subparagraph, and (3),
   — Article 8(1)(d),
   — Article 9.

2. In Article 3, the first sentence of paragraph 4 shall be replaced by the following:

   '4. By way of derogation from paragraph 2, the procedure referred to in Article 5 shall apply to foods or food ingredients referred to in Article 1(2)(d) and (e) which, on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4(3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.'

Article 39

Amendment to Directive 82/471/EEC

The following paragraph shall be added to Article 1 of Directive 82/471/EEC with effect from the date of application of this Regulation:

'3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

(*) OJ L 268, 18.10.2003, p. 1.'

Article 40

Amendments to Directive 2002/53/EC

Directive 2002/53/EC is hereby amended with effect from the date of application of this Regulation as follows:

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

'5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 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 (*) is accepted only if it has been authorised under the relevant legislation.

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

Article 41

Amendments to Directive 2002/55/EC

Directive 2002/55/EC is hereby amended with effect from the date of application of this Regulation as follows:

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

'3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 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 (*) is accepted only if it has been authorised under the relevant legislation.

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

Article 42

Amendment to Directive 68/193/EEC

Article 5ba(3) of Directive 68/193/EEC shall be replaced by the following wording with effect from the date of application of this Regulation:

'3. (a) Where products derived from vine-propagating material are intended to be used as or in food falling within the scope of Article 3 or as or in a feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the vine variety concerned shall be accepted only if it has been authorised pursuant to the said Regulation.

(b) Member States shall ensure that a vine variety, from the propagating material of which products were derived intended for use in food and feed pursuant to Articles 2 and 3 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 (**) shall be accepted only if it has been authorised pursuant to the relevant legislation.

(*) OJ L 268, 18.10.2003, p. 1.
(**) OJ L 31, 1.2.2002, p. 1.'

Article 43

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is hereby amended with effect from the date of entry into force of this Regulation, as follows:

1. The following Article shall be inserted:

'*Article 12a*

Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation

1. Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to

21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

2. This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

(*) OJ L 268, 18.10.2003, p. 1.'

2. The following Article shall be inserted:

'*Article 26a*

Measures to avoid the unintended presence of GMOs

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.'

Article 44

Information to be provided in accordance with the Cartagena Protocol

1. Any authorisation, renewal, modification, suspension or revocation of authorisation of a GMO, food or feed referred to in Articles 3(1)(a) or (b) or 15(1)(a) or (b) shall be notified by the Commission to the Parties to the Cartagena Protocol through the biosafety clearing house in accordance with Article 11(1) or Article 12(1) of the Cartagena Protocol, as the case may be.

The Commission shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the biosafety clearing house.

2. The Commission shall also process requests for additional information made by any Party in accordance with Article 11(3) of the Cartagena Protocol and shall provide copies of the laws, regulations and guidelines in accordance with Article 11(5) of that Protocol.

Article 45

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission six months after the date of entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 46

Transitional measures for requests, labelling and notifications

1. Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be transformed into applications under Chapter II, Section 1 of this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of this Regulation.

2. The labelling requirements referred to in this Regulation shall not apply to products, the manufacturing process of which has commenced before the date of application of this Regulation, provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation.

3. Notifications concerning products including their use as feed submitted under Article 13 of Directive 2001/18/EC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation where the assessment report provided for in Article 14 of Directive 2001/18/EC has not yet been sent to the Commission.

4. Requests submitted for products referred to in Article 15(1)(c) of this Regulation under Article 7 of Directive 82/471/EEC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation.

5. Requests submitted for products referred to in Article 15(1) of this Regulation under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be supplemented by applications under Chapter III, Section 1 of this Regulation.

Article 47

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

1. The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:

(a) this presence is adventitious or technically unavoidable;

(b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;

(c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and

(d) detection methods are publicly available.

2. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

3. The thresholds referred to in paragraph 1 may be lowered in accordance with the procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer.

4. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.

Article 48

Review

1. No later than 7 November 2005 and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47, accompanied, where appropriate, by any suitable proposal. The report and any proposal shall be made accessible to the public.

2. Without prejudice to the powers of national authorities, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 49

Entry into force

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

It shall apply from six months after the date of publication of this Regulation.

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

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

ANNEX

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 32 is the Commission's Joint Research Centre.

2. For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of national reference laboratories, which will be referred to as the 'European Network of GMO laboratories'.

3. The Community reference laboratory shall be responsible, in particular, for:

   — reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples,

   — testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed,

   — evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,

   — submitting full evaluation reports to the Authority.

4. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [5] requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.

(2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should therefore be amended accordingly.

(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [6], so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

(5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(6) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.

(7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.

(8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No 1829/2003.

(9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

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[1] OJ C 304 E, 30.10.2001, p. 327 and OJ C 331 E, 31.12.2002, p. 308.
[2] OJ C 125, 27.5.2002, p. 69.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 21), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).
[6] See page 1 of this Official Journal.

(10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material consisting, containing or produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article 47 of Regulation (EC) No 1829/2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.

(11) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.

(12) The measures necessary for the implementation of this Regulation 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 [1].

(13) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.

(14) The Commission should submit a report to the European Parliament and the Council on the implementation of this Regulation and, more specifically, on the effectiveness of the rules on traceability and labelling.

(15) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

Article 1

Objectives

This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

Article 2

Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:

(a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;

(b) food produced from GMOs, placed on the market in accordance with Community legislation;

(c) feed produced from GMOs, placed on the market in accordance with Community legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93 [2].

Article 3

Definitions

For the purpose of this Regulation:

1. 'Genetically modified organism' or 'GMO' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

2. 'Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

4. 'Unique identifier' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;

5. 'Operator' means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

[1] OJ L 184, 17.7.1999, p. 23.

[2] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (OJ L 214, 24.8.1993, p. 1). Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6. 'Final consumer' means the ultimate consumer who will not use the product as part of any business operation or activity;

7. 'Food' means food as defined in Article 2 of Regulation (EC) No 178/2002 ([1]);

8. 'Ingredient' means ingredient as referred to in Article 6(4) of Directive 2000/13/EC ([2]);

9. 'Feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

10. 'Placing on the market' means placing on the market as defined in the specific Community legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;

11. 'The first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;

12. 'Pre-packaged product' means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

Article 4

Traceability and labelling requirements for products consisting of or containing GMOs

A. TRACEABILITY

1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) that it contains or consists of GMOs;

(b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

3. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

4. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

5. Paragraphs 1 to 4 shall be without prejudice to other specific requirements in Community legislation.

B. LABELLING

6. For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;

(b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

C. EXEMPTIONS

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.

8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

([1]) 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 (OJ L 31, 1.2.2002, p. 1).

([2]) 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 (OJ L 109, 6.5.2000, p. 29). Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

Article 5

Traceability requirements for products for food and feed produced from GMOs

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) an indication of each of the food ingredients which is produced from GMOs;

(b) an indication of each of the feed materials or additives which is produced from GMOs;

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available.

3. Paragraphs 1 and 2 shall be without prejudice to other specific requirements in Community legislation.

4. Paragraphs 1, 2 and 3 shall not apply to traces of GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

Article 6

Exemptions

1. In cases where Community legislation provides for specific identification systems, such as lot numbering for prepackaged products, operators shall not be obliged to hold the information specified in Articles 4(1), 4(2), 4(3) and 5(1), provided that this information and the lot number is clearly marked on the package and that information about lot numbers is held for the periods of time referred to in Articles 4(4) and 5(2).

2. Paragraph 1 shall not apply to the first stage of placing on the market of a product or to primary manufacture or repackaging of a product.

Article 7

Amendment of Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

1. Article 4(6) is deleted;

2. the following paragraph is added to Article 21:

'3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.'

Article 8

Unique identifiers

In accordance with the procedure referred to in Article 10(2), the Commission shall:

(a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;

(b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

Article 9

Inspection and control measures

1. Member States shall ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with this Regulation. Inspection and control measures may also include inspection and control regarding the holding of a product.

2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(3), shall develop and publish technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No 1829/2003.

3. In order to help the Member States meet the requirements set out in paragraphs 1 and 2, the Commission shall ensure that a central register is put in place at Community level, which shall contain all available sequencing information and reference material for GMOs authorised to be put into circulation in the Community. The competent authorities in the Member States shall have access to the register. The register shall also contain, where available, relevant information concerning GMOs which are not authorised in the European Union.

Article 10

Committee

1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/EC.

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 three months.

3. 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.

4. The Committee shall adopt its rules of procedure.

Article 11

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them.

Article 12

Review clause

No later than 18 October 2005, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, in particular with regard to Article 4(3) and, where appropriate, bring forward a proposal.

Article 13

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. Articles 1 to 7 and Article 9(1) shall apply with effect from the 90th day following the date of publication in the *Official Journal of the European Union* of the measure referred to in Article 8(a).

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

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

COMMISSION REGULATION (EC) No 65/2004

of 14 January 2004

establishing a system for the development and assignment of unique identifiers for genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1830/2003, of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1], and in particular Article 8 thereof,

Whereas:

(1) Regulation (EC) No 1830/2003 lays down a harmonised framework for the traceability of genetically modified organisms, hereinafter 'GMOs', and of food and feed products produced from GMOs through the transmission and holding of relevant information by operators for such products at each stage of their placing on the market.

(2) Under that Regulation, an operator placing on the market products containing or consisting of GMOs is required to include, as part of that relevant information, the unique identifier assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorisation for placing that GMO on the market.

(3) Unique identifiers should be developed in accordance with a particular format in order to ensure consistency both at Community and international level.

(4) The consent or authorisation granted for the placing on the market of a given GMO under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2] or other Community legislation should specify the unique identifier for that GMO. Moreover, the person applying for such consent should ensure that the application specifies the appropriate unique identifier.

(5) Where, prior to the entry into force of this Regulation, consents have been granted for the placing on the market of GMOs under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [3], it is necessary to ensure that a unique identifier is or has been developed, assigned and appropriately recorded for each GMO covered by those consents.

(6) In order to take account of and maintain consistency with developments in international fora, it is appropriate to have regard to the formats for unique identifiers established by the Organisation for Economic Cooperation and Development (OECD), for use in the context of its BioTrack product database and in the context of the Biosafety clearing house established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

(7) For the purposes of the full application of Regulation (EC) No 1830/2003, it is essential that this Regulation apply as a matter of urgency.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SCOPE

Article 1

1. This Regulation shall apply to genetically modified organisms, hereinafter 'GMOs', authorised for the placing on the market in accordance with Directive 2001/18/EC or other Community legislation, and applications for placing on the market under such legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Council Regulation (EEC) No 2309/93 [4], or applications for authorisation under that Regulation.

CHAPTER II

APPLICATIONS FOR THE PLACING ON THE MARKET OF GMOs

Article 2

1. Applications for the placing on the market of GMOs shall include a unique identifier for each GMO concerned.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.
[3] OJ L 117, 8.5.1990, p. 15. Directive as last amended by Directive 2001/18/EC.
[4] OJ L 214, 24.8.1993, p. 1.

2. Applicants shall, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats.

Article 3

Where consent or authorisation is granted for the placing on the market of a GMO:

(a) the consent or authorisation shall specify the unique identifier for that GMO;

(b) the Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house;

(c) The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

CHAPTER III

GMOs FOR WHICH CONSENT FOR THEIR PLACING ON THE MARKET HAS BEEN GRANTED PRIOR TO THE ENTRY INTO FORCE OF THIS REGULATION

Article 4

1. Unique identifiers shall be assigned to all GMOs in respect of which, prior to the entry into force of this Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market.

2. Relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application shall consult the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with the formats set out in the Annex.

Article 5

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO and where a unique identifier has been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3 and 4 shall apply.

2. Each consent holder, or where appropriate the competent authority that has taken the final decision on the original application, shall within 90 days following the date of entry into force of this Regulation, communicate the following, in writing, to the Commission:

(a) the fact that the unique identifier has already been developed in accordance with the formats set out in the Annex;

(b) the details of the unique identifier.

3. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

4. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

Article 6

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3, 4 and 5 shall apply.

2. Each consent holder or, where appropriate, the competent authority that has taken the final decision on the original application, shall develop a unique identifier for the GMO concerned in accordance with the formats set out in the Annex.

3. The consent holder shall, within 90 days following the date of entry into force of this Regulation, communicate the details of the unique identifier, in writing, to the competent authority granting consent, which in turn shall immediately transmit these details to the Commission.

4. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

5. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

CHAPTER IV

FINAL PROVISION

Article 7

This Regulation shall enter into force on the date 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, 14 January 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

FORMATS FOR UNIQUE IDENTIFIERS

The Annex below defines the format for the unique identifier for plants in Section A and for micro-organisms and animals in Section B.

SECTION A

1. **Overall format**

This Annex provides details as to the format to be used for unique identifiers for GMOs pending or authorised for the placing on the market under Community legislation. The format consists of three components comprising a number of alphanumeric digits and providing reference to the applicant/consent holder, transformation event and a means for verification.

The format comprises nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of a unique identifier developed using this format.

C	E	D	-	A	B	8	9	1	-	6

or

C	E	-	A	B	C	8	9	1	-	5

The following sections provide guidance as to how the three individual components of the unique identifier should be developed.

2. **Applicant/consent holder component**

The first two or three alphanumeric digits represent the applicant/consent holder (for example, the first two or three letters of the applicant/consent holder organisation name), followed by a dash, such;

C	E	D	-

or

C	E	-

Applicants may already have assigned alphanumeric digits to indicate their identity and these appear in the applicant's code table within the OECD BioTrack product database. These applicants should continue to use these digits.

Any new applicant that is not identified within the database will not be permitted to use the existing codes listed in the applicant's code table within the database. The new applicant Should inform the national authorities, which should update the OECD BioTrack product database by including a new code (digits) that will be designed to identify the new applicant in the code table.

3. **Transformation event component**

The second set of five or six alphanumerical digits should represent the specific transformation event(s), which is the subject of the application for the placing on the market and/or consent, such as:

A	B	8	9	1	-

or

A	B	C	8	9	1	-

Clearly, an individual transformation event may occur in different organisms, species and varieties and the digits should be representative of the specific event in question. Again, applicants should, prior to formulating unique identifiers, consult the OECD BioTrack product database in terms of the unique identifiers that have been assigned to similar transformation events of the same organism/species in order to provide consistency and to avoid duplication.

Applicants should develop their own internal mechanism to avoid applying the same designation (digits) to a 'transformation event' if used in a different organism. Where similar transformation events are developed by two or more organisations, the 'applicant information' (see section 2) should enable applicants to generate a unique identifier for their own product, while at the same time ensuring its uniqueness from those generated by other applicants.

As regards new GMOs compromising more than one transformation event (often referred to as stacked-gene transformation events), applicants or consent holders should generate a novel unique identifier for such GMOs.

4. **Verification component**

The final digit of the unique identifier is for verification, which shall be separated from the rest of the unique identifier digits by a dash, such as:

- 6

or

- 5

The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric identifier, entered by the users of the database.

The rule to calculate the verification digit is as follows. The verification digit is made up of a single numerical digit. It is calculated by adding together the numerical values of each of the alphanumerical digits in the unique identifier. The numerical value of each of the digits is from ∅ to 9 for the numerical digits (∅ to 9) and 1 to 26 for the alphabetical digits (A to Z) (see sections 5 and 6). The total sum, if made up of several numerical digits, will be further calculated by adding the remaining digits together using the same rule, in an iterative process, until the final sum is a single numerical digit.For example, the verification digit for the code CED-AB891 is calculated as follows:

step one: 3 + 5 + 4 + 1 + 2 + 8 + 9 + 1 = 33;

step two: 3 + 3 = 6; therefore the verification digit is 6.

Therefore, the final unique identifier then becomes — CED-AB891-6.

5. **Form of digits to be used in the unique identifier**

∅
1
2
3
4
5
6
7
8
9

6. **Form of alphabetic characters to be used, plus numerical equivalents for calculating verification digit.**

A=1
B=2
C=3
D=4
E=5
F=6
G=7
H=8
I=9
J=10
K=11
L=12
M=13
N=14
O=15
P=16
Q=17
R=18
S=19
T=20
U=21
V=22
W=23
X=24
Y=25
Z=26

Zero should be reflected by the symbol ϕ to avoid confusion with the letter O.

SECTION B

The provisions of section A of this Annex shall apply to micro-organisms and animals unless another format for a unique identifier is adopted internationally and endorsed at Community level.

COMMISSION REGULATION (EC) No 641/2004

of 6 April 2004

on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 5(7), 8(8), 17(7), 20(8) and 47(4) thereof,

After consulting the European Food Safety Authority in accordance with Articles 5(7) and 17(7) of Regulation (EC) No 1829/2003,

Whereas:

(1) Regulation (EC) No 1829/2003 lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed.

(2) It is necessary to provide detailed rules concerning applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003.

(3) In addition, Regulation (EC) No 1829/2003 provides that the European Food Safety Authority (the Authority) is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation.

(4) In order to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules.

(5) It is also necessary to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004.

(6) Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications.

(7) The scope of Regulation (EC) No 1829/2003 includes food which consists of, contains or is produced from genetically modified organisms (GMOs) such as genetically modified plants and micro-organisms. Therefore, in the interests of consistency of Community legislation, the scope of the present Regulation should also cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms.

(8) The scope of Regulation (EC) No 1829/2003 covers feed, including feed additives as defined in Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs ([2]) consisting of, containing or produced from GMOs such as genetically modified plants and micro-organisms. Therefore, the scope of the present Regulation should also cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms.

(9) The scope of Regulation (EC) No 1829/2003 does not cover processing aids, including enzymes used as processing aids. Therefore, the scope of the present Regulation similarly should not cover existing processing aids.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

(10) Regulation (EC) No 1829/2003 provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied.

(11) It is necessary for this Regulation to apply as a matter of urgency as Regulation (EC) No 1829/2003 applies from 18 April 2004.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Applications for authorisation

Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation.

SECTION 1

Requirements for applications for authorisation of genetically modified food and feed

Article 2

1. Without prejudice to Article 5(3) and (5) and Article 17(3) and (5) of Regulation (EC) No 1829/2003, and taking into account the guidance of the European Food Safety Authority (the Authority) provided for in Articles 5(8) and 17(8) of that Regulation, applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (the applications) shall comply with the requirements of paragraphs 1 to 4 of this Article and with Articles 3 and 4 of this Regulation.

2. In supplying the information required under Article 5(3)(b) and Article 17(3)(b) of Regulation (EC) No 1829/2003, the application shall clearly identify the products covered by it in accordance with Articles 3(1) and 15(1) of that Regulation. Where the application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation should not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

3. The application shall clearly state which parts of the application are considered to be confidential, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts shall be submitted in separate documents.

4. The application shall specify, in supplying the information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003, whether the information included in the application may be notified as such to the biosafety clearing house under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) approved by Council Decision 2002/628/EC [1].

If the application may not be notified as such, it shall include the information which complies with Annex II to the Cartagena Protocol and which may be notified to the biosafety clearing house by the Commission as provided in Article 44 of Regulation (EC) No 1829/2003 in a separate and clearly identified document.

5. Paragraph 4 shall not apply to applications concerning only food and feed produced from genetically modified organisms (GMOs) or containing ingredients produced from GMOs.

Article 3

1. The application shall include the following:

(a) the monitoring plan referred to in Article 5(5)(b) and Article 17(5)(b) of Regulation (EC) No 1829/2003, taking into account Council Decision 2002/811/EC [2];

(b) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for labelling complying with the requirements of Annex IV to Directive 2001/18/EC of the European Parliament and of the Council [3];

[1] OJ L 201, 31.7.2002, p. 48.
[2] OJ L 280, 18.10.2002, p. 27.
[3] OJ L 106, 17.4.2001, p. 1.

(c) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for a unique identifier for the GMO in question, developed in accordance with Commission Regulation (EC) No 65/2004 [1];

(d) a proposal for labelling in all official Community languages, where a proposal for specific labelling is needed in accordance with Article 5(3)(f) and Article (g) and 17(3)(f) and (g) of Regulation (EC) No 1829/2003;

(e) a description of a method(s) of detection, sampling and event specific identification of the transformation event, as provided for in Article 5(3)(i) and Article 17(3)(i) of Regulation (EC) No 1829/2003, in accordance with Annex I to this Regulation;

(f) a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption, as provided for in Article 5(3)(k) and Article 17(3)(k) of Regulation (EC) No 1829/2003, and according to the characteristics of the products concerned, or a verifiable justification to the effect that a post-market monitoring is not necessary.

2. Points (a), (b) and (c) of paragraph 1 shall not apply to applications concerning only food and feed produced from GMOs or containing ingredients produced from GMOs.

Article 4

1. Samples of the food and feed and their control samples which are to be submitted in accordance with Article 5(3)(j) and Article 17(3)(j) of Regulation (EC) No 1829/2003 shall be in accordance with the requirements set out in Annexes I and II to this Regulation.

The application shall be accompanied by information concerning the place where the reference material developed in accordance with Annex II may be found.

2. The summary to be provided in accordance with Article 5(3)(l) and Article 17(3)(l) of Regulation (EC) No 1829/2003 shall:

(a) be presented in an easily comprehensible and legible form;

(b) not contain parts which are considered to be confidential.

[1] OJ L 10, 16.1.2004, p. 5.

SECTION 2

Transformation of requests and notifications into applications in accordance with Regulation (EC) No 1829/2003

Article 5

1. Where a request submitted under Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council [2] is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(1) of that Regulation, the national competent authority of the Member State in which the request was submitted shall, without delay, ask the applicant to submit a complete dossier in accordance with Article 5 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt. The acknowledgement shall state the date of receipt: of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the initial assessment report provided for in Article 6(3) of Regulation (EC) No 258/97, as well as any comments or objections which may have been made by Member States or the Commission under Article 6(4) of that Regulation.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the request under Article 4 of Regulation (EC) No 258/97 has been transformed into an application under Regulation (EC) No 1829/2003 and make the application and any supplementary information supplied by the applicant available to them;

(b) make the summary of the dossier referred to in Article 5(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 6(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 5 of Regulation (EC) No 1829/2003.

[2] OJ L 43, 14.2.1997, p. 1.

Article 6

1. Where a notification concerning a product including its use as feed submitted under Article 13 of Directive 2001/18/EC is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(3) of that Regulation, the national competent authority, within the meaning of Directive 2001/18/EC, of the Member State in which the notification was submitted shall ask without delay the notifier to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the notifier in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;

(b) inform the Authority without delay;

(c) make the notification and the information supplied by the notifier in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the assessment report provided for in Article 14(2) of Directive 2001/18/EC.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the notification under Article 13 of Directive 2001/18/EC has been transformed into an application under Regulation (EC) No 1829/2003 and shall make the application and any supplementary information supplied by the notifier available to them;

(b) make the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

Article 7

1. Where a request submitted under Article 7 of Council Directive 82/471/EEC [1], concerning products produced from GMOs, is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(4) of that Regulation, the Commission shall ask the applicant without delay to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

The applicant shall send the complete dossier to the Member States and to the Commission.

2. The Commission shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the dossier provided for in Article 7(1) of Directive 82/471/EEC.

3. The Authority shall make:

(a) any supplementary information supplied by the applicant available to the Member States and the Commission;

(b) the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

SECTION 3

Supplementation of requests under Directive 70/524/EEC by an application under Regulation (EC) No 1829/2003

Article 8

1. Where a request submitted under Article 4 of Directive 70/524/EEC, concerning products referred to in Article 15(1) of Regulation (EC) No 1829/2003, is supplemented by an application under Regulation (EC) No 1829/2003, in accordance with Article 46(5) of that Regulation, the Member State acting as rapporteur shall ask the applicant without delay to submit a separate application for authorisation in accordance with Article 17 of Regulation (EC) No 1829/2003.

[1] OJ L 213, 21.7.1982, p. 8.

2. The application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

CHAPTER II

Notification of existing products

Article 9

This chapter provides the requirements concerning the preparation and presentation of notifications of existing products submitted to the Commission in accordance with Articles 8 and 20 of Regulation (EC) No 1829/2003 and applies to existing products covered by the scope of that Regulation and placed on the market in the Community prior to 18 April 2004.

SECTION 1

General requirements for notifications of certain products placed on the market before 18 April 2004

Article 10

1. Notifications submitted in accordance with Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003 shall:

(a) clearly identify the products covered by the notification, taking account of Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003;

(b) include relevant information and studies, including, where available, independent and peer-reviewed studies, which demonstrate that the product complies with the requirements provided for in Articles 4(1) or 16(1) of Regulation (EC) No 1829/2003;

(c) clearly indicate which parts of the notification are considered to be confidential, together with a verifiable justification, and those parts shall be submitted in separate documents;

(d) include a method(s) of detection, sampling and identification of the transformation event in accordance with Annex I to this Regulation;

(e) in accordance with Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 provide:

(i) samples of the food and feed and their control samples in accordance with Annex I to this Regulation;

(ii) information as to the place where the reference material, which shall be developed in accordance with Annex II to this Regulation, may be found.

2. The notifications referred to in paragraph 1 shall be submitted to the Commission before 18 October 2004.

SECTION 2

Additional requirements for notifications of certain products placed on the market before 18 April 2004

Article 11

1. In addition to the requirements of Article 10, notifications of GMOs which have been placed on the market in accordance with part C of Council Directive 90/220/EEC [1] or part C of Directive 2001/18/EC shall include a copy of the relevant consent granted under those directives.

2. The date of publication in the *Official Journal of the European Union* of the Decision to grant consent under Directive 90/220/EEC or Directive 2001/18/EC shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date

Article 12

1. In addition to the requirements of Article 10, notifications of food produced from GMOs which have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 shall include a copy of the original notification letter to the Commission.

2. The date of the letter from the Commission forwarding the original notification to the Member States shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date.

Article 13

1. In addition to the requirements of Article 10, notifications of genetically modified food which have been placed on the market in accordance with Articles 6 and 7 of Regulation (EC) No 258/97 shall include a copy of the authorisation of that food.

[1] OJ L 117, 8.5.1990, p. 15.

2. The date the authorisation of the product took effect under Regulation No (EC) 258/97 shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 14

1. In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been placed on the market in accordance with Articles 3 and 4 of Directive 82/471/EEC shall include a copy of the authorisation at Community level or, where applicable, the authorisation granted by a Member State.

2. The date the authorisation of the product took effect in accordance with Directive 82/471/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 15

1. In addition to the requirements of Article 10, notifications of feed containing, consisting of or produced from GMOs which have been authorised in accordance with Directive 70/524/EEC shall include:

(a) the identification of the feed additive(s) to be covered by the number or the EC number, where applicable, as laid down in Article 9(l) of Directive 70/524/EEC;

(b) a copy of the authorisation.

2. The date the authorisation of the product took effect under Directive 70/524/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 16

In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been lawfully placed on the market in the Community, which are not covered by Articles 11, 14 and 15, and for which the GMO(s) has been notified for authorisation for use as animal feed under part C of Directive 2001/18/EC shall:

(a) contain a reference to the notification under evaluation submitted according to Article 13 of Directive 2001/18/EC;

(b) include a declaration that the product was placed on the market before 18 April 2004.

Article 17

In addition to the requirements of Article 10, notifications of food and feed produced from GMOs which have been lawfully placed on the market in the Community and which are not covered by Articles 11 to 16 shall include a declaration that the product was placed on the market before 18 April 2004.

CHAPTER III

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

Article 18

1. For the purpose of implementing Article 47 of Regulation (EC) No 1829/2003, the Commission shall, on 18 April 2004, publish a list of the genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before that date and for which an application for authorisation has not been rejected in accordance with the relevant Community legislation.

2. This list shall distinguish between:

(a) material in respect of which the Commission has been informed, by any interested party, that a detection method is publicly available; an indication of where the detection method has been made available shall be included;

(b) material in respect of which the Commission has not yet been informed that a detection method is publicly available.

Any interested party may, at any time, inform the Commission that a detection method for material referred to in point (b) of the first subparagraph is publicly available, with an indication of where the detection method is available.

3. The list referred to in paragraph 1 shall be maintained by the Commission. Amendments to the list may result, in particular, from:

(a) the granting of an authorisation or the rejection of an application for authorisation for material included in the list, in accordance with the relevant Community legislation;

(b) notifications to the Commission, in accordance with Articles 8 or 20 of Regulation (EC) No 1829/2003, that material included in the list has been lawfully placed on the market in the Community before 18 April 2004, or adoption by the Commission of a measure in accordance with Article 8(6) or 20(6) of Regulation (EC) No 1829/2003;

(c) information received by the Commission that a detection method in respect of material included in the list is publicly available.

Information about amendments brought to the list shall be compiled in an Annex to the list.

Article 19

1. The 0,5 % threshold provided for in Article 47(1) of Regulation (EC) No 1829/2003 shall apply to genetically modified material included in part (a) of the list referred to in Article 18(2) of the present Regulation. Where a lower threshold has been established in accordance with Article 47(3) of Regulation (EC) No 1829/2003, it shall be specified in that list.

2. The thresholds provided for in Article 47 of Regulation (EC) No 1829/2003 shall apply to food ingredients considered individually or food consisting of a single ingredient and to feed and each feed of which it is composed.

CHAPTER IV

Final provision

Article 20

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

It shall apply from 18 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

METHOD VALIDATION

1. INTRODUCTION

A. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, this Annex provides technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant. All guidance documents referred to in this Annex or produced by the Community Reference Laboratory (CRL) shall be made available by the CRL.

B. The method acceptance criteria and method performance requirements have been compiled by the European Network of GMO Laboratories (ENGL) in a document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing', which shall be made available by the CRL. 'Method acceptance criteria' are criteria, which should be fulfilled prior to the initiation of any method validation by the CRL. The 'method performance requirements' define the minimum performance criteria that the method should demonstrate upon completion of a validation study carried out by the CRL according to internationally accepted technical provisions and this in order to certify that the method validated is fit for the purpose of enforcement of Regulation (EC) No 1829/2003.

C. The CRL, established under Regulation (EC) No 1829/2003 and assisted by ENGL, will evaluate the provided information for its completeness and fitness for the purpose. Here, the method acceptance criteria recommended by ENGL, which are described under 1(B), will be taken into account.

D. If the information provided about the method is considered adequate and fulfils the method acceptance criteria, the CRL will initiate the validation process for the method.

E. The validation process will be carried out by the CRL according to internationally accepted technical provisions.

F. The CRL, together with ENGL, shall provide further information about the operational procedures of the validation process and shall make the documents available.

G. The CRL, assisted by ENGL, shall evaluate the results obtained in the validation study for the fitness for the purpose. Here, the method performance requirements as described under 1(B) shall be taken into account.

2. INFORMATION ABOUT THE METHOD

A. The method shall refer to all the methodological steps needed to analyse the relevant material in accordance with Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003.

For a particular material this must include the methods for DNA extraction and the subsequent quantification in a polymerase chain reaction (PCR) system. In such a case, the whole process from extraction up to the PCR-technique (or equivalent) constitutes a method. The applicant shall provide information about the whole method.

B. As described in the document referred to under 1(B), ENGL recognises the modularity of a method. According to this principle, the applicant is allowed to refer to existing methods for a certain module(s), if available and appropriate. This could be, for instance, a DNA extraction method from a certain matrix. In such a case, the applicant shall provide experimental data from an in-house validation in which the method module has been successfully applied in the context of the application for authorisation.

C. The applicant shall demonstrate that the method fulfils the following requirements.

1. The method shall be event-specific and thus must only be functional with the GMO or GM based product considered and shall not be functional if applied to other events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised events and conventional counterparts, in the case of GM plants. This testing shall include closely related events, where relevant, and cases where the limits of the detection are truly tested. The same specificity principle must be applied for products that consist of or contain GMOs other than plants.

2. The method shall be applicable to samples of the food or feed, to the control samples and to the reference material, which is referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003.

3. The method shall be developed taking the following documents in consideration as appropriate:
   — General requirements and definitions: draft European standard prEN ISO 24276:2002,
   — Nucleic acid extraction prEN ISO 21571:2002,
   — Quantitative nucleic acid based methods: draft European standard prEN ISO 21570:2002,
   — Protein based methods: adopted European standard EN ISO 21572:2002,
   — Qualitative nucleic acid based methods: draft European standard prEN ISO 21569:2002.

D. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, the applicant shall provide:

(a) in the case of an application for authorisation covering a GMO, products consisting of or containing a GMO or products produced from a GMO, the event-specific quantitative detection method of the GM material;

(b) in addition, in the case of an application for authorisation covering products produced from a GMO where the genetically modified material is detectable, the event-specific quantitative detection method in the foods or feeds produced from the GMO.

E. The applicant shall provide a complete and detailed description of the method. The following points shall be clearly addressed.

1. Scientific basis: An overview of the principles of how the method works, such as DNA molecular biology based (e.g. for real-time PCR) information must be provided. It is recommended to provide references to relevant scientific publications.

2. Scope of the method: Indication of the matrix (e.g. processed food, raw materials), the type of samples and the percentage range to which the method can be applied.

3. Operational characteristics of the method: The required equipment for the application of the method shall be clearly mentioned, with regard to the analysis *per se* and the sample preparation. Further information of any specific aspects crucial for the application of the method shall also be mentioned here.

4. Protocol: The applicant shall provide a complete optimised protocol of the method. The protocol shall present all the details as required to transfer and apply the method independently in other laboratories. It is recommended to use a protocol template, which can be obtained from the CRL. The protocol shall include details of:
   — analyte to be tested,
   — working conditions, instructions and rules,
   — all the materials needed, including an estimation of their amounts and storage and handling instructions,
   — all the equipment needed, including not only the main equipment such as a PCR system or centrifuge but also small items such as micropipettes and reaction tubes with an indication of their appropriate sizes, etc.,
   — all the steps of the operative protocol, clearly described,
   — instructions for the data recording (e.g. the programme settings or parameters to be included).

5. The prediction model (or alike) needed to interpret results and to make inferences must be described in full details. Instructions for the correct application of the model should be provided.

3. INFORMATION ABOUT THE METHOD TESTING CARRIED OUT BY THE APPLICANT

A. The applicant shall provide all the available and relevant data of the method optimisation and testing carried out. These data and results shall be presented, where possible and appropriate, by using the performance parameters recommended by the ENGL as referred to under 1(B). A summary of the testing carried out and the main results as well as all the data including the outliers shall be provided. The CRL, together with ENGL, shall continue to provide further technical provisions about the appropriate formats for these data.

B. The information provided shall demonstrate the robustness of the method for inter-laboratory transferability. This means that the method should have been tested by at least one laboratory that is independent from the laboratory which has developed the method. This is an important pre-condition for the success of the validation of the method.

C. Information required about the method development and the method optimisation:

1. primer pairs tested (in the case of a PCR-based test): justification shall be given of how and why the proposed primer pair has been selected;

2. stability testing: experimental results from testing the method with different varieties shall be provided;

3. specificity: the applicant shall submit the full sequence of the insert(s), together with the base pairs of the host flanking sequences needed to establish an event-specific detection method. The CRL shall enter these data in a molecular database. By running homology searches, the CRL will thus be in a position to assess the specificity of the proposed method.

D. Testing report. Besides the values obtained for the performance indices, the following information regarding the testing shall be provided, as appropriate:

— participating laboratories, time of the analysis and outline of the experimental design, including the details about the number of runs, samples, replicates etc.,

— description of the laboratory samples (e.g. size, quality, date of sampling), positive and negative controls as well as reference material, plasmids and alike used,

— description of the approaches that have been used to analyse the test results and outliers,

— any particular points observed during the testing,

— references to relevant literature or technical provisions used in the testing.

4. SAMPLES OF THE FOOD AND FEED AND THEIR CONTROL SAMPLES

In view of implementing Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, the applicant shall, together with the information specified under sections 1, 2 and 3 of this Annex, also provide samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation.

ANNEX II

REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 shall be produced in accordance with internationally accepted technical provisions such as ISO Guides 30 to 34 (and more particularly ISO Guide 34, specifying the general requirements for the competence of reference material producers). The reference material shall be preferably certified and, if such is the case, certification shall be done in accordance with ISO Guide 35.

For verification and value assignment, a method that has been properly validated (see ISO/IEC 17025:5.4.5) shall be used. Uncertainties have to be estimated according to GUM (ISO Guide to the Expression of Uncertainty in Measurement: GUM). Major characteristics of these internationally accepted technical provisions are given below.

A. Terminology:

reference material (RM): material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials;

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

B. GM RM containers:

— GM RM container (bottles, vials, ampoules, etc.) must be tight and contain not less than the stated amount of material,

— samples must have appropriate homogeneity and stability,

— the commutability of the GM RM has to be assured,

— packaging must be appropriate to the purpose,

— labelling must be of good aspect and quality.

C. Homogeneity testing:

between-bottle homogeneity must be examined;

any possible between-bottle heterogeneity must be accounted for in the overall estimated RM uncertainty. This requirement applies even when no statistically significant between-bottle variation is present. In this case, the method variation or the actual calculated between-bottle variation (whichever is larger) must be included in the overall uncertainty;

D. Stability testing:

stability must be positively demonstrated by appropriate statistical extrapolation for the GM RM shelf-life to be within the stated uncertainty; the uncertainty related to this demonstration is normally part of the estimated RM uncertainty;

assigned values are valid only for a limited time and must be subject to a stability monitoring.

E. Batch characterisation:

the methods used for verification and for certification must:

— be applied under metrologically valid conditions,

— have been properly technically validated before use,

— have precision and accuracy compatible with the target uncertainty;

each set of measurements must:

— be traceable to the stated references, and

— be accompanied by an uncertainty statement whenever possible;

participating laboratories must:

— have the required competence for the execution of the task,

— be able to achieve traceability to the required stated references,

— be able to estimate its measurement uncertainty,

— have in place a sufficient and appropriate quality assurance system.

F. Final storage:

— to avoid a posterior degradation, all samples are best stored under conditions designated for the final storage of the GM RM before measurements are started,

— otherwise, they must be transported from door to door keeping them at all times under such storage conditions for which it has been demonstrated that there is no influence on the assigned values.

G. Establishment of a certificate for CRMs:

— a certificate complemented by a certification report has to be established, containing all information relevant to and needed by the user. The certificate and report must be made available when the GM CRM is distributed,

— certified values must be traceable to stated references and be accompanied by an expanded uncertainty statement valid for the entire shelf-life of the GM CRM.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 24 January 2006

authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2006) 42)

(Only the Finnish and Swedish texts are authentic)

(Text with EEA relevance)

(2006/58/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 24 September 2001 Pharmaconsult Oy Ltd (formerly MultiBene Health Oy Ltd) made a request to the competent authorities of Finland for placing phytosterols on the market.

(2) On 17 January 2002 the competent authorities of Finland issued their initial assessment report.

(3) In their initial assessment report, Finland's competent food assessment body came to the conclusion that the phytosterols/stanols are safe for human consumption.

(4) The Commission forwarded the initial assessment report to all Member States on 5 March 2002.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day.

(7) Furthermore, the SCF, in its opinion on an application from MultiBene for approval of plant sterol enriched foods of 4 April 2003, reiterated its concerns about cumulative intakes from a wide range of foods with added phytosterols. However, at the same time the SCF confirmed that the addition of phytosterols to a wide range of bakery products was safe.

(8) In order to meet the concerns on cumulative intakes of phytosterols/phytostanols from different products Pharmaconsult Oy consequently agreed to reduce the original application on bakery products exclusively to rye bread.

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(9) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters [1], ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(10) The Standing Committee on the Food Chain and Animal Health has not given a favourable opinion; the Commission therefore submitted a proposal to the Council on 22 August 2005 in accordance with Article 5(4) of the Council Decision 1999/468/EC [2], the Council being required to act within three months.

(11) However, the Council has not acted within the required time-limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients as described in Annex I with added phytosterols/phytostanols as specified in Annex II, hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can be easily divided into portions that contain either maximum 3 g (in case of one portion per day) or maximum 1 g (in case of three portions per day) of added phytosterols/phytostanols.

Article 3

This Decision is addressed to Pharmaconsult Oy, Riippakoivunkuja 5, FIN-02130 Espoo.

Done at Brussels, 24 January 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

[1] OJ L 97, 1.4.2004, p. 44.
[2] OJ L 184, 17.7.1999, p. 23.

ANNEX I

PRODUCTS REFERRED TO IN ARTICLE 1

Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but no fat added.

ANNEX II

SPECIFICATIONS OF PHYTOSTEROLS AND PHYTOSTANOLS FOR THE ADDITION TO FOODS AND FOOD INGREDIENTS

Definition

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method)

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

COMMISSION DECISION

of 24 January 2006

authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2006) 115)

(Only the Finnish and Swedish texts are authentic)

(Text with EEA relevance)

(2006/59/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 21 September 2000 Karl Fazer Ltd made a request to the competent authorities of Finland to place foods with added phytosterols on the market as novel foods or novel food ingredients.

(2) On 29 January 2001 the competent authorities of Finland issued their initial assessment report.

(3) In their initial assessment report, Finland's competent food safety assessment body came to the conclusion that the phytosterols/phytostanols are safe for human consumption.

(4) The Commission forwarded this initial assessment report to all Member States on 13 March 2001.

(5) Within the 60-day period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the products were raised in accordance with that provision.

(6) The Scientific Committee on Food (SCF) in its opinion 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β-carotene' of 26 September 2002 indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day.

(7) Furthermore, the SCF, in its opinion on applications for approval of a variety of plant sterol enriched foods of 5 March 2003, reiterated its concerns about cumulative intakes from a wide range of foods with added phytosterols. However, at the same time the SCF confirmed with regard to the application of Oy Karl Fazer Ab that the addition of phytosterols to a wide range of bakery products was safe.

(8) In order to meet the concerns on cumulative intakes of phytosterols/phytostanols from different products Oy Karl Fazer Ab consequently agreed to reduce the original application to rye bread.

(9) Commission Regulation (EC) No 608/2004 of 31 March 2004 [2] concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols.

(10) The Standing Committee on the Food Chain and Animal Health has not given a favourable opinion; the Commission therefore submitted a proposal to the Council on 22 August 2005 in accordance with Article 5(4) of the Council Decision 1999/468/EC [3], the Council being required to act within three months.

(11) However, the Council has not reacted within the required time-limit; a Decision should now be adopted by the Commission,

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 97, 1.4.2004, p. 44.

[3] OJ L 184, 17.7.1999, p. 23.

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients as described in Annex I with added phytosterols/phytostanols as specified in Annex II hereinafter called the products, may be placed on the market in the Community.

Article 2

The products shall be presented in such a manner that they can easily be divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytostanols.

Article 3

This Decision is addressed to Oy Karl Fazer Ab, Fazerintie 6, FIN-00941 Helsinki.

Done at Brussels, 24 January 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

PRODUCTS REFERRED TO IN ARTICLE 1

Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but no fat added.

ANNEX II

SPECIFICATIONS OF PHYTOSTEROLS AND PHYTOSTANOLS FOR THE ADDITION TO FOODS AND FOOD INGREDIENTS

Definition

Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids.

Composition (with GC-FID or equivalent method)

< 80 % β-sitosterol

< 15 % β-sitostanol

< 40 % campesterol

< 5 % campestanol

< 30 % stigmasterol

< 3 % brassicasterol

< 3 % other sterols/stanols

Contamination/Purity (GC-FID or equivalent method)

Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 13 January 2006

authorising the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2005) 5939)

(Only the French and Dutch texts are authentic)

(2006/68/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 15 July 2002, Monsanto submitted to the competent authorities of Germany a request, in accordance with Article 4 of the Regulation, for placing on the market foods and food ingredients derived from genetically modified maize line MON 863 (hereinafter referred to as MON 863 maize) as novel foods or novel food ingredients, in accordance with Regulation (EC) No 258/97.

(2) In its initial assessment report of 8 April 2003, Germany's competent food assessment body came to the conclusion that an additional assessment was required because of the presence of an antibiotic resistance marker gene (*nptII*) used in the product concerned.

(3) The Commission forwarded the initial assessment report to all Member States on 3 June 2003 with additional comments raised by the Member States.

(4) On 9 December 2003 the Commission requested a scientific opinion from the European Food Safety Authority (EFSA) in accordance with Article 11 of the Regulation. On 2 April 2004 the EFSA delivered its opinion that from the point of view of consumer health, MON 863 maize and derived products are as safe as grain and derived products from conventional maize lines [2]. In delivering its opinion the EFSA addressed all specific questions and concerns raised by the Member States.

(5) Article 46(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [3] provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) or 6(4) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[2] EFSA Journal (2004) 50, 1-25; http://www.efsa.eu.int/science/gmo/gmo_opinions/383/opinion_gmo_07_en1.pdf

[3] OJ L 268, 18.10.2003, p. 1.

(6) The Joint Research Centre of the European Commission (JRC), in collaboration with the European Network of GMO Laboratories (ENGL), has validated a method for detection of MON 863 maize. The JRC has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the MON 863 transformation event in maize. The materials needed in the study had been provided by Monsanto. The JRC has considered that the method performance was appropriate for its purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been made publicly available.

(7) Reference material for MON 863 maize has been produced by the JRC.

(8) Food and food ingredients from MON 863 maize should be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and should be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1].

(9) In accordance with Commission Regulation (EC) No 65/2004 [2], a unique identifier has been assigned to the product for the purposes of Regulation (EC) No 1830/2003.

(10) Information, contained in the Annex, on the identification of foods and food ingredients derived from MON 863 maize, including the validated detection method and the reference material, should be retrievable from the Register referred to in Article 28 of Regulation (EC) No 1829/2003.

(11) On the basis of the information available, it is established that MON 863 maize complies with criteria laid down in Regulation (EC) No 258/97.

(12) The Standing Committee on the Food Chain and Animal Health has not given an opinion; the Commission has therefore submitted a proposal to the Council on 26 July 2005 in accordance with Article 5(4) of the Council Decision 1999/468/EC [3], the Council being required to act within three months.

(13) However, the Council has not acted within the required time limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients derived from genetically modified maize line MON 863 (hereinafter referred to as the products), as designated and specified in the Annex, may be placed on the Community market as novel foods or novel food ingredients.

Article 2

The products shall be labelled as 'genetically modified maize' or 'produced from genetically modified maize' in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) No 1829/2003.

Article 3

The products and the information included in the Annex shall be entered in the Community Register of genetically modified food and feed.

Article 4

This Decision is addressed to Monsanto Europe SA, Belgium, representing Monsanto Company, USA. It shall be valid for a period of 10 years.

Done at Brussels, 13 January 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 10, 16.1.2004, p. 5.
[3] OJ L 184, 17.7.1999, p. 23.

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED

1. **Applicant and authorisation holder:**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, B-1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, USA.

2. **Designation and specification of the products:**

Foods and food ingredients derived from genetically modified maize (*Zea maize* L.) line MON 863 with increased protection to insects and from all its crosses with traditionally bred maize lines. MON 863 maize contains two cassettes:

(a) cassette 1:

A modified *cry3Bb1* gene derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which confers resistance to the corn rootworm *Diabrotica spp.*, under the regulation of the 4AS1 promoter derived from *Cauliflower Mosaic Virus*, the wtCAB translation enhancer from wheat (*Triticum aestivum*), the transcription enhancer *ract1* intron from the actin 1 gene of rice (*Oryza sativa*) and terminator sequences tahsp 17 3' from wheat;

(b) cassette 2:

The *nptII* gene from *E. coli*, which confers resistance to aminoglycosides comprising kanamycin and neomycin, under the regulation of the 35S *Cauliflower Mosaic Virus* promoter, and the NOS 3' terminator sequences from *Agrobacterium tumefaciens* as well as the non-functional, truncated *ble* gene from *E. coli*.

3. **Labelling:**

'Genetically modified maize' or 'produced from genetically modified maize'.

4. **Method for detection:**

— Event-specific real-time quantitative PCR based method for genetically modified maize line MON 863.

— Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), published at http://gmo-crl.jrc.it/statusofdoss.htm

— Reference material: IRMM-416 produced by the Joint Research Centre (JRC) of the European Commission.

5. **Unique identifier:**

MON-ØØ863-5

6. **Information required under Annex II to the Cartagena Protocol:**

Not applicable.

7. **Conditions or restrictions for the placing on the market of the product:**

Not applicable.

8. **Post market monitoring requirements:**

Not applicable.

COMMISSION DECISION

of 13 January 2006

authorising the placing on the market of foods and food ingredients produced from genetically modified Roundup Ready maize line GA21 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2005) 5940)

(Only the French and Dutch texts are authentic)

(2006/69/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 24 July 1998, Monsanto submitted to the competent authorities of the Netherlands a request, in accordance with Article 4 of Regulation (EC) No 258/97, for placing on the market foods and food ingredients derived from genetically modified maize line GA21 as novel foods or novel food ingredients.

(2) In its initial assessment report of 21 December 1999, the Netherlands' competent food assessment body came to the conclusion that GA21 maize and foodstuffs and food ingredients made from it are as safe to eat as maize and maize products that have not been genetically modified.

(3) The Commission forwarded the initial assessment report to all Member States on 18 February 2000. Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97, reasoned objections to the marketing of the product were raised in accordance with that provision.

(4) On 18 May 2000, the Commission requested an opinion from the Scientific Committee on Foods (SCF) in accordance with Article 11 of Regulation (EC) No 258/97. On 27 February 2002 the SCF delivered its opinion that from the point of view of consumer health, GA21 maize and derived products are as safe as grain and derived products from conventional maize lines [2]. In delivering its opinion the SCF considered all specific questions and concerns raised by the Member States.

(5) On 24 April 2002, Monsanto asked to limit the request to food and food ingredients produced from genetically modified maize line GA21.

(6) With respect to the use of the product as or in feed, Monsanto submitted, on 12 December 1997, a notification under Part C of Council Directive 90/220/EEC [3]. The opinion adopted on 22 September 2000 by the Scientific Committee on Plants concluded that there is no evidence to indicate that the placing on the market of GA21 maize for this use is likely to cause any adverse effects on human health and the environment. However, the application was withdrawn for commercial reasons.

(7) Article 46(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [4] provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) or 6(4) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.

(8) The Joint Research Centre of the European Commission (JRC) in collaboration with the European Network of GMO Laboratories (ENGL), has validated a method for detection of GA21 maize. The JRC has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the GA21 transformation event in maize. The materials needed in the study had been provided by Monsanto. The JRC has considered that the method performance was appropriate for its aimed purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been published by the JRC.

(9) Reference material for GA21 maize has been produced by the JRC.

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[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10. 2003, p. 1).

[2] http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

[3] OJ L 117, 8.5.1990 p. 15. Directive repealed by Directive 2001/18/EC of the European Parliament and of the Council (OJ L 106, 17.4.2001, p. 1).

[4] OJ L 268, 18.10.2003, p. 1.

(10) Food and food ingredients from GA21 maize should be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and should be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1].

(11) In accordance with Commission Regulation (EC) No 65/2004 [2], a unique identifier has been assigned to the product for the purposes of Regulation (EC) No 1830/2003.

(12) Information, contained in the Annex, on the identification of foods and food ingredients produced from GA21 maize, including the validated detection method and the reference material, should be retrievable from the Register referred to in Article 28 of Regulation (EC) No 1829/2003.

(13) The Standing Committee on the Food Chain and Animal Health has not given an opinion; the Commission has therefore submitted a proposal to the Council on 29 July 2005 in accordance with Article 5(4) of the Council Decision 1999/468/EC [3], the Council being required to act within three months.

(14) However, the Council has not acted within the required time-limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients produced from genetically modified maize line GA21 (hereinafter referred to as the products), as designated and specified in the Annex, may be placed on the Community market as novel foods or novel food ingredients.

Article 2

The products shall be labelled as 'genetically modified maize' or 'produced from genetically modified maize' in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) No 1829/2003.

Article 3

The products and the information included in the Annex shall be entered in the Community Register of genetically modified food and feed.

Article 4

This Decision is addressed to Monsanto Europe SA, Belgium, representing Monsanto Company, USA. It shall be valid for a period of 10 years.

Done at Brussels, 13 January 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 10, 16.1.2004, p. 5.
[3] OJ L 184, 17.7.1999, p. 23.

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED

1. **Applicant and authorisation holder:**

Name: Monsanto Europe SA.

Address: Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St Louis, Missouri 63167, USA.

2. **Designation and specification of the products:**

Foods and food ingredients produced from genetically modified maize (*Zea mays* L.) line GA21 with increased tolerance to the herbicide glyphosate and from all its crosses with traditionally bred maize lines. GA21 maize contains the modified 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS) coding sequence under the regulation of the rice actin 1 promoter (r-act) and an optimised transit peptide (OPT) sequence based on chloroplast transit peptide sequences from *Helianthus annuus* and the RuBisCo gene from *Zea mays* L.

3. **Labelling:**

'Genetically modified maize' or 'produced from genetically modified maize'.

4. **Method for detection:**

— Event specific real-time quantitative PCR based method for genetically modified maize line GA21,

— Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), published at http://gmo-crl.jrc.it/statusofdoss.htm

— Reference Material: IRMM-414 produced by the Joint Research Centre (JRC) of the European Commission.

5. **Unique identifier:**

MON-ØØØ21-9.

6. **Information required under Annex II to the Cartagena Protocol:**

Not applicable.

7. **Conditions or restrictions for the placing on the market of the product:**

Not applicable.

8. **Post market monitoring requirements:**

Not applicable.