ANNEX

1. ENTERPRISE

1.1. **Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery**[(1)]

As regards Directive 97/68/EC, the Commission should be empowered in particular to establish the conditions under which amendments which are necessary in the light of adaptation to technical progress should be adopted. Since those measures are of general scope and are designed to amend non-essential elements of Directive 97/68/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 97/68/EC is hereby amended as follows:

1. in Article 4(2), the last sentence shall be replaced by the following:

   ‘The Commission shall amend Annex VIII. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).’;

2. Article 7a(4) shall be replaced by the following:

4. The Commission shall adapt Annex VII to integrate the additional and specific information which may be required as regards the type-approval certificate for engines to be installed in inland waterway vessels. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).;

3. Article 14 shall be replaced by the following:

Article 14

The Commission shall adopt any amendments which are necessary in order to adapt the Annexes, with the exception of the requirements specified in section 1, sections 2.1 to 2.8 and section 4 of Annex I, to technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).;

4. Article 14a shall be replaced by the following:

Article 14a

The Commission shall study possible technical difficulties in complying with the stage II requirements for certain uses of the engines, in particular mobile machinery in which engines of classes SH:2 and SH:3 are installed. If the Commission studies conclude that for technical reasons certain mobile machinery, in particular, multi-positional, hand-held engines intended for professional use, cannot meet those requirements by the deadlines laid down, it shall submit, by 31 December 2003, a report accompanied by appropriate proposals for extensions of the period referred to in Article 9a(7) and/or further derogations, not exceeding five years in duration, save in exceptional circumstances, for such machinery. Those measures, designed to amend non-essential

elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).;

5. Article 15 shall be amended as follows:

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

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) paragraph 3 shall be deleted;

6. in Annex I, point 4.1.2.7, the last sentence shall be replaced by the following:

'The Commission shall define the control area to which the percentage not to be exceeded is to apply and the excluded engine operating conditions. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

7. in Annex III, the last paragraph of point 1.3.2 shall be replaced by the following:

Prior to the introduction of the cold/hot composite test sequence, the Commission shall modify the symbols (Annex I, section 2.18), the test sequence (Annex III) and the calculation equations (Annex III, Appendix 3). Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2)..

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

As regards Directive 98/79/EC, the Commission should be empowered in particular to adopt particular health monitoring measures and to amend Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Directive 98/79/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of prohibitions, restrictions or particular requirements for certain products.

Accordingly, Directive 98/79/EC is hereby amended as follows:

1. Article 7 shall be 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 paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(3)] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 10(5) shall be replaced by the following:

5. Member States shall take all necessary measures to ensure that the notifications referred to in paragraphs 1 and 3 are registered immediately in the databank described in Article 12.

The procedures for implementing this Article and in particular those referring to the notification and the concept of significant change shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

3. Article 11(5) shall be replaced by the following:

5. Member States shall on request inform the other Member States of the details referred to in paragraphs 1 to 4. The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

4. Article 12(3) shall be replaced by the following:

3. The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

5. Article 13 shall be replaced by the following:

Article 13

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or made subject to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States, giving the reasons for its decision. The Commission shall consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).;

6. Article 14(1) shall be replaced by the following:

1. Where a Member State considers that:

a the list of devices in Annex II should be amended or extended; or

b the conformity of a device or category of devices should be established, by way of derogation from the provisions of Article 9, by applying one or more given procedures taken from amongst those referred to in Article 9,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures.

Where those measures concern matters referred to in point (a), designed to amend non-essential elements of this Directive, they shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

Where those measures concern matters referred to in point (b), they shall be adopted in accordance with the regulatory procedure referred to in Article 7(2)..

1.3. **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**[(4)]

As regards Directive 1999/5/EC, the Commission should be empowered in particular to adopt a decision specifying, for apparatus within certain equipment classes or apparatus of particular types, which of the additional requirements apply, to determine the date of application, including, where appropriate, a transitional period, of certain additional essential requirements to specific equipment classes or apparatus of particular types, and to decide on the form of the equipment class identifier to be affixed on specific types of radio equipment. Since those measures are of general scope and are designed to amend non-essential elements of Directive 1999/5/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 1999/5/EC is hereby amended as follows:

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

3. The Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:

a it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

b it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

c it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

d it supports certain features ensuring avoidance of fraud; and/or that

e it supports certain features ensuring access to emergency services; and/or that

f it supports certain features in order to facilitate its use by users with a disability.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a.;

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

3. In the case of shortcomings of harmonised standards with respect to the essential requirements, the Commission may, after consulting the committee and in accordance with the procedure laid down in Article 14, publish in the *Official Journal of the European Union* recommendations on the interpretation of harmonised standards or on the conditions under which compliance with those standards raises a presumption of conformity. After consultation of the committee and in accordance with the procedure laid down in Article 14, the Commission may withdraw harmonised standards by publication of a notice in the *Official Journal of the European Union*.;

3. Article 6(2) shall be replaced by the following:

2. In taking a decision regarding the application of essential requirements under Article 3(3), the Commission shall determine the date of application of the requirements.

If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date of application of the Commission's determination can continue to be placed on the market for a reasonable period to be determined by the Commission.

The measures referred to in the first and second subparagraphs, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a.;

4. the following Article shall be inserted:

Article 15a

Regulatory procedure with scrutiny

Where reference is made to this Article, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

5. point 5 of Annex VII shall be replaced by the following:

5. The equipment class identifier must take a form to be decided by the Commission.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a..

1.4. **Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[(5)]**

As regards Regulation (EC) No 141/2000, the Commission should be empowered in particular to adopt definitions of 'similar medicinal product' and 'clinical superiority'. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 141/2000, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 141/2000 is hereby amended as follows:

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

2. The Commission shall, in accordance with the regulatory procedure referred to in Article 10a(2), adopt the necessary provisions for implementing paragraph 1 of this Article in the form of an implementing Regulation.;

2. Article 5(8) shall be replaced by the following:

8. The Agency shall forthwith forward the final opinion of the Committee to the Commission, which shall adopt a decision within 30 days of receipt of the opinion. Where, in exceptional circumstances, the draft decision is not in accordance with

the opinion of the Committee, the decision shall be adopted in accordance with the regulatory procedure referred to in Article 10a(2). The decision shall be notified to the sponsor and communicated to the Agency and to the competent authorities of the Member States.;

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

4. The Commission shall adopt definitions of "similar medicinal product" and "clinical superiority" in the form of an implementing Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10a(3).;

4. the following Article shall be inserted:

Article 10a

1 The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, referred to in Article 121(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use[(6)].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(7)] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

1.5. **Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[(8)]**

As regards Directive 2001/20/EC, the Commission should be empowered in particular to adopt principles relating to good clinical practice and detailed rules in line with those principles, to lay down specific requirements and to adapt certain provisions. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/20/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/20/EC is hereby amended as follows:

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

3. The Commission shall adopt the principles relating to good clinical practice and detailed rules in line with those principles and shall, if necessary, revise those principles and detailed rules to take account of technical and scientific progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).

The principles and detailed rules shall be published by the Commission.;

2. Article 13(1) shall be replaced by the following:

1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation.

The Commission shall lay down the minimum requirements which the applicant and, subsequently, the holder of the authorisation must meet in order to obtain the authorisation.

Those measures, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).;

3. Article 20 shall be replaced by the following:

Article 20

The Commission shall adapt this Directive to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).;

4. Article 21 shall be replaced by the following:

Article 21

1 The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, referred to in Article 121(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use[9].

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 referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

1.6. **Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[10]**

As regards Directive 2001/82/EC, the Commission should be empowered in particular to adapt certain provisions and annexes, and to lay down specific conditions of application. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/82/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/82/EC is hereby amended as follows:

1. [X1. . . . .

2. . . . .]

3. in Article 13(1), the fourth subparagraph shall be replaced by the following:

However, the 10-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated by the Commission.

That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

4. in Article 17(1), the second subparagraph shall be replaced by the following:

If it appears justified in the light of new scientific evidence, the Commission may adapt points (b) and (c) of the first subparagraph. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

5. in Article 39(1), the third subparagraph shall be replaced by the following:

The Commission shall adopt those arrangements in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

6. Article 50a(2) shall be replaced by the following:

2. The Commission shall adopt any amendments which may be necessary in order to adapt the provisions of paragraph 1 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

7. in Article 51, the first paragraph shall be replaced by the following:

The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 50(f) shall be adopted by the Commission in the form of a Directive addressed to the Member States. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

8. in Article 67, point (aa) shall be replaced by the following:

(aa) veterinary medicinal products for food-producing animals.

However, Member States may grant exemptions from this requirement according to criteria established by the Commission. The establishment of those criteria, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).

Member States may continue to apply national provisions until either:

(i) the date of application of the decision adopted in accordance with the first subparagraph; or

(ii) 1 January 2007, if no such decision has been adopted by 31 December 2006;;

9. Article 68(3) shall be replaced by the following:

3. The Commission shall adopt any amendments to the list of substances referred to in paragraph 1.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

10. Article 75(6) shall be replaced by the following:

6. The Commission may amend paragraph 5 in the light of the experience gained from its operation.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

11. Article 79 shall be replaced by the following:

Article 79

The Commission shall adopt any amendments which may be necessary to update Articles 72 to 78 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

12. Article 88 shall be replaced by the following:

Article 88

The Commission shall adopt any changes which are necessary in order to adapt Annex I to take account of technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

13. Article 89 shall be amended as follows:

(a) the following paragraph shall be inserted:

2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) paragraph 4 shall be replaced by the following:

4. The rules of procedure of the Standing Committee shall be made public..

Editorial Information

X1 Deleted by Corrigendum to Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of

the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (Official Journal of the European Union L 188 of 18 July 2009).

1.7. **Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery[11]**

As regards Directive 2006/42/EC, the Commission should be empowered in particular to establish the conditions for updating the indicative list of safety components and for the measures regarding the restriction of the placing on the market of potentially hazardous machinery. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/42/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/42/EC is hereby amended as follows:

1. Article 8 shall be replaced by the following:

Article 8

Specific measures

1 The Commission may take any appropriate measure relating to the following:

a updating the indicative list of safety components in Annex V referred to in Article 2(c);

b restricting the placing on the market of machinery referred to in Article 9.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

2 The Commission, acting in accordance with the advisory procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).;

2. Article 9(3) shall be replaced by the following:

3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties, indicating the measures it intends to take in order to ensure, at Community level, a high level of protection of the health and safety of persons.

Taking due account of the results of this consultation, it shall adopt the necessary measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

3. Article 22 shall be amended as follows:

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

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) paragraph 4 shall be deleted.

2. ENVIRONMENT

2.1. **Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)[(12)]**

As regards Directive 96/59/EC, the Commission should be empowered in particular to fix the reference methods of measurement to determine the PCB content of contaminated materials and the technical standards for the other methods of disposing of PCBs, and, if necessary, to determine, solely for the purpose of Article 9(1)(b) and (c), other less hazardous substitutes for PCBs. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/59/EC by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/59/EC is hereby amended as follows:

1. Article 10 shall be replaced by the following:

Article 10

1 The Commission shall make available, in accordance with the regulatory procedure referred to in Article 10a(2), a list of the production names of capacitors, resistors and inductance coils containing PCBs.

2 The Commission shall:

a fix the reference methods of measurement to determine the PCB content of contaminated materials. Measurements effected before the determination of the reference methods shall remain valid;

b if necessary determine, solely for the purpose of Article 9(1)(b) and (c), other less hazardous substitutes for PCBs.

The Commission may fix technical standards for the other methods of disposing of PCBs referred to in the second sentence of Article 8(2).

The measures referred to in the first and second subparagraphs, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10a(3).;

2. the following Article shall be inserted:

Article 10a

1 The Commission shall be assisted by the Committee set up by Article 18 of Directive 2006/12/EC of the European Parliament and of the Council[(13)].

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.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

2.2. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[14]

As regards Directive 98/83/EC, the Commission should be empowered in particular to adapt Annexes II and III to scientific and technical progress and to set out certain details on monitoring in Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Directive 98/83/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 98/83/EC is hereby amended as follows:

1. Article 7(4) shall be replaced by the following:

4. Community guidelines for the monitoring prescribed in this Article may be drawn up in accordance with the management procedure referred to in Article 12(2).;

2. Article 11(2) shall be replaced by the following:

2. At least every five years, the Commission shall amend Annexes II and III to make the necessary adaptations to scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

3. Article 12(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

4. Article 13 shall be amended as follows:

(a) paragraph 4 shall be replaced by the following:

4. The formats and the minimum information for the reports provided for in paragraph 2 shall be determined having special regard to the measures referred to in Article 3(2), Article 5(2) and (3), Article 7(2), Article 8, Article 9(6) and (7) and Article 15(1), and shall if necessary be amended in accordance with the management procedure referred to in Article 12(2).;

(b) paragraph 6 shall be replaced by the following:

6. Together with the first report on this Directive as mentioned in paragraph 2, Member States shall also produce a report to be forwarded to the Commission on the measures they have taken or plan to take to fulfil their obligations pursuant to Article 6(3) and Annex I, Part B, note 10. As appropriate, a proposal on the format of this report shall be submitted in accordance with the management procedure referred to in Article 12(2).;

5. Article 15(3) shall be replaced by the following:

3. That request shall be examined in accordance with the management procedure referred to in Article 12(2).;

6. in Annex I, Part C, point 1 of note 10 shall be replaced by the following:

1. The Commission shall adopt the measures required under Note 8 on monitoring frequencies, and Note 9 on monitoring frequencies, monitoring methods and the most relevant locations for monitoring points in Annex II. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

When elaborating those measures the Commission shall take into account, inter alia, the relevant provisions under existing legislation or appropriate monitoring programmes including monitoring results as derived from them.;

7. in Annex II, table A, point 2 shall be replaced by the following:

2. *Audit monitoring*

The purpose of audit monitoring is to provide the information necessary to determine whether or not all of the Directive's parametric values are being complied with. All parameters set in accordance with Article 5(2) and (3) must be subject to audit monitoring unless it can be established by the competent authorities, for a period of time to be determined by them, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This point does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Annex I, Part C, will be monitored in accordance with monitoring requirements adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

8. in Annex III, point 1, the first subparagraph shall be replaced by the following:

The following principles for methods of microbiological parameters are given either for reference, whenever a CEN/ISO method is given, or for guidance, pending the possible future adoption by the Commission of further CEN/ISO international methods for those parameters. Member States may use alternative methods, providing the provisions of Article 7(5) are met.

Those measures on further CEN/ISO international methods, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3)..

2.3. Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer[(15)]

As regards Regulation (EC) No 2037/2000, the Commission should be empowered in particular to amend Annex VI; to establish and reduce the calculated level of methyl bromide that can be placed on the market or used by importers or producers for their own account for quarantine and preshipment purposes; to determine a mechanism for the allocation of quotas of the calculated levels of methyl bromide to each producer and importer; to adopt, if necessary, modifications and, where appropriate, time frames for phase-out of the critical uses of halons listed in Annex VII; to take a decision on whether to adapt the end-date of prohibition of the use of hydrochlorofluorocarbons; to modify the list and dates with regard to control of the use of hydrochlorofluorocarbons; to modify the list of items related to the request for an import licence and Annex IV; to amend the list of products containing controlled substances and of Combined Nomenclature codes in Annex V; and to advance the date of export prohibition of recovered, recycled and reclaimed halon for critical uses, and to modify the reporting requirements. Since

those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2037/2000, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2037/2000 is hereby amended as follows:

1. in Article 2, the 16th indent shall be replaced by the following:

— "processing agent" means controlled substances used as chemical processing agents in those applications listed in Annex VI, in installations existing on 1 September 1997, and where emissions are insignificant. The Commission shall, in the light of those criteria, and in accordance with the management procedure referred to in Article 18(2), establish a list of undertakings in which the use of controlled substances as processing agents shall be permitted, laying down maximum emission levels for each of the undertakings concerned.

In the light of new information or technical developments, including the review provided for in Decision X/14 of the Meeting of the Parties to the Protocol, the Commission may:

(a) amend the list of undertakings referred to above in accordance with the management procedure referred to in Article 18(2);

(b) amend Annex VI. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

2. Article 4 shall be amended as follows:

(a) the third subparagraph of point (iii) of paragraph 2 shall be replaced by the following:

The Commission shall take measures to reduce the calculated level of methyl bromide which producers and importers may place on the market or use for their own account for quarantine and preshipment in the light of technical and economic availability of alternative substances or technologies, and of the relevant international developments under the Protocol. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) paragraph 3(ii) shall be replaced by the following:

(ii) The Commission may amend the mechanism for the allocation of quotas to each producer and importer of the calculated levels set out in points (d) to (f), applicable for the period 1 January 2003 to 31 December 2003 and for each 12-month period thereafter.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(c) paragraph 4(iv) shall be replaced by the following:

(iv) Paragraph 1(c) shall not apply to the placing on the market and use of halons that have been recovered, recycled or reclaimed in existing fire protection systems until 31 December 2002 or to the placing on the market and use of halons for critical uses as set out in Annex VII. Each year the competent authorities of the Member States shall notify to the Commission the quantities of halons used for critical uses, the measures taken to reduce their emissions and an estimate of such emissions, and the current activities to identify and use adequate alternatives.

Each year the Commission shall review the critical uses listed in Annex VII and, if necessary, adopt modifications and, where appropriate, time frames for phase-out, taking into account the availability of both technically and economically feasible alternatives or technologies that are acceptable from the standpoint of the environment and health.

Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

3. Article 5 shall be amended as follows:

(a) the fifth subparagraph of point (c)(v) of paragraph 1 shall be replaced by the following:

The Commission shall submit the result of the review to the European Parliament and to the Council. It shall, as appropriate, take a decision on whether to adapt the date of 1 January 2015. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) paragraph 6 shall be replaced by the following:

6. The Commission may, in the light of experience with the operation of this Regulation or to reflect technical progress, amend the list and the dates set out in paragraph 1 but may in no case extend the periods set out therein, without prejudice to the exemptions provided for in paragraph 7.

Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

4. Article 6(5) shall be replaced by the following:

5. The Commission may amend the list of items mentioned in paragraph 3 and Annex IV.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

5. Article 9(2) shall be replaced by the following:

2. A list of products containing controlled substances and of Combined Nomenclature codes is given in Annex V for guidance of the Member States' customs authorities. The Commission may add to, delete items from or amend that list in the light of the lists established by the Parties.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

6. Article 11(1)(d) shall be replaced by the following:

(d) recovered, recycled and reclaimed halon stored for critical uses in facilities authorised or operated by the competent authority to satisfy critical uses listed in Annex VII until 31 December 2009, and products and equipment containing halon to satisfy critical uses listed in Annex VII. Following a review undertaken by 1 January 2005 by the Commission of exports of such recovered, recycled and reclaimed halon for critical uses the Commission may prohibit such exports earlier than 31 December 2009. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

7. Article 18(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

8. Article 19(6) shall be replaced by the following:

6. The Commission may amend the reporting requirements laid down in paragraphs 1 to 4 to meet commitments under the Protocol or to improve the practical application of those reporting requirements.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3)..

2.4. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register[(16)]

As regards Regulation (EC) No 166/2006, the Commission should be empowered in particular to adopt measures referred to in Article 8(3); to adapt Annexes II or III to scientific or technical progress; and to adapt Annexes II and III as a result of the adoption by the Meeting of the Parties to the UNECE Protocol on Pollutant Release and Transfer Registers of any amendment to the Annexes to that Protocol. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 166/2006, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 166/2006 is hereby amended as follows:

1. Article 8(3) shall be replaced by the following:

3. Where the Commission determines that no data on the releases from diffuse sources exist, measures to initiate reporting on releases of relevant pollutants from one or more diffuse sources shall be taken using, where appropriate, internationally approved methodologies.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).;

2. Article 18 shall be replaced by the following:

Article 18

Amendments to the Annexes

The Commission shall make any necessary amendments to the annexes for the following purposes:

(a) the adaptation of Annexes II or III to scientific or technical progress;

(b) the adaptation of Annexes II and III as a result of the adoption by the Meeting of the Parties to the Protocol of any amendment to the Annexes to the Protocol.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).;

3. the following paragraph shall be added to Article 19:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

2.5. **Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality[17]**

As regards Directive 2006/7/EC, the Commission should be empowered in particular to adapt, in the light of scientific and technical progress, the methods of analysis for the parameters and sampling rules set out in Annex I and Annex V respectively, and to specify the EN/ISO standard on the equivalence of microbiological methods. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/7/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/7/EC is hereby amended as follows:

1. Article 15 shall be replaced by the following:

Article 15

Technical adaptations and implementing measures

1 The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), lay down the following:

a detailed rules for the implementation of Article 8(1), Article 12(1)(a) and Article 12(4);

b guidelines for a common method for the assessment of single samples.

2 The Commission shall adopt the following measures:

a the specification of EN/ISO standard on the equivalence of microbiological methods for the purposes of Article 3(9);

b any amendments necessary in order to adapt the methods of analysis for the parameters set out in Annex I in the light of scientific and technical progress;

c any amendments necessary in order to adapt Annex V in the light of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(3).

3 The Commission shall present a draft of the measures to be taken in accordance with paragraph 1(a) with respect to Article 12(1)(a) by 24 March 2010. Before doing so, it shall consult representatives of Member States, regional and local authorities, relevant tourist and consumer organisations and other interested parties. After the adoption of relevant rules, it shall publicise them via the Internet.;

2. Article 16(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

2.6. Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries[(18)]

As regards Directive 2006/21/EC, the Commission should be empowered in particular to adopt provisions necessary for the implementation of Article 13(6); to complete the technical requirements for waste characterisation contained in Annex II; to interpret the definition in point 3 of Article 3; to define the criteria for the classification of waste facilities in accordance with Annex III; to determine harmonised standards for sampling and analysis methods; and to adapt the Annexes to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/21/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/21/EC is hereby amended as follows:

1. Article 22 shall be replaced by the following:

Article 22

1 The Commission shall, in accordance with the regulatory procedure referred to in Article 23(2), adopt the following:

a provisions necessary for the harmonisation and regular transmission of the information referred to in Article 7(5) and Article 12(6);

b technical guidelines for the establishment of the financial guarantee in accordance with the requirements of Article 14(2);

c technical guidelines for inspections in accordance with Article 17.

2 The Commission shall lay down provisions necessary for the following, prioritising points (b), (c) and (d):

a the implementation of Article 13(6), including technical requirements relating to the definition of weak acid dissociable cyanide and its measurement method;

b the completion of the technical requirements for waste characterisation contained in Annex II;

c the interpretation of the definition contained in point 3 of Article 3;

d the definition of the criteria for the classification of waste facilities in accordance with Annex III;

e the determination of any harmonised standards for sampling and analysis methods needed for the technical implementation of this Directive.

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

3 The Commission shall make the necessary amendments to the Annexes for the purpose of adapting them to scientific and technical progress. Those amendments shall be made with a view to achieving a high level of environmental protection.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).;

2. Article 23(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

3. EUROSTAT

3.1. **Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices**[19]

As regards Regulation (EC) No 2494/95, the Commission should be empowered in particular to adopt rules to be followed to ensure the comparability of HICPs and to maintain and improve their reliability and relevance. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2494/95, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2494/95 is hereby amended as follows:

1. in Article 3, the words ‘in Article 14’ shall be replaced by the words ‘in Article 14(2)’;

2. the third paragraph of Article 4 shall be replaced by the following:

> The Commission (Eurostat) shall adopt rules to be followed to ensure the comparability of HICPs. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

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

3. The Commission shall adopt implementing measures for this Regulation which are necessary in order to ensure the comparability of HICPs and to maintain and improve their reliability and relevance. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). The Commission shall request the ECB to provide an opinion on the measures which it proposes to submit to the Committee.;

4. in Article 8(3), the words 'in Article 14' shall be replaced by the words 'in Article 14(2)';

5. Article 9 shall be replaced by the following:

Article 9

Production of results

Member States shall process the data collected in order to produce the HICP, which shall be a Laspeyres-type index, covering the categories of the Coicop international classification (classification of individual consumption by purpose)[(20)], which shall be adapted by the Commission for the purposes of establishing comparable HICPs. The Commission shall determine the methods, procedures and formulae to ensure that the comparability requirements are met. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

6. in Article 11, the words 'in Article 14' shall be replaced by the words 'in Article 14(2)';

7. Article 14 shall be replaced by the following:

Article 14

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[(21)], hereinafter referred to as "the Committee".

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(22)] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

8. the second paragraph of Article 15 shall be replaced by the following:

In those reports, the Commission shall state its views on the operation of the procedures described in Article 14 and shall propose any amendments it considers appropriate..

3.2. Council Regulation (EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community[(23)]

As regards Regulation (EC) No 577/98, the Commission should be empowered in particular to adopt additional variables, to adapt the definitions, the edits to be used and the codification of the variables, and to draw up the list of structural variables, the minimum sample size and the survey frequency. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 577/98, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 577/98 is hereby amended as follows:

1. in the third indent of the fifth paragraph of Article 1, the words ‘in Article 8’ shall be replaced by the words ‘in Article 8(2)’;

2. paragraphs 2, 3 and 4 of Article 4 shall be replaced by the following:

2. A further set of variables, hereinafter referred to as an “ad hoc module”, may be added to supplement the information described in paragraph 1.

Each year a programme of ad hoc modules covering several years shall be adopted by the Commission.

That programme shall specify, for each ad hoc module, the subject, the reference period, the sample size (equal to or less than the sample size determined according to Article 3) and the deadline for the transmission of the results (which may be different from the deadline according to Article 6).

The Member States and regions covered and the detailed list of information to be collected in an ad hoc module shall be drawn up at least 12 months before the beginning of the reference period for that module.

The volume of an ad hoc module shall not exceed 11 variables.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3).

3 The definitions, the edits to be used, the codification of the variables, the adjustment of the list of survey variables made necessary by the evolution of techniques and concepts, and a list of principles for the formulation of the questions concerning the labour status shall be drawn up by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3).

4 On a proposal from the Commission, a list of variables, hereinafter referred to as “structural variables”, may be identified from among the survey characteristics specified in paragraph 1 which need to be surveyed only as annual averages with reference to 52 weeks rather than as quarterly averages. That list of structural variables, the minimum sample size and the survey frequency shall be drawn up by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). Spain, Finland and the United

Kingdom may survey the structural variables with reference to a single quarter during a transition period until the end of 2007.;

3. Article 8 shall be replaced by the following:

Article 8

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[24].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[25] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

3.3. **Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics[26]**

As regards Regulation (EC) No 1165/98, the Commission should be empowered in particular to approve and implement the European sample schemes, to adapt the Annexes and to determine the measures for implementing this Regulation, including the measures to accommodate economic and technical developments concerning the collection and statistical processing of data and the transmission of the variables. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1165/98, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1165/98 is hereby amended as follows:

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

(d) participation in European sample schemes coordinated by Eurostat in order to produce European estimates.

The details of the schemes referred to in the first subparagraph shall be as specified in the Annexes. Measures for their approval and implementation shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

European sample schemes shall be established when national sample schemes do not meet the European requirements. Furthermore, Member States may opt to take part in European sample schemes when such schemes create possibilities for substantial reductions in the cost of the statistical system or the burden on business which meeting the European requirements entails. Participation in a European sample scheme shall satisfy the conditions of a Member State for the supply of the variable concerned in

accordance with the objective of such a scheme. European sample schemes may target the conditions, the level of detail and the deadlines for data transmission.;

2. in Article 16(1), the words ‘in Article 18’ shall be replaced by the words ‘in Article 18(2)’;

3. Articles 17 and 18 shall be replaced by the following:

Article 17

Implementing measures

The Commission shall determine the measures for implementing this Regulation, including the measures to accommodate economic and technical developments concerning the collection and statistical processing of data and the transmission of the variables. In doing so, consideration shall be given to the principle that the benefits of the measure must outweigh its cost, and to the principle that major additional resources are not involved either for Member States or for enterprises as compared with the original provisions of this Regulation. In particular, the measures for implementing this Regulation shall include:

(a) the use of particular units (Article 2);

(b) the updating of the list of variables (Article 3);

(c) the definitions and the appropriate forms of the transmitted variables (Article 3);

(d) the establishment of European sample schemes (Article 4);

(e) the frequency of compilation of the statistics (Article 5);

(f) the levels of breakdown and aggregation to be applied to the variables (Article 6);

(g) the transmission deadlines (Article 8);

(h) the criteria for the measurement of quality (Article 10);

(i) the transition periods (Article 13(1));

(j) derogations granted during the transition periods (Article 13(2));

(k) the institution of pilot studies (Article 16);

(l) the first base year to be applied for time series in NACE Rev. 2;

(m) for time series prior to 2009, to be transmitted according to NACE Rev. 2, the level of detail, the form, the first reference period, and the reference period.

The measures referred to in points (j) and (k) shall be adopted in accordance with the regulatory procedure referred to in Article 18(2).

The measures referred to in points (a) to (i) and (l) and (m), designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

Article 18

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[27].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[28] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

4. Annex A (Industry) shall be amended as follows:

(a) point (a) (Scope) shall be replaced by the following:

(a) Scope

This Annex applies to all activities listed in Sections B to E of NACE Rev. 2, or, as the case may be, to all products listed in Sections B to E of the CPA. The information is not required for 37, 38.1, 38.2 and 39 of NACE Rev. 2. The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) paragraph 3 of point (b) (Observation unit) shall be replaced by the following:

3. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(c) point (c) (List of variables) shall be amended as follows:

(i) the last sentence of paragraph 2 shall be replaced by the following:

‘The Commission shall determine the conditions for assuring the necessary data quality. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).’;

(ii) paragraphs 3 and 4 shall be replaced by the following:

3. Starting from the beginning of the first reference period the information on new orders (Nos 130, 131, 132) may be approximated by an alternative leading indicator,

which may be calculated from business opinion survey data. This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

4. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(iii) the last sentence of paragraph 8 shall be replaced by the following:

‘The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).’;

(iv) the last sentence of paragraph 10 shall be replaced by the following:

‘The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).’;

(d) paragraph 2 of point (d) (Form) shall be replaced by the following:

2. In addition, the production variable (No 110) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form.

Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(e) paragraphs 8 and 9 of point (f) (Level of detail) shall be replaced by the following:

8. For the import price variable (No 340), the Commission may determine the terms for applying a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2). Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

9. The variables on the non-domestic markets (Nos 122, 132 and 312) are to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as NACE Rev. 2 Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of NACE Rev. 2. The information on NACE Rev. 2 D and E is not required for variable 122. In addition, the import price variable (No 340) is to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as CPA Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of CPA. For the distinction into the euro-zone and non-euro-zone, the Commission may determine the terms for applying European sample schemes as defined in point (d) of the first subparagraph of Article 4(2). Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3). The European sample scheme may limit the scope of the import price variable to the import of products from non-euro-zone countries. The distinction into the euro-zone and non-euro-zone for the variables 122, 132, 312 and 340 does not need to be transmitted by those Member States that have not adopted the euro as their currency.;

(f) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

5. Annex B (Construction) shall be amended as follows:

(a) paragraph 4 of point (b) (Observation unit) shall be replaced by the following:

4. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) point (c) (List of variables) shall be amended as follows:

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

3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended for up to five years more

unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(ii) the last subparagraph of paragraph 6 shall be replaced by the following:

The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to replace the construction costs variable with the output price variable with effect from base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

2. In addition, the variables on production (Nos 110, 115, 116) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(d) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

6. Annex C (Retail trade and repair) shall be amended as follows:

(a) paragraph 2 of point (b) (Observation unit) shall be replaced by the following:

2. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) point (c) (List of variables) shall be amended as follows:

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

3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended for up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of

this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(ii) the last subparagraph of paragraph 4 shall be replaced by the following:

The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to include the variable hours worked (No 220) and the variable gross wages and salaries (No 230) with effect from the base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

2. The turnover variable (No 120) and the volume of sales variable (No 123) are also to be transmitted in a working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(d) paragraph 2 of point (g) (Deadlines for data transmission) shall be replaced by the following:

2. The variables shall be transmitted for turnover (No 120) and the deflator of sales/volume of sales (No 330/123) within one month for the level of detail specified in paragraph 3 under heading (f) of this Annex. Member States may choose to participate for the turnover and deflator of sales/volume of sales variables No 120 and 330/123 with contributions according to the allocation of a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2). The terms of the allocation are to be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(e) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

7. Annex D (Other services) shall be amended as follows:

(a) paragraph 2 of point (b) (Observation unit) shall be replaced by the following:

2. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted

in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(b) point (c) (List of variables), is amended as follows:

(i) paragraph 2 shall be replaced by the following:

2. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. The period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(ii) the last subparagraph of paragraph 4 shall be replaced by the following:

The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to include the variable hours worked (No 220) and the variable gross wages and salaries (No 230) with effect from base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

2. The turnover variable (No 120) is also to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(d) the last paragraph of point (e) (Reference period) shall be replaced by the following:

The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(e) in connection with a revision of the frequency of compilation of the turnover variable. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(e) paragraph 6 of point (f) (Level of detail) shall be replaced by the following:

6. The Commission may amend the list of activities and groupings no later than 11 August 2008. Those measures, designed to amend

non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

(f) in points (i) (First reference period) and (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2).

3.4. **Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs[29]**

As regards Regulation (EC) No 530/1999, the Commission should be empowered in particular to adapt the definition and breakdown of the information to be provided, and to lay down the quality evaluation criteria. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 530/1999, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 530/1999 is hereby amended as follows:

1. Articles 11 and 12 shall be replaced by the following:

Article 11

Implementation measures

The following measures necessary for the implementation of this Regulation, including measures to take account of economic and technical changes, shall be adopted by the Commission for each reference period at least nine months before the beginning of the reference period:

(i) the definition and breakdown of the information to be provided (Article 6),

(ii) the appropriate technical format for the transmission of the results (Article 9),

(iii) quality evaluation criteria (Article 10),

(iv) derogations, in duly justified cases, for the years 2004 and 2006 respectively (Article 13(2)).

The measures referred to in points (ii) and (iv) shall be adopted in accordance with the regulatory procedure referred to in Article 12(2).

The measures referred to in points (i) and (iii), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Article 12

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[30].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(31)] shall apply, having regard to the provisions 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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 13(2) shall be replaced by the following:

2. For the years 2004 and 2006 respectively, derogations from Articles 3 and 6 may be decided in so far as the national statistical system requires major adaptations, in accordance with the regulatory procedure set out in Article 12(2)..

3.5. Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index[(32)]

As regards Regulation (EC) No 450/2003, the Commission should be empowered in particular to adapt the definitions and amend the technical specifications, include new sections in the survey, adapt the breakdown of indices by economic activities, define the quality criteria, establish feasibility studies and take decisions pursuant to their results, and determine the methodology to be used for chaining the index. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 450/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 450/2003 is hereby amended as follows:

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

4. The Commission may take measures to redefine the technical specification of the index and revise the weighting structure. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

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

2. The inclusion of economic activities defined by NACE Rev.2 sections O to S in the scope of this Regulation shall be determined by the Commission, taking into account the feasibility studies defined in Article 10. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

3. Article 4 shall be replaced by the following:

Article 4

Breakdown of variables

1 The data shall be broken down by economic activities defined by NACE Rev. 2 sections and by further disaggregations, defined by the Commission, not beyond the level of NACE Rev. 2 divisions (2-digit level) or groupings of divisions, taking account of contributions to total employment and to labour costs at Community and national levels. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Labour cost indices shall be provided separately for the three labour cost categories identified below:

a total labour costs;

b wages and salaries, defined by reference to item D.11 in Annex II to Regulation (EC) No 1726/1999;

c employers' social contributions plus taxes paid by the employer less subsidies received by the employer, as defined by the sum of items D.12 and D.4 less D.5 in Annex II to Regulation (EC) No 1726/1999.

2 An index estimating total labour costs, excluding bonuses, where bonuses are defined by D.11112 in Annex II to Regulation (EC) No 1726/1999, shall be provided, broken down by economic activities defined by the Commission, and shall be based on the NACE Rev. 2 classification, taking into account the feasibility studies defined in Article 10. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

4. Article 8 shall be replaced by the following:

Article 8

Quality

1 The current data and back data transmitted shall satisfy separate quality criteria to be defined by the Commission. That measure, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

2 The Member States shall provide annual quality reports to the Commission, beginning in 2003. The content of the reports shall be defined by the Commission. That measure, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).;

5. Articles 11 and 12 shall be replaced by the following:

Article 11

Implementing measures

The following measures for implementing this Regulation, including measures to take account of economic and technical changes, shall be laid down by the Commission:

(a) the definition, in accordance with Article 4(1), of the disaggregations to be included in the fixed structure;

(b) the technical specification of the index (Article 2);

(c) the inclusion of NACE Rev. 2 sections O to S (Article 3);

(d) the breakdown of indices by economic activities (Article 4);

(e) the format for transmission of results and the adjustment procedures to be applied (Article 6);

(f) the separate quality criteria for current and back data transmitted and contents of quality reports (Article 8);

(g) the transition period (Article 9);

(h) the establishment of feasibility studies and decisions pursuant to their results (Article 10); and

(i) the methodology to be used for chaining the index (Annex).

The measures referred to in points (e), (g) and (h) shall be adopted in accordance with the regulatory procedure referred to in Article 12(2).

The measures referred to in points (a), (b), (c), (d), (f) and (i), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Article 12

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[33].

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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

6. point 3 of the Annex shall be replaced by the following:

3. The methodology for chaining the index will be defined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3)..

3.6. Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises[(34)]

As regards Regulation (EC) No 1552/2005, the Commission should be empowered in particular to adapt the definitions and sampling methods, to define the specific data to be collected and to determine the quality requirements for the data and the transmission arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1552/2005, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1552/2005 is hereby amended as follows:

1. Article 5(2) shall be replaced by the following:

2. Having regard to the specific national size distribution of enterprises and the evolution of policy needs, Member States may extend the definition of the statistical unit in their country. The Commission may also decide to extend that definition, if such extension would substantially enhance the representativeness and the quality of the result of the survey in the Member States concerned. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

2. Article 7(3) shall be replaced by the following:

3. Sampling and precision requirements, the sample sizes needed to meet those requirements, and the detailed specifications of the NACE Rev. 2 and size categories into which the results can be broken down shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

3. Article 8(2) shall be replaced by the following:

2. The specific data to be collected with respect to training and non-training enterprises and to the different forms of vocational training shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

4. Article 9(4) shall be replaced by the following:

4. The quality requirements for the data to be collected and transmitted for Community statistics on vocational training in enterprises, the structure of the quality reports referred to in paragraph 2 and any measures necessary for assessing or improving the quality of the data shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

5. Article 10(2) shall be replaced by the following:

2. The Commission shall determine the first reference year for which the data are to be collected. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

6. Articles 13 and 14 shall be replaced by the following:

Article 13

Implementing measures

The measures necessary to take account of economic and technical developments concerning the collection, transmission and processing of the data shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other measures for the implementation of this Regulation, including the appropriate technical format and interchange standard of the electronically transmitted data, shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 14(2).

Article 14

Committee procedure

1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom[(35)].

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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

4. INTERNAL MARKET

4.1. **Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV)[(36)]**

As regards Regulation (EC) No 2195/2002, the Commission should be empowered in particular to update the structure and codes of the CPV and to make technical adjustments to any of the Annexes to that Regulation in order to provide users with a tool adapted to their needs and to developments in the market. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2195/2002, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the

urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Articles 2 and 3 of Regulation (EC) No 2195/2002 shall be replaced by the following:

Article 2

The Commission shall adopt the measures necessary for the revision of the CPV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 3(2). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 3(3).

Article 3

1 The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC[37].

2 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

4.2. **Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors[38]**

As regards Directive 2004/17/EC, the Commission should be empowered in particular to make technical adjustments to certain provisions of the Directive and its Annexes, in line with technical progress or developments in Member States, and to revise the thresholds for application of the arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/17/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and because of the time-limits imposed by the procedures laid down for calculation and publication, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the revision of certain thresholds.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Directive 2004/17/EC is hereby amended as follows:

1. Article 68 shall be replaced by the following:

Article 68

Committee procedure

1 The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC[39].

2 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.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be set at four, two and six weeks respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 69 shall be amended as follows:

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

> The Commission shall verify the thresholds established in Article 16 every two years from 30 April 2004, and shall, if necessary, with regard to the second subparagraph, revise them. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5).;

(b) the first subparagraph of paragraph 2 shall be replaced by the following:

> At the same time as performing the revision under paragraph 1, the Commission shall align the thresholds laid down in Article 61 (design contests) with the revised threshold applicable to service contracts. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5).;

3. Article 70 shall be replaced by the following:

Article 70

Amendments

1 The Commission may amend, in accordance with the advisory procedure referred to in Article 68(2):

a the procedure for sending and publishing data referred to in Annex XX, on grounds of technical progress or for administrative reasons;

b the procedures for the drawing-up, transmission, receipt, translation, collection and distribution of the notices referred to in Articles 41, 42, 43 and 63;

c in the interests of administrative simplification as provided for in Article 67(3), the procedures for the use, drawing-up, transmission, receipt,

translation, collection and distribution of the statistical reports referred to in Article 67(1) and (2).

2 The Commission may amend the following:

a the list of contracting entities in Annexes I to X so that they fulfil the criteria set out in Articles 2 to 7;

b the procedures for specific references to particular positions in the CPV nomenclature in the notices;

c the reference numbers in the nomenclature set out in Annex XVII, in so far as this does not change the material scope of the Directive, and the procedures for reference in the notices to particular positions in that nomenclature within the categories of services listed in the Annex;

d the reference numbers in the nomenclature set out in Annex XII, insofar as this does not change the material scope of the Directive, and the procedures for reference to particular positions of that nomenclature in the notices;

e Annex XI;

f the technical details and characteristics of the devices for electronic receipt referred to in points (a), (f) and (g) of Annex XXIV;

g the technical procedures for the calculation methods set out in the second subparagraph of Article 69(1) and the second subparagraph of Article 69(2).

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5)..

4.3. **Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts**[(40)]

As regards Directive 2004/18/EC, the Commission should be empowered in particular to make technical adjustments to certain provisions of the Directive and its Annexes, in line with technical progress or developments in Member States, and to revise the thresholds for application of the arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/18/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and because of the time-limits imposed by the procedures laid down for calculation and publication, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the revision of certain thresholds.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Directive 2004/18/EC is hereby amended as follows:

1. Article 77 shall be replaced by the following:

Article 77

Committee procedure

1 The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC[41].

2 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.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be set at four, two and six weeks respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 78 shall be amended as follows:

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

> The Commission shall verify the thresholds established in Article 7 every two years from 30 April 2004 and shall, if necessary, revise them. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 77(5).;

(b) paragraph 2 shall be replaced by the following:

> 2. At the same time as the revision under paragraph 1, the Commission shall align:
>
> a the thresholds established in point (a) of the first paragraph of Article 8, in Article 56 and in the first subparagraph of Article 63(1) on the revised threshold applying to public works contracts;
>
> b the threshold established in Article 67(1)(a) on the revised threshold applying to public service contracts awarded by the contracting authorities referred to in Annex IV;
>
> c the thresholds established in point (b) of the first paragraph of Article 8 and in Article 67(1)(b) and (c) on the revised threshold applying to public service contracts awarded by contracting authorities other than those referred to in Annex IV.
>
> Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(4). On imperative grounds of urgency, the

Commission may have recourse to the urgency procedure referred to in Article 77(5).;

3. Article 79 shall be replaced by the following:

Article 79

Amendments

1 The Commission may amend, in accordance with the advisory procedure referred to in Article 77(2):

a the procedures for the drawing-up, transmission, receipt, translation, collection and distribution of the notices referred to in Articles 35, 58, 64 and 69 and the statistical reports provided for in the fourth subparagraph of Article 35(4) and in Articles 75 and 76;

b the procedure for sending and publishing data referred to in Annex VIII, on grounds of technical progress or for administrative reasons.

2 The Commission may amend the following:

a the technical procedures for the calculation methods set out in the second subparagraph of Article 78(1) and in Article 78(3);

b the procedures for specific reference to specific positions in the CPV nomenclature in the notices;

c the lists of bodies and categories of bodies governed by public law in Annex III, when, on the basis of the notifications from the Member States, such amendment proves necessary;

d the lists of central government authorities in Annex IV, following the adaptations necessary to give effect to the Agreement;

e the reference numbers in the nomenclature set out in Annex I, in so far as this does not change the material scope of this Directive, and the procedures for reference to particular positions of that nomenclature in the notices;

f the reference numbers in the nomenclature set out in Annex II, in so far as this does not change the material scope of this Directive, and the procedures for reference in the notices to particular positions in that nomenclature within the categories of services listed in the Annex;

g the technical details and characteristics of the devices for electronic receipt referred to in points (a), (f) and (g) of Annex X.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 77(5)..

5. HEALTH AND CONSUMER PROTECTION

5.1. **Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(42)]**

As regards Regulation (EEC) No 315/93, the Commission should be empowered in particular to establish maximum tolerances for specific contaminants. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EEC) No 315/93 by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Any delay in the establishment of maximum tolerances for specific contaminants could represent a threat to human or animal health. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of those tolerances.

Accordingly Regulation (EEC) No 315/93 is hereby amended as follows:

1. the first subparagraph of Article 2(3) shall be replaced by the following:

> In order to protect public health and pursuant to paragraph 1, the Commission may where necessary establish the maximum tolerances for specific contaminants. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 8(4).;

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

2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee for Foodstuffs, set up by Council Decision 69/414/EEC[(43)], and shall deliver its opinion immediately and take any necessary measures aimed at confirming, amending or repealing the national measure, in accordance with the regulatory procedure laid down in Article 8(2).;

3. in the fourth subparagraph of Article 5(3), the words ‘Article 8’ shall be replaced by the words ‘Article 8(2)’;

4. Article 8 shall be amended as follows:

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

   > 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Council Decision 1999/468/EC[(44)] shall apply, having regard to the provisions of Article 8 thereof.;

   (b) the following paragraph shall be added:

   > 4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.2. Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes[(45)]

As regards Directive 93/74/EEC, the Commission should be empowered in particular to adopt general provisions regarding the application of the indications contained in the list of intended uses and to adopt amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses. Since those measures are of general scope and are designed to amend non-essential elements of Directive 93/74/EEC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Feedingstuffs intended for particular nutritional purposes are playing an increasing role in the diet of pet animals and are also used in the rearing of productive livestock. The composition and preparation of such feedingstuffs must be specially designed to meet the particular nutritional needs of categories of pets or productive livestock whose process of assimilation, absorption or metabolism could briefly be impaired or is temporarily or irreversibly impaired. Users of such feedingstuffs therefore need to be provided immediately with accurate and meaningful information so that they can make appropriate choices. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of general provisions regarding the application of the indications contained in the list of intended uses and for the adoption of amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses.

Accordingly, Directive 93/74/EEC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

Article 6

The Commission shall adopt:

(a) a list of intended uses as set out in the Annex no later than 30 June 1994 in accordance with the regulatory procedure referred to in Article 9(2). That list shall contain:

— the indications referred to in points (b), (c), (d) and (e) of Article 5(1), and,

— where appropriate, the indications referred to in Article 5(2) and Article 5(4), second subparagraph,

(b) general provisions regarding the application of the indications referred to in point (a), including applicable tolerances;

(c) amendments to the measures adopted in accordance with points (a) and (b) in line with developments in scientific and technical knowledge.

The measures provided for in points (b) and (c), designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 9(4).;

2. Article 8(2) shall be replaced by the following:

2. The Commission shall initiate as soon as possible the regulatory procedure laid down in Article 9(2) with a view to adopting any appropriate measures aimed at confirming, amending or repealing the national measure.;

3. Article 9(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.3. **Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products**[46]

As regards Directive 96/23/EC, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/23/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/23/EC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

Article 6

1 The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the regulatory procedure referred to in Article 33(2), adjust for the Member States concerned the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2 Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall be carried out by the Commission and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, the Commission shall take account of experience gained under existing national measures and of information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).;

2. Article 8 shall be amended as follows:

(a) the second and third subparagraphs of paragraph 1 shall be replaced by the following:

> Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the regulatory procedure referred to in Article 33(3).
>
> In order to take account of changes in the situation in a given Member State or in a region thereof, of the results of national surveys or of investigations carried out in the framework of Articles 16 and 17, the Commission may, at the request of the Member State concerned or on its own initiative, decide, in accordance with the regulatory procedure referred to in Article 33(2), to approve an amendment or addition to a plan previously approved pursuant to paragraph 2.;

(b) the fifth subparagraph of paragraph 2 shall be replaced by the following:

> Where there are comments from Member States or where the Commission deems the update not to be in conformity or to be insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the regulatory procedure referred to in Article 33(3).;

3. the third subparagraph of Article 14(1) shall be replaced by the following:

> A list of such designated laboratories shall be drawn up in accordance with the regulatory procedure referred to in Article 33(3).;

4. the second subparagraph of Article 15(1) shall be replaced by the following:

> The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).;

5. the sixth subparagraph of Article 20(2) shall be replaced by the following:

> In the light of the experts' opinion, appropriate measures may be taken in accordance with the regulatory procedure referred to in Article 33(2).;

6. the second subparagraph of paragraph 1 and paragraph 2 of Article 21 shall be replaced by the following:

> The Member State concerned shall take the measures necessary to take account of the results of those verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with the Member State in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the regulatory procedure referred to in Article 33(2).

2 The general rules for implementing this Article, especially as regards the frequency and method of carrying out the verifications referred to in the first subparagraph of paragraph 1 (including cooperation with the competent authorities), shall be determined in accordance with the regulatory procedure referred to in Article 33(3).;

7. Article 29 shall be amended as follows:

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

> The Commission shall approve the plan in accordance with the regulatory procedure referred to in Article 33(3). Under the same procedure, guarantees other than those resulting from the implementation of this Directive may be accepted.;

(b) paragraph 2 shall be replaced by the following:

> 2. Where the requirements of paragraph 1 are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the regulatory procedure referred to in Article

33(3), at the request of a Member State or by the Commission on its own initiative.;

8. the first subparagraph of Article 30(3) shall be replaced by the following:

3. If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfil their obligations and the guarantees given by the plans referred to in Article 29(1), it shall cease to allow the country concerned, under the regulatory procedure referred to in Article 33(2), to benefit from the said agreements for the animals and products in question until that third country has made good its shortcomings. The suspension shall be revoked under the same procedure.;

9. Article 32 shall be deleted;

10. Articles 33, 34 and 35 shall be replaced by the following:

Article 33

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 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 matter of food safety[(47)].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(48)] shall apply, having regard to the provisions of Article 8 thereof.

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

3 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.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 34

Without prejudice to Article 6(2), Annexes I, III, IV and V may be amended or supplemented by the Commission. In particular, those Annexes may be amended with a view to risk assessment of the following factors:

— potential toxicity of residues in foodstuffs of animal origin,

— likelihood of residues occurring in foodstuffs of animal origin,

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).

Article 35

The Commission may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Transitional measures of general scope, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, and in particular further specifications of the requirements laid down in this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2)..

5.4. **Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[49]**

As regards Regulation (EC) No 258/97, the Commission should be empowered in particular to adopt data protection arrangements. Since those measures are of general scope and are designed to supplement Regulation (EC) No 258/97 with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 258/97 is hereby amended as follows:

1. in Article 1(3), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

2. in the second subparagraph of Article 3(4), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

3. in Article 4(5), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

4. in Article 7(1), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

5. in Article 8(3), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

6. Article 10 shall be replaced by the following:

Article 10

Detailed rules for the protection of the information provided by the applicant shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).;

7. Article 12(2) shall be replaced by the following**:**

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 aimed at confirming, amending or repealing the national measure in accordance with the regulatory procedure laid down in Article 13(2). The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.;

8. Article 13(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.5. **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[50]**

As regards Decision No 2119/98/EC, the Commission should be empowered in particular to establish the communicable diseases and the criteria for selection of those diseases to be covered by the Community network, as well as the epidemiological and microbiological surveillance methods. Since those measures are of general scope and are designed to amend non-essential elements of Decision No 2119/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When an emergency situation occurs with regard to the appearance or to new developments of a serious communicable disease, the epidemiological surveillance system should be triggered as soon as possible, in order to ensure protection of the population and public health. When on imperative grounds of urgency the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions determining the communicable diseases, the criteria for the selection of those diseases and the epidemiological and microbiological surveillance methods, as well as for the amendments to the Annex to Decision No 2119/98/EC containing the list of categories of communicable diseases.

Accordingly, Decision No 2119/98/EC is hereby amended as follows:

1. Article 3 shall be amended as follows:

   (a) the introductory words shall be replaced by the following:

   > With a view to the effective operation of the Community network with regard to epidemiological surveillance and to achieving uniform information within this framework, the following shall be adopted by the Commission:;

   (b) the following paragraphs shall be added:

   > The measures referred to in points (a), (b) and (e), designed to amend non-essential elements of this Decision, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).
   >
   > The measures referred to in points (c), (d), (f), (g) and (h) shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

2. Article 6(5) shall be replaced by the following:

5. Procedures concerning the information and consultation referred to in paragraphs 1, 2 and 3 and procedures concerning the coordination referred to in paragraphs 1 and 4 shall be established in accordance with the regulatory procedure referred to in Article 7(2).;

3. Article 7 shall be amended as follows:

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

   > 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

   (b) the following paragraph shall be added:

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

4. Article 8 shall be replaced by the following:

Article 8

The Annex may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Decision, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4)..

5.6. 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[51]

As regards Directive 2000/13/EC, the Commission should be empowered in particular to adopt certain measures necessary for its implementation. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2000/13/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the amendment of the lists of certain categories of ingredients.

Accordingly, Directive 2000/13/EC is hereby amended as follows:

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

3. The Community provisions referred to in paragraphs 1 and 2 shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

2. Article 6 shall be amended as follows:

(a) point (d) of the second subparagraph of paragraph 3a shall be replaced by the following:

(d) as regards other products, being measures designed to amend non-essential elements of this Directive, in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) the second subparagraph of paragraph 6 shall be amended as follows:

(i) the first indent shall be replaced by the following:

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

Alterations to the list of categories in Annex I may be effected by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall

be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

However, the designation "starch" listed in Annex I must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,;

(ii) the second indent shall be replaced by the following:

— ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated.

Amendments to Annex II based on advances in scientific and technical knowledge, being measures designed to amend non-essential elements of this Directive, shall be adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).

However, the designation "modified starch" listed in Annex II must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,;

(c) the third subparagraph of paragraph 7 shall be replaced by the following:

The Community provisions referred to in this paragraph shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(d) the third subparagraph of paragraph 11 shall be replaced by the following:

Without prejudice to the second subparagraph, Annex IIIa may be amended by the Commission, after an opinion has been obtained from the European Food Safety Authority issued on the basis of Article 29 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[52]. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).;

3. Article 7 shall be amended as follows:

(a) paragraph 2(d) shall be replaced by the following:

(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) paragraph 3(d) shall be replaced by the following:

(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(c) the third sentence of paragraph 4 shall be replaced by the following:

'Such provisions shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

4. Article 8 shall be amended as follows:

(a) the third subparagraph of paragraph 4 shall be replaced by the following:

This list may be supplemented by the Commission. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) paragraph 6 shall be replaced by the following:

6. The Community provisions referred to in paragraphs 1, second subparagraph, 2(b) and (d) and 5, second subparagraph, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

5. in Article 11(2), the third subparagraph shall be replaced by the following:

The Community provisions referred to in this paragraph shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

6. in Article 12, the second paragraph shall be replaced by the following:

In the case of other beverages containing more than 1,2 % by volume of alcohol, these rules shall be laid down by the Commission.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

7. Article 16(1) shall be replaced by the following:

1. Member States shall ensure that the sale is prohibited within their own territories of foodstuffs for which the particulars provided for in Article 3 and Article 4(2) do not appear in a language easily understood by the consumer, unless the consumer is in fact informed by means of other measures, determined as regards one or more labelling particulars. Determination of such measures, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

8. Article 20 shall be amended as follows:

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

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) the following paragraph shall be added:

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

9. Article 21 shall be replaced by the following:

Article 21

The Commission shall adopt temporary measures, if these prove necessary in order to facilitate the application of this Directive.

Temporary measures of general scope designed to amend non-essential elements of this Directive, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

Other temporary measures may be adopted in accordance with the regulatory procedure referred to in Article 20(2)..

5.7. Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[(53)]

As regards Directive 2001/37/EC, the Commission should be empowered in particular to adopt rules for the use of colour photographs or the illustrations on tobacco products and to adapt the provisions on the measurement methods and on the health warnings to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/37/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/37/EC is hereby amended as follows:

1. the first subparagraph of Article 5(3) shall be replaced by the following:

3. The rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking shall be adopted by the Commission

with a view to ensuring that internal market provisions are not undermined. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;

2. Article 9 shall be replaced by the following:

Article 9

Adaptations

1 The adaptation to scientific and technical progress of the measurement methods laid down in Article 4 and the definitions relating thereto shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

2 The adaptation to scientific and technical progress of health warnings to be shown on unit packets of tobacco products as set out in Annex I and the frequency of rotation of the health warnings shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

3 The Commission shall, in accordance with the procedure laid down in Article 10(2), adapt to scientific and technical progress the marking for identification and tracing purposes of tobacco products.;

3. Article 10 shall be replaced by the following:

Article 10

Committee procedure

1 The Commission shall be assisted by a 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.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.8. **Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety**[(54)]

As regards Directive 2001/95/EC, the Commission should be empowered in particular to set out and adapt the principal rules and procedures of notification of serious risks from products. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/95/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and in particular because the adequacy of the principal rules and procedures regarding notifications of serious risks from products is a precondition for the proper

functioning of the rapid alert system, the time-limits for the regulatory procedure with scrutiny should be curtailed.

Accordingly, Directive 2001/95/EC is hereby amended as follows:

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

   (a) the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4);;

2. the second subparagraph of Article 5(3) shall be replaced by the following:

   The Commission shall adapt the specific requirements relating to the obligation to provide information laid down in Annex I. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).;

3. Article 12(3) shall be replaced by the following:

3. Detailed procedures for RAPEX are set out in Annex II. They shall be adapted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).;

4. Article 15 shall be replaced by the following:

Article 15

1 The Commission shall be assisted by a 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 15 days.

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 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively..

5.9. **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**[(55)]

As regards Regulation (EC) No 178/2002, the Commission should be empowered in particular to adopt provisions relating to the number and names of the Scientific Panels, the rules of procedure

for submitting a request for an opinion to the Authority and the criteria for inclusion of an institute on the list of competent organisations designated by the Member States. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 178/2002, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 178/2002 is hereby amended as follows:

1. the second subparagraph of Article 28(4) shall be replaced by the following:

> The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).;

2. Article 29(6) shall be replaced by the following:

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority. Those rules shall specify in particular:

   a the procedure to be applied by the Authority to the requests referred to it;

   b the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

The measure referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

The guidelines referred to in point (b) shall be adopted in accordance with the regulatory procedure referred to in Article 58(2).;

3. Article 36(3) shall be replaced by the following:

3. The Commission, after consulting the Authority, shall lay down rules establishing the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2).;

4. paragraphs 2 and 3 of Article 58 shall be replaced by the following:

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, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.10. **Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[(56)]**

As regards Regulation (EC) No 1774/2002, the Commission should be empowered in particular to establish rules on the disposal, processing, importation/exportation and transformation of Category 1, 2 and 3 material of animal by-products, as well as rules on the placing on the market of animal by-products coming from territories subject to animal health restrictions and of organic fertilisers and soil improvers; to define the conditions for the importation from third countries of petfood and raw material for petfood production; and to define specific or alternative hygiene requirements laid down in the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1774/2002, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of the rules regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions, for the adoption of alternative rules for specific situations regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions and for amendment of the Annexes.

Accordingly, Regulation (EC) No 1774/2002 is hereby amended as follows:

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

2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Member States shall immediately inform the Commission of the use that they make of this possibility.;

2. Article 4 shall be amended as follows:

(a) paragraph 2(e) shall be replaced by the following:

(e) in the light of developments in scientific knowledge, disposed of by other means that are approved by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means may either supplement or replace those provided for in points (a) to (d) of this paragraph.;

(b) the first sentence of paragraph 4 shall be replaced by the following:

'Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

3. Article 5 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) in point (c), point (i) shall be replaced by the following:

(i) in the case of resulting proteinaceous material, used as an organic fertiliser or soil improver in compliance with requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3),;

(ii) point (d) shall be replaced by the following:

(d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);;

(iii) in point (e), point (iii) shall be replaced by the following:

(iii) transformed in a biogas plant or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);;

(iv) point (g) shall be replaced by the following:

(g) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (f) of this paragraph.;

(b) paragraph 4 shall be replaced by the following:

4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of

this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

4. points (g), (h) and (i) of Article 6(2) shall be replaced by the following:

(g) in the case of catering waste referred to in paragraph 1(l), transformed in a biogas plant or composted in accordance with rules laid down by the Commission, or, pending the adoption of such rules, in accordance with national law. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

(h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3); or

(i) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee; those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (h).;

5. Article 12(5) shall be replaced by the following:

5. The requirements of paragraphs 2 and 3 may be amended by the Commission in the light of developments in scientific knowledge, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

6. Article 16(3) shall be amended as follows:

(a) point (d) shall be replaced by the following:

(d) comply with the requirements laid down in Annexes VII and VIII, or with detailed rules to be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).;

(b) the first sentence of the second subparagraph shall be replaced by the following:

‘Conditions alternative to those set out in the first subparagraph may be laid down in specific situations by decisions adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds

of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).';

7. Article 20(2) shall be replaced by the following:

2. Member States shall ensure that organic fertilisers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

8. Article 22(2) shall be replaced by the following:

2. The Commission shall establish rules concerning control measures. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Other rules for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 33(2).

Derogations from paragraph 1(a) may be granted in relation to fish and fur animals, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

9. Article 23 shall be amended as follows:

(a) paragraph 2(d) shall be replaced by the following:

(d) In addition, Member States may authorise the use, under the supervision of the competent authorities, of Category 1 material referred to in Article 4(1)(b)(ii) for the feeding of endangered or protected species of necrophagous birds in accordance with rules laid down by the Commission after consultation of the European Food Safety Authority. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) paragraph 5 shall be replaced by the following:

5. Detailed rules concerning verification measures may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

10. Article 25(3) shall be replaced by the following:

3. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).;

11. Article 26(5) shall be replaced by the following:

5. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).;

12. the second paragraph of Article 28 shall be replaced by the following:

> However, the importation from third countries of petfood and raw material for petfood production, derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

13. Article 32(1) shall be replaced by the following:

1. After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Annexes may be amended or supplemented and any appropriate transitional measures may be adopted by the Commission.

Transitional measures and measures amending or supplementing the Annexes, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2).;

14. Article 33 shall be replaced as follows:

Article 33

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, 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 15 days.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

15. in Annex III, Chapter II, Part B, point 11 shall be replaced by the following:

11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

16. Annex V shall be amended as follows:

(a) point 4 of Chapter II shall be replaced by the following:

4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 5 of Chapter V shall be replaced by the following:

5. Validation procedures based on testing methods may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

17. Annex VI shall be amended as follows:

(a) point 8 in Part C of Chapter I shall be replaced by the following:

8. Processed products derived from Category 1 or 2 material, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 2(b) of Chapter III shall be replaced by the following:

(b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down by the

Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

18. Annex VII shall be amended as follows:

(a) point 13(b) in Part C of Chapter II shall be replaced by the following:

(b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.;

(b) Chapter V shall be amended as follows:

(i) point 5 of Part A shall be replaced by the following:

5. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(ii) point 3 of Part B shall be replaced by the following:

3. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(c) point 3(c) in Part B of Chapter VI shall be replaced by the following:

(c) an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(d) point 1 in Part A of Chapter VII shall be replaced by the following:

1. Dicalcium phosphate must be produced by a process that:

(a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid

(at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

(b) following the procedure provided for in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C, or

by an equivalent process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(e) point 1 in Part A of Chapter VIII shall be replaced by the following:

1. Tricalcium phosphate must be produced by a process that ensures:

(a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;

(c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

19. Annex VIII shall be amended as follows:

(a) point 2(e) in Part A of Chapter VI shall be replaced by the following:

(e) preserved by a process other than tanning specified by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 4(a)(iii) in Part A of Chapter VII shall be replaced by the following:

(iii) preserved by a treatment other than tanning approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3)..

5.11. **Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[(57)]**

As regards Directive 2002/98/EC, the Commission should be empowered in particular to adapt the technical requirements set out in Annexes I to IV to technical and scientific progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

In the event that scientific and technical developments indicate that additional information should be provided to or obtained from donors, in order, for instance, to exclude donors presenting a health risk to others, an adaptation should be made without delay. Similarly, if scientific progress suggests new eligibility criteria concerning the suitability of blood and plasma donors, new deferral criteria should be added to the list immediately. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adaptation to scientific and technical progress of the technical requirements concerning information to be provided to or obtained from donors, as well as requirements related to the suitability of blood and plasma donors, set out in Annexes I to IV.

Accordingly, Directive 2002/98/EC is hereby amended as follows:

1. Article 28 shall be replaced by the following:

Article 28

Committee procedure

1 The Commission shall be assisted by a 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 referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 29 shall be amended as follows:

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

> The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements set out in Annexes III and IV.;

(b) the introductory wording in the second paragraph shall be replaced by the following:

> The following technical requirements and their adaptation to technical and scientific progress shall be decided by the Commission:;

(c) the following paragraphs are added:

> Technical requirements referred to in points (a) to (i) of the second paragraph, being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).
>
> On imperative grounds of urgency the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements referred to in points (b), (c),(d), (e), (f) and (g) of the second paragraph..

5.12. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[58]

As regards Regulation (EC) No 1831/2003, the Commission should be empowered in particular to establish, as a result of technological progress or scientific development, additional feed additive categories and functional groups, to adopt amendments to Annex III and to the general conditions of Annex IV to take technological progress and scientific development into account and to adopt amendments to Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1831/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1831/2003 is hereby amended as follows:

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

5. Where necessary, as a result of technological progress or scientific development, the Commission may adapt the general conditions set out in Annex IV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

2. Article 6(3) shall be replaced by the following:

3. Where necessary, as a result of technological progress or scientific development, the Commission shall establish additional feed additive categories and functional groups. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

3. the second subparagraph of Article 7(5) shall be replaced by the following:

> After the Authority has been consulted, further rules for the implementation of this Article may be established.
>
> Rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*,

by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

Other implementing rules may be adopted in accordance with the regulatory procedure referred to in Article 22(2). Those rules should, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets.;

4. Article 16(6) shall be replaced by the following:

6. The Commission may adopt amendments to Annex III to take technological progress and scientific development into account. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

5. the third paragraph of Article 21 shall be replaced by the following:

Detailed rules for implementing Annex II shall be adopted in accordance with the regulatory procedure referred to in Article 22(2).

Annex II may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

6. Article 22(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.13. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods[(59)]

As regards Regulation (EC) No 2065/2003, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2065/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2065/2003 is hereby amended as follows:

1. Article 17(3) shall be replaced by the following:

3. If necessary, the Commission shall, after requesting scientific and technical assistance from the Authority, adopt quality criteria for validated analytical methods proposed in accordance with point 4 of Annex II, including substances to be measured.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).;

2. Article 18 shall be replaced by the following:

Article 18

Amendments

1 Amendments to the Annexes shall be adopted by the Commission following a request to the Authority for scientific and/or technical assistance. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

2 Amendments to the list referred to in Article 6(1) shall be adopted in accordance with the regulatory procedure referred to in Article 19(2) following a request to the Authority for scientific and/or technical assistance.;

3. Article 19(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.14. **Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[(60)]**

As regards Regulation (EC) No 2160/2003, the Commission should be empowered in particular to adopt Community targets for the reduction of the prevalence of zoonoses and zoonotic agents, specific control methods and specific rules concerning the criteria for the evaluation of the testing methods, and to lay down the responsibilities and tasks of the reference laboratories and the rules for the implementation of Community controls. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2160/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2160/2003 is hereby amended as follows:

1. Article 4 shall be amended as follows:

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

The targets, and any amendments thereto, shall be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(b) paragraph 6(a) shall be replaced by the following:

(a) Annex I may be amended by the Commission for the purposes listed in point (b), after taking account in particular of the criteria listed in point (c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(c) paragraph 7 shall be replaced by the following:

7. Annex III may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

2. Article 5(6) shall be replaced by the following:

6. The requirements and minimum sampling rules laid down in Annex II may be amended, adapted or supplemented by the Commission, after taking account in particular of the criteria listed in Article 4(6)(c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

3. Article 8(1) shall be amended as follows:

(a) the introductory words shall be replaced by the following:

At the initiative of the Commission or at the request of a Member State:;

(b) the following subparagraph shall be added:

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

4. Article 9(4) shall be replaced by the following:

4. Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

5. Article 10(5) shall be replaced by the following:

5. The Member State of final destination may be authorised, in accordance with the regulatory procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in paragraph 4 of this Article fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

6. Article 11 shall be amended as follows:

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

2. The responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(b) paragraph 4 shall be replaced by the following:

4. Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a), may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

7. the third subparagraph of Article 12(3) shall be replaced by the following:

Where necessary, other methods for testing may be approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

8. Article 13 shall be replaced by the following:

Article 13

Implementing and transitional measures

Appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted by the Commission. Transitional measures of general scope designed to amend non-essential elements of this Regulation, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).;

9. Article 14(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

10. Article 17(2) shall be replaced by the following:

2. Practical arrangements for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the regulatory procedure referred to in Article 14(2)..

5.15. **Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[(61)]**

As regards Directive 2004/23/EC, the Commission should be empowered in particular to establish traceability requirements for tissues and cells and the related procedures of enforcement as well as certain technical requirements regarding, *inter alia*, an accreditation system for tissue establishments and the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/32/EC, *inter*

alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

In the event that scientific and technical developments on selection criteria and laboratory tests for donors provide for new evidence of diseases transmissible through donation, prompt adaptation of Community legislation should follow consequently. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions concerning the criteria for selection of the donor of tissues and/or cells and the laboratory tests required for donors.

Accordingly, Directive 2004/23/EC is hereby amended as follows:

1. Article 8 shall be amended as follows:

   (a) paragraph 5 shall be replaced by the following:

   > 5. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety, shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).;

   (b) paragraph 6 shall be replaced by the following:

   > 6. The procedures for ensuring traceability at Community level shall be established by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).;

2. Article 9(4) shall be replaced by the following:

4. The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).;

3. Article 28 shall be amended as follows:

   (a) the introductory wording shall be replaced by the following:

   > The following technical requirements and their adaptation to scientific and technical progress shall be decided by the Commission:;

   (b) the following paragraphs shall be added:

   > Technical requirements referred to in points (a) to (i), being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).
   >
   > On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 29(4) as regards technical requirements referred to in points (d) and (e) of this Article.;

4. Article 29 shall be amended as follows:

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

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) the following paragraph shall be added:

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

5.16. **Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(62)]**

As regards Regulation (EC) No 882/2004, the Commission should be empowered in particular to adopt implementing measures concerning methods of sampling and analysis, to lay down the conditions in which special treatment may take place, to update the minimum rates for any fees or charges, to determine the circumstances in which official certification is required, to amend and update the lists of Community reference laboratories, and to lay down the criteria for assessing the risk of products exported to the Community and specific import conditions. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 882/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 882/2004 is hereby amended as follows:

1. Article 11(4) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

The following implementing measures may be taken by the Commission:;

(b) the following subparagraph shall be added:

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

2. Article 20(2) shall be replaced by the following:

2. The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In the absence of such conditions, the special treatment shall take place in accordance with national rules.;

3. the second subparagraph of Article 27(3) shall be replaced by the following:

The rates in Annex IV, Section B and Annex V, Section B shall be updated by the Commission at least every two years, in particular to take account of inflation. Those measures, designed to amend non-essential elements of this Regulation, shall

be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

4. Article 30(1) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted by the Commission concerning:;

(b) the following subparagraphs are added:

The measures referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

The measures referred to in points (b) to (g) shall be adopted in accordance with the regulatory procedure referred to in Article 62(3).;

5. Article 32 shall be amended as follows:

(a) paragraph 5 shall be replaced by the following:

5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In accordance with the same procedure, Annex VII may be updated.;

(b) paragraph 6 shall be replaced by the following:

6. Additional responsibilities and tasks for Community reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

6. Article 33(6) shall be replaced by the following:

6. Additional responsibilities and tasks for national reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

7. the second subparagraph of Article 46(3) shall be replaced by the following:

The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

8. Article 48(1) shall be replaced by the following:

1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by

Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

9. Article 62(4) shall be replaced by the following:

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

10. Article 63 shall be replaced by the following:

Article 63

Implementing and transitional measures

1 Transitional measures of general scope, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular

— any modification of the standards referred to in Article 12(2),

— a definition of what feed is to be regarded as feed of animal origin for the purpose of this Regulation,

and further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

Other transitional and implementing measures necessary in order to ensure the uniform application of this Regulation may be laid down in accordance with the regulatory procedure referred to in Article 62(3). This applies in particular to:

— the delegation of control tasks to control bodies referred to in Article 5, where those control bodies were already in operation before the entry into force of this Regulation,

— non-compliance as referred to in Article 28 which gives rise to expense arising from additional official controls,

— expenditure incurred pursuant to Article 54,

— rules on microbiological, physical and/or chemical analysis in official controls, in particular in cases involving a suspicion of risk and including the surveillance of the safety of products imported from third countries,

2 In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted by the Commission may provide for the necessary derogations from, and adjustments to, the rules laid down in this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

11. Article 64 shall be replaced by the following:

Article 64

Amendment of Annexes and references to European standards

The following measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4):

(1) the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

(2) the references to the European standards mentioned in this Regulation may be updated in the event that CEN amends those references..

5.17. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[(63)]

As regards Regulation (EC) No 1935/2004, the Commission should be empowered in particular to adopt specific measures for groups of materials and articles, Community authorisation of a substance, and the modification, suspension or revocation of such authorisation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1935/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

In order to strengthen the competitiveness and innovation of the European industry, materials and articles intended to come into contact with food should be marketed as soon as possible once their safety has been established. On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a list of substances authorised for use in the manufacturing of materials and articles; list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for those substances and/or the materials and articles in which they are incorporated; purity standards; special conditions of use for certain substances and/or the materials and articles in which they are used; specific limits on the migration of certain constituents or groups of constituents into or on to food; amendments of existing specific directives on materials and articles; Community authorisations and the modification, suspension or revocation thereof.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of specific measures regarding the modification, suspension or revocation of Community authorisations.

Accordingly, Regulation (EC) No 1935/2004 is hereby amended as follows:

1. Article 5 shall be amended as follows:

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

For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled

materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended by the Commission.;

(b) the following subparagraphs shall be added to paragraph 1:

The specific measures referred to in point (m) shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 23(2).

The specific measures referred to in points (f), (g), (h), (i), (j), (k), (l) and (n), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

The specific measures referred to in points (a) to (e), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

(c) paragraph 2 shall be replaced by the following:

2. The Commission may amend the existing specific directives on materials and articles. Those measures, designed to amend the non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

2. Article 11(3) shall be replaced by the following:

3. Community authorisation in the form of specific measure, as referred to in paragraph 1, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

3. Article 12(6) shall be replaced by the following:

6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 23(5).;

4. Article 22 shall be replaced by the following:

Article 22

Amendments to Annexes I and II shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).;

5. Article 23 shall be amended as follows:

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

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) the following paragraphs shall be added:

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4(e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

6. ENERGY AND TRANSPORT

6.1. **Council Directive 96/98/EC of 20 December 1996 on marine equipment**[(64)]

As regards Directive 96/98/EC, the Commission should be empowered in particular to adopt testing standards where international organisations fail or refuse to adopt them within a reasonable time, to transfer equipment from Annex A.2 to Annex A.1, and to authorise, in exceptional circumstances, the placing on board of technically innovative equipment. The Commission should also be empowered to apply, for the purposes of that Directive, subsequent amendments of international instruments, to update Annex A, to add the possibility of using certain modules for equipment listed in Annex A.1, to amend the columns for the conformity assessment modules, and to include standardisation organisations in the definition of 'testing standards' in Article 2. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/98/EC is hereby amended as follows:

1. Article 7(5) and (6) shall be replaced by the following:

5. Should the international organisations, including the IMO, fail or refuse to adopt appropriate testing standards for a specific item of equipment within a reasonable time, standards based on the work of the European standardisation organisations may be adopted. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

6 When the testing standards referred to in paragraphs 1 or 5 are adopted or enter into force, as appropriate, for a specific item of equipment, that equipment may be transferred from Annex A.2 to Annex A.1. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

Article 5 shall apply to that equipment from the date of that transfer.;

2. in Article 13(2), the first indent shall be replaced by the following:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the testing standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 18(1) within two

months if the Member State which has taken the decision intends to maintain it, and shall initiate the regulatory procedure referred to in Article 18(2).;

3. Article 14(5) shall be replaced by the following:

5. Equipment such as is referred to in paragraph 1 shall be added to Annex A.2. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

4. the first paragraph of Article 17 shall be replaced by the following:

This Directive may be amended in order:

(a) to apply subsequent amendments of international instruments for the purposes of this Directive;

(b) to update Annex A, both by introducing new equipment and by transferring equipment from Annex A.2 to Annex A.1 and vice versa;

(c) to add the possibility of using modules B + C and module H for equipment listed in Annex A.1, and by amending the columns for the conformity assessment modules;

(d) to include other standardisation organisations in the definition of "testing standards" in Article 2.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).;

5. Article 18 shall be replaced by the following:

Article 18

1 The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) created by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council[(65)].

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC[(66)] shall apply, having regard 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 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

6.2. **Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships[(67)]**

As regards Regulation (EC) No 2099/2002, the Commission should be empowered in particular to amend Article 2(2) in order to include a reference to the Community acts conferring implementing powers on COSS that have entered into force following the adoption of this Regulation. Since those measures are of general scope and are designed to amend non-essential

elements of Regulation (EC) No 2099/2002, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2099/2002 is hereby amended as follows:

1. Article 3 shall be replaced by the following:

Article 3

Establishment of a Committee

1 The Commission shall be assisted by a Committee on Safe Seas and the Prevention of Pollution from Ships (hereinafter called COSS).

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.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 7 shall be replaced by the following:

Article 7

Powers of COSS

COSS shall exercise the powers conferred on it by virtue of the Community legislation in force. Article 2(2) may be amended in accordance with the regulatory procedure with scrutiny referred to in Article 3(3) in order to include a reference to the Community acts conferring implementing power on COSS that have entered into force following the adoption of this Regulation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the procedure referred to in Article 3(3)..

6.3. **Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation[(68)]**

As regards Directive 2003/42/EC, the Commission should be empowered in particular to amend the Annexes in order to expand upon, or change, the examples, to facilitate the exchange of information and to adopt measures for the dissemination to interested parties of the information. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2003/42/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2003/42/EC is hereby amended as follows:

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

2. The Commission may decide to amend the Annexes in order to expand upon, or change, the examples. Those measures, designed to amend non-essential elements

of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;

2. Article 7(2) shall be replaced by the following:

2. Without prejudice to the public's right of access to the Commission's documents as laid down in Regulation (EC) No 1049/2001 of the European Parliament and the Council[69], the Commission shall adopt on its own initiative measures for the dissemination to interested parties of the information referred to in paragraph 1 and the associated conditions. Those measures, which may be general or individual, shall be based on the need:

— to provide persons and organisations with the information they need to improve civil aviation safety,

— to limit the dissemination of information to what is strictly required for the purpose of its users, in order to ensure appropriate confidentiality of that information,

The individual measures shall be adopted in accordance with the regulatory procedure referred to in Article 10(2).

The general measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

The decision to disseminate information under this paragraph shall be limited to what is strictly required for the purpose of its user, without prejudice to the provisions of Article 8.;

3. Article 10 shall be replaced by the following:

Article 10

1 The Commission shall be assisted by the committee established by Article 12 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation[70].

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

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

6.4. Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports[71]

As regards Directive 2004/36/EC, the Commission should be empowered in particular to adopt measures for the dissemination to interested parties of the information obtained through ramp inspections conducted under the European Community (EC) SAFA Programme, and measures amending the Annexes to the Directive, laying down the elements of technical procedures for the conduct and reporting of SAFA ramp inspections. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/36/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2004/36/EC is hereby amended as follows:

1. Article 6(3) shall be replaced by the following:

3. Without prejudice to the public's right of access to the Commission's documents as laid down in Regulation (EC) No 1049/2001, the Commission shall adopt, on its own initiative, measures for the dissemination to interested parties of the information referred to in paragraph 1 and the associated conditions. Those measures, which may be general or individual, shall be based on the need:

— to provide persons and organisations with the information they need to improve civil aviation safety,

— to limit the dissemination of information to what is strictly required for the purposes of its users, in order to ensure appropriate confidentiality of that information,

The individual measures shall be adopted in accordance with the advisory procedure referred to in Article 10(3).

The general measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4).;

2. Article 8(2) shall be replaced by the following:

2. On the basis of the information collected under paragraph 1, the Commission may

a in accordance with the regulatory procedure referred to in Article 10(2), take any appropriate measures to facilitate the implementation of Articles 3, 4 and 5, such as:

— define the format for the storage and dissemination of data,

— create or support the appropriate bodies for managing or operating the tools necessary for the collection and exchange of information,

b detail conditions for conducting ramp inspections, including systematic ones, and establish the list of information to be collected. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4).;

3. Article 10 shall be replaced by the following:

Article 10

1 The Commission shall be assisted by the committee set up by Article 12 of Regulation (EEC) No 3922/91.

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 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 The Committee may furthermore be consulted by the Commission on any other matter concerning the application of this Directive.;

4. Article 12 shall be replaced by the following:

Article 12

The Commission may amend the Annexes to this Directive.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4)..

6.5. **Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community**[(72)]

As regards Regulation (EC) No 868/2004, the Commission should be empowered in particular to develop a detailed methodology for determining the existence of unfair pricing practices. This methodology should cover, *inter alia*, the manner in which normal competitive pricing, actual costs and reasonable profit margins are to be assessed in the specific context of the aviation sector. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 868/2004 by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 868/2004 is hereby amended as follows:

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

3. The Commission shall develop a detailed methodology for determining the existence of unfair pricing practices. This methodology shall cover, *inter alia*, the manner in which normal competitive pricing, actual costs and reasonable profit margins are to be assessed in the specific context of the aviation sector. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).;

2. Article 15 shall be replaced by the following:

Article 15

Committee procedure

1 The Commission shall be assisted by the Committee established by Article 11 of Council Regulation (EEC) No 2408/92 of 23 July 1992 on access for Community air carriers to intra-Community air routes[(73)].

2 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.

3 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.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

6.6. **Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network[(74)]**

As regards Directive 2004/54/EC, the Commission should be empowered in particular to make the necessary amendments to adapt the Annexes to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/54/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2004/54/EC is hereby amended as follows:

1. Article 13(3) shall be replaced by the following:

3. By 30 April 2009 the Commission shall publish a report on the practice followed in the Member States. Where necessary, it shall make recommendations for the adoption of a common harmonised risk analysis methodology in accordance with the regulatory procedure referred to in Article 17(2).;

2. Article 16 shall be replaced by the following:

Article 16

Adaptation to technical progress

The Commission shall adapt to technical progress the Annexes to this Directive. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3).;

3. Article 17 shall be replaced by the following:

Article 17

Committee procedure

1 The Commission shall be assisted by a 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 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

6.7. Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier[(75)]

As regards Regulation (EC) No 2111/2005, the Commission should be empowered in particular to modify the common criteria for imposing an operating ban on an air carrier in order to take account of scientific and technical developments. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2111/2005, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the modification of the Annex setting out the common criteria for consideration of an operating ban for safety reasons at Community level.

Accordingly, Regulation (EC) No 2111/2005 is hereby amended as follows:

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

2. The common criteria for imposing an operating ban on an air carrier, which shall be based on the relevant safety standards, are set out in the Annex (and are hereinafter referred to as the common criteria). The Commission may modify the Annex, in particular in order to take account of scientific and technical developments. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).;

2. Article 8(1) shall be replaced by the following:

1. The Commission shall, where appropriate, adopt implementing measures in order to lay down detailed rules in respect of the procedures referred to in this Chapter. Those measures, designed to amend non-essential elements of this regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).;

3. Article 15 shall be replaced by the following:

Article 15

1 The Commission shall be assisted by the Committee referred to in Article 12 of Regulation (EEC) No 3922/91 (hereinafter referred to as the Committee).

2 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.

3 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 referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be one month, one month and two months respectively.

5 The Commission may consult the Committee on any other matter concerning the application of this Regulation..

Chronological index

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

(2) Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes.

(3) Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonized indices of consumer prices.

(4) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products.

(5) Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls.

(6) Council Directive 96/98/EC of 20 December 1996 on marine equipment.

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

(8) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery.

(9) Council Regulation EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community.

(10) Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics.

(11) Decision 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.

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

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

(14) 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.

(15) Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs.

(16) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

(17) 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.

(18) Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer.

(19) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

(20) Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

(21) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

(22) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

(23) 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.

(24) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption.

(25) Regulation (EC) 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships.

(26) Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV).

(27) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

(28) Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index.

(29) Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation.

(30) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

(31) Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.

(32) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents.

(33) Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors.

(34) Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

(35) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

(36) Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports.

(37) Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community.

(38) Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network.

(39) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

(40) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

(41) Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises.

(42) Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier.

(43) Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register.

(44) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality.

(45) Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries.

(46) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.

(**1**) OJ L 59, 27.2.1998, p. 1.

(**2**) OJ L 331, 7.12.1998, p. 1.

(**3**) OJ L 184, 17.7.1999, p. 23.';

(**4**) OJ L 91, 7.4.1999, p. 10.

(**5**) OJ L 18, 22.1.2000, p. 1.

(**6**) OJ L 311, 28.11.2001, p. 67.

(**7**) OJ L 184, 17.7.1999, p. 23.'.

(**8**) OJ L 121, 1.5.2001, p. 34.

(**9**) OJ L 311, 28.11.2001, p. 67.'

(**10**) OJ L 311, 28.11.2001, p. 1.

(**11**) OJ L 157, 9.6.2006, p. 24.

(**12**) OJ L 243, 24.9.1996, p. 31.

(**13**) OJ L 114, 27.4.2006, p. 9.'.

(**14**) OJ L 330, 5.12.1998, p. 32.

(**15**) OJ L 244, 29.9.2000, p. 1.

(**16**) OJ L 33, 4.2.2006, p. 1.

(**17**) OJ L 64, 4.3.2006, p. 37.

(**18**) OJ L 102, 11.4.2006, p. 15.

(**19**) OJ L 257, 27.10.1995, p. 1.

(**20**) Published by the United Nations, series F No 2, revision 3, table 6.1, amended by the OECD (DES/NI/86,9), Paris 1986.';

(**21**) OJ L 181, 28.6.1989, p. 47.

(**22**) OJ L 184, 17.7.1999, p. 23.';

(**23**) OJ L 77, 14.3.1998, p. 3.

(**24**) OJ L 181, 28.6.1989, p. 47.

(**25**) OJ L 184, 17.7.1999, p. 23.'.

(**26**) OJ L 162, 5.6.1998, p. 1.

(**27**) OJ L 181, 28.6.1989, p. 47.

(**28**) OJ L 184, 17.7.1999, p. 23.';

(**29**) OJ L 63, 12.3.1999, p. 6.

(**30**) OJ L 181, 28.6.1989, p. 47.

(**31**) OJ L 184, 17.7.1999, p. 23.';

(**32**) OJ L 69, 13.3.2003, p. 1.

(**33**) OJ L 181, 28.6.1989, p. 47.';

(**34**) OJ L 255, 30.9.2005, p. 1.

(**35**) OJ L 181, 28.6.1989, p. 47.'.

(**36**) OJ L 340, 16.12.2002, p. 1.

(**37**) OJ L 185, 16.8.1971, p. 15.'.

(**38**) OJ L 134, 30.4.2004, p. 1.

(**39**) OJ L 185, 16.8.1971, p. 15.';

(**40**) OJ L 134, 30.4.2004, p. 114.
(**41**) OJ L 185, 16.8.1971, p. 15.';
(**42**) OJ L 37, 13.2.1993, p. 1.
(**43**) OJ L 291, 19.11.1969, p. 9.';
(**44**) OJ L 184, 17.7.1999, p. 23.';
(**45**) OJ L 237, 22.9.1993, p. 23.
(**46**) OJ L 125, 23.5.1996, p. 10.
(**47**) OJ L 31, 1.2.2002, p. 1.
(**48**) OJ L 184, 17.7.1999, p. 23.'.
(**49**) OJ L 43, 14.2.1997, p. 1.
(**50**) OJ L 268, 3.10.1998, p. 1.
(**51**) OJ L 109, 6.5.2000, p. 29.
(**52**) OJ L 31, 1.2.2002, p. 1.';
(**53**) OJ L 194, 18.7.2001, p. 26.
(**54**) OJ L 11, 15.1.2002, p. 4.
(**55**) OJ L 31, 1.2.2002, p. 1.
(**56**) OJ L 273, 10.10.2002, p. 1.
(**57**) OJ L 33, 8.2.2003, p. 30.
(**58**) OJ L 268, 18.10.2003, p. 29.
(**59**) OJ L 309, 26.11.2003, p. 1.
(**60**) OJ L 325, 12.12.2003, p. 1.
(**61**) OJ L 102, 7.4.2004, p. 48.
(**62**) OJ L 165, 30.4.2004, p. 1.
(**63**) OJ L 338, 13.11.2004, p. 4.
(**64**) OJ L 46, 17.2.1997, p. 25.
(**65**) OJ L 324, 29.11.2002, p. 1.
(**66**) OJ L 184, 17.7.1999, p. 23.'.
(**67**) OJ L 324, 29.11.2002, p. 1.
(**68**) OJ L 167, 4.7.2003, p. 23.
(**69**) OJ L 145, 31.5.2001, p. 43.';
(**70**) OJ L 373, 31.12.1991, p. 4.'.
(**71**) OJ L 143, 30.4.2004, p. 76.
(**72**) OJ L 162, 30.4.2004, p. 1.
(**73**) OJ L 240, 24.8.1992, p. 8.'.
(**74**) OJ L 167, 30.4.2004, p. 39.
(**75**) OJ L 344, 27.12.2005, p. 15.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 596/2009 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.