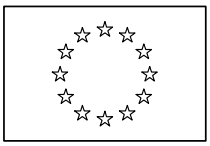

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.2.2008
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2008/0032 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC, as amended by Decision 2006/512/EC, with regard to the regulatory procedure with scrutiny

Adaptation to the regulatory procedure with scrutiny
Part Four

(presented by the Commission)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Articles 47(2), 55, 71(1), 80(2), 95, 152(4)(a) and (b), 175(1), and 285(1) thereof,

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

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

Having regard to the opinion of the European Central Bank[3],

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[5] was amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure laid down in Article 251 of the Treaty, inter alia by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

(2) In accordance with the joint statement of the European Parliament, the Council and the Commission[6] on Decision 2006/512/EC, for this new procedure to be applicable to

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1 OJ C [...], [...], p. [...].
2 OJ C [...], [...], p. [...].
3 OJ C [...], [...], p. [...].
4 OJ C [...], [...], p. [...].
5 OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
6 OJ C 255, 21.10.2006, p. 1.

instruments adopted in accordance with the procedure laid down in Article 251 of the Treaty which are already in force, those instruments must be adopted in accordance with the applicable procedures.

(3) The amendments that need to be made to instruments for this purpose concern only the committee procedures and so, in the case of Directives, do not require transposition by the Member States,

HAVE ADOPTED THIS REGULATION:

Article 1

The instruments listed in the Annex are hereby adapted, in accordance with that Annex, to Decision 1999/468/EC, as amended by Decision 2006/512/EC.

Article 2

References to provisions of the instruments listed in the Annex are understood to be references to those provisions as adapted by this Regulation.

Article 3

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

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

Done at Brussels, […]

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

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[7]

As regards Directive 97/68/EC, power should in particular be conferred on the Commission 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 that Directive, 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 amended as follows:

(1) In Article 4, paragraph 2, the last sentence is 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) In Article 7a, paragraph 4 is replaced by the following:

"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 is replaced by the following:

"Article 14

The Commission shall adopt any amendments which are necessary 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 the 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 is replaced by the following:

[7] OJ L 59, 27.2.1998, p.1.

"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, professional use, multi-positional, hand-held engines, cannot meet these deadlines, 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, unless 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 is amended as follows:

(a) Paragraph (2) is 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) is deleted.

(6) In Annex I, point 4.1.2.7, the last sentence is replaced by the following:

"The Commission shall define the control area to which the percentage not to be exceeded shall 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 is 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 calculation equations (Annex III, Appendix III). 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[8]

As regards Directive 98/79/EC, power should in particular be conferred on the Commission to adopt common technical specifications to establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials, and to adopt particular health monitoring measures, and to amend Annex II. Since those measures are of general scope and are designed to amend or supplement non-essential elements of

[8] OJ L 331, 7.12.1998, p. 1.

Directive 98/79/EC, 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 use the urgent 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 amended as follows:

(1) In Article 5(3), the second subparagraph is replaced by the following:

"The Commission shall lay down the common technical specifications which shall be published in the *Official Journal of the European Union*.

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)."

(2) Article 7 is replaced by the following:

"Article 7

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

2. Where reference is made to this 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 a 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."

(3) Article 10(5) is replaced by the following:

"5. The 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)."

(4) Article 11(5) is replaced by the following:

"5. The 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)."

(5) Article 12(3) is 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)."

(6) Article 13 is 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 use the urgent procedure referred to in Article 7(4)."

(7) Article 14(1) is replaced by the following:

"1. Where a Member State considers either of the following it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures:

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

(b) that 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.

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

The Commission shall, in accordance with the procedure referred to in Article 7(2) adopt the measures referred to in point (b) of this paragraph."

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[9]

As regards Directive 1999/5/EC, power should in particular be conferred on the Commission 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 that Directive, 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 amended as follows:

(1) Article 3(3) is 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 15."

(2) Article 6(2) is 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.

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[9] OJ L 91, 7.4.1999, p.10.

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.

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 15."

(3) Article 15 is replaced by the following:

"Article 15

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."

(4) Point 5 of Annex VII is 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 oft this Directive by supplementing it, shall be in accordance with the regulatory procedure with scrutiny referred to in Article 15."

1.4. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[10]

As regards Regulation (EC) No 141/2000 power should be conferred on the Commission to adopt definitions of 'similar medicinal product' and 'clinical superiority'. Since this measure is of general scope and is designed to amend non-essential elements of that Regulation or to supplement its elements, it 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 amended as follows:

(1) Article 3(2) is replaced by the following:

"2. The Commission shall, in accordance with the 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) is replaced by the following:

[10] OJ L 18, 22.1.2000, p. 1

"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 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) is 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 10a is inserted:

"Article 10a

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use.

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."

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[11]

As regards Directive 2001/20/EC power should in particular be conferred on the Commission 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 that Directive and to supplement that Directive by the addition of 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.

Directive 2001/20/EC is amended as follows:

(1) Article 13(1) is replaced by the following:

[11] OJ L 121, 1.5.2001, p. 34.

"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 requirements which the applicant and, subsequently, the holder of the authorisation must at least 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)."

(2) Article 20 is 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)."

(3) Article 21 is 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 (*).

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 No 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 311, 28.11.2001, p. 67".

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[12]

As regards Directive 2001/82/EC power should in particular be conferred on the Commission 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 that Directive and/or to supplement it by the addition of 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 amended as follows:

(1) Article 10(3) is replaced by the following:

"3. By way of derogation from Article 11, the Commission shall establish a list of substances essential for the treatment of equidae and for which the withdrawal period shall be not less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

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)."

(2) In Article 11(2), the third subparagraph is replaced by the following:

"However, the Commission may modify these specific withdrawal periods. 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)."

(3) In Article 13(1), the fourth subparagraph is replaced by the following:

"However, the ten-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 is 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 is replaced by the following:

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[12] OJ L 311, 28.11.2001, p. 1.

"The Commission shall adopt these arrangements in the form of an implementing regulation. That regulation, 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)."

(6) Article 50a(2) is replaced by the following:

"2. The Commission shall adopt any amendments which may be necessary 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 is 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) is 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, 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) is 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) is 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 is 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 is 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 is amended as follows:

(a) The following paragraph 2a is inserted:

"2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision No 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof".

(b) Paragraph 4 is replaced by the following:

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

1.7. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)[13]

As regards Directive 2006/42/EC, power should in particular be conferred on the Commission 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-

[13] OJ L 157, 9.6.2006, p.24.

essential elements of that Directive, 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 amended as follows:

(1) Article 8(1) is replaced by the following:

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

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

(b) the restriction of 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) Article 9(3) is 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 is amended as follows:

(a) paragraph (3) is 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) is deleted.

2. ENVIRONMENT

2.1. Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls[14]

As regards Directive 96/59/EC, power should in particular be conferred on the Commission 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 supplement Directive 96/59/EC by the addition of 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 amended as follows:

(1) Article 10 is replaced by the following:

"Article 10

1. The Commission shall, in accordance with the procedure referred to in Article 10a(2), make available 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 points (b) and (c) of Article 9(1) 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 10a is inserted:

"Article 10a

1. The Commission shall be assisted by the Committee set up by Article 18 of Directive 2006/12/EC (*), hereinafter referred to as 'the Committee'.

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[14] OJ L 243, 24.9.1996, p. 31.

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.

(*) OJ L 114, 27.4.2006"

2.2. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[15]

As regards Directive 98/83/EC, power should in particular be conferred on the Commission 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, 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 amended as follows:

(1) In Article 7, paragraph 4 is replaced by the following:

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

(2) In Article 11, paragraph 2 is 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) In Article 12, paragraph 3 is 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) In Article 13, paragraph 4 is 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 15(1), and shall if necessary be amended in accordance with the procedure referred to in Article 12(2)."

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15 OJ L 330, 5.12.1998, p. 32

(5) In Article 13, paragraph 6 is 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 procedure referred to in Article 12(2)."

(6) In Article 15, paragraph 3 is replaced by the following:

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

(7) In Annex I, Part C, note 10 point 1 is replaced by the following:

"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 these 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."

(8) In Annex III, paragraph 1, the first subparagraph is 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 these 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[16]

As regards Regulation (EC) No 2037/2000, power should in particular be conferred on the Commission 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 Pre-Shipment purpose; 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

16 OJ L 244, 29.9.2000, p. 1.

use of hydrochlorofluorocarbons; to modify the list and dates with regards to control of the use of hydrochlorofluorocarbons; to modify the list of items related to the request of an import license 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 and to supplement Regulation (EC) No 2037/2000 by the addition of 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 amended as follows:

(1) In Article 2, the 16th indent on "processing agent" is replaced by the following:

"- 'processing agent' means controlled substances used as chemical processing agents in those applications listed in Annex VI, in installations existing at 1 September 1997, and where emissions are insignificant The Commission shall, in the light of those criteria, and in accordance with the 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 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)."

(3) Article 4 is amended as follows:

(a) in paragraph 2 the third subparagraph of point (iii) is 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) in paragraph 3, point (ii) is 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 (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) in paragraph 4, point (iv) is 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 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).”

(4) Article 5 is amended as follows:

(a) In paragraph 1, the fifth subparagraph of point (c)(v), is 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 is 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 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).”

(5) Article 6(5) is 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)."

(6) Article 9 (2) is 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)."

(7) Article 11(1), point (d) is 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)."

(8) In Article 18, paragraph 3 is 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."

(9) In Article 19, paragraph 6 is 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 and amending Council Directives 91/689/EEC and 96/61/EC[17]

As regards Regulation (EC) No 166/2006, power should in particular be conferred on the Commission to adopt measures referred to in Article 8(3); to adapt Annexes II or III to this Regulation to scientific or technical progress; and to adapt Annexes II and III to this Regulation 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 this Protocol. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 166/2006 and to supplement Regulation (EC) No 166/2006 by the addition of 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 amended as follows:

(1) In Article 8, paragraph 3 is 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 is replaced by the following:

"Article 18

Amendments to the Annexes

The Commission shall make the 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) In Article 19, the following paragraph 3 is added:

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17 OJ L 33, 4.2.2006, p. 1.

"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 and repealing Directive 76/160/EEC[18]

As regards Directive 2006/7/EC, power should in particular be conferred on the Commission 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 and to supplement that Directive by the addition of 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 amended as follows:

(1) Article 15 is replaced by the following:

"Article 15

"1. The Commission shall, in accordance with the 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 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 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)".

(2) In Article 16, paragraph 3 is replaced by the following:

[18] OJ L 64, 4.3.2006, p. 3.

"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 and amending Directive 2004/35/EC[19]

As regards Directive 2006/21/EC*,* power should in particular be conferred on the Commission 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 and to supplement Directive 2006/21/EC by the addition of 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 amended as follows:

(1) Article 22 is replaced by the following:

"Article 22

1. By 1 May 2008, the Commission shall, in accordance with the 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 Article12(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. By 1 May 2008, the Commission shall lay down provisions necessary for the following, prioritising (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;

[19] OJ L 102, 11.4.2006, p. 1.

(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 for adapting them 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 23(3)."

(2) In Article 23, paragraph 3 is 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 harmonized indices of consumer prices[20]

As regards Regulation (EC) No 2494/95, power should in particular be conferred on the Commission 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 by supplementing it by the addition of 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 amended as follows:

(1) In Article 3, the words "in Article 14" are replaced by the words "in Article 14 (2)".

(2) In Article 4, the third paragraph is 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) In Article 5, paragraph 3 is replaced by the following:

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[20] OJ L 257, 27.10.1995, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)

"3. The Commission shall adopt implementing measures for this Regulation which are necessary for ensuring the comparability of HICPs and for maintaining and improving their reliability and relevance, after consultation of the ECB. 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) In Article 8(3) the words "in Article 14" are replaced by the words "in Article 14(2)".

(5) Article 9 is 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) (*), which shall be adapted by the Commission to establish 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).

(*) Published by the United Nations, series F No 2, revision 3, table 6.1, amended by the OECD (DES/NI/86.9), Paris 1986."

(6) In Article 11, the words "in Article 14" are replaced by the words "in Article 14(2)".

(7) Article 14 is replaced by the following:

"Article 14

Committee

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

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.

(*) OJ L 181, 28.6.1989, p. 47."

(8) In Article 15, the second paragraph is 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[21]

As regards Regulation (EC) No 577/98, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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 amended as follows:

(1) In the third indent of the fifth paragraph of Article 1, the words "in Article 8" are replaced by the words "in Article 8(2)".

(2) In Article 4, paragraphs 2, 3 and 4 are 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 above in paragraph 1.

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

- this 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 twelve months before the beginning of the reference period for that module,

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[21] OJ L 77, 14.3.1998, p. 3. Regulation as last amended by Regulation (EC) No 1372/2007 of the European Parliament and of the Council (OJ L 315, 3.12.2007, p. 6).

- the volume of an ad hoc module shall not exceed eleven 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. This 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 is replaced by the following:

"Article 8

Committee

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

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.

(*) OJ L 181, 28.6.1989, p. 47."

3.3. Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics[22]

As regards Regulation (EC) No 1165/98, powers should in particular be conferred on the Commission 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 by the addition of 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 amended as follows:

(1) In Article 4, paragraph 2 (d) is 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)."

(2) In Article 16(1), the words "in Article 18" are replaced by the words "in Article 18 (2)".

(3) Articles 17 and 18 are 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);

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[22] OJ L 162, 5.6.1998, p. 1. Regulation as last amended by Regulation (EC) No 1893/2006 of the European Parliament and of the Council (OJ L 393, 30.12.2006, p. 1).

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

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

(f) the transmission deadlines (Article 8);

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

(h) the transition periods and derogations granted during the transition period (Article 13);

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

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

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

(l) 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 (h) and (i) shall be adopted in accordance with the regulatory procedure referred to in Article 18(2).

The measures referred to in points (a) to (g) and (j) to (l), 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).

Article 18

Committee

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

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.

(*) OJ L 181, 28.6.1989, p.47."

(4) Annex A ('Industry') is amended as follows:

(a) Point (a) (*'Scope'*) is 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) In point (b) (*'Observation unit*'), paragraph 3 is replaced by the following:

"3. The use of other observation units can 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'*), is amended as follows:

(i) In paragraph 2, the last sentence is 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 are 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 more years 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 more years 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) In paragraph 8, the last sentence is 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) in paragraph 10, the last sentence is 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) In point (d) (*'Form'*), paragraph 2 is 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) In point (f) (*'Level of detail'*), paragraphs 8 and 9 are 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 are replaced by references to Article 18 (2).

(5) Annex B ('Construction') is amended as follows:

(a) In point (b) (*'Observation unit'*), paragraph 4 is replaced by the following:

"4. The use of other observation units can 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 3 is 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. The procedure shall be extended for up to five more years 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) In paragraph 6, the last subparagraph is replaced by the following:

"The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) 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) In point (d) (*'Form'*), paragraph 2 is 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 are replaced by references to Article 18 (2).

(6) Annex C ('Retail trade and repair) is amended as follows:

(a) In point (b) (*'Observation unit'*), paragraph 2 is replaced by the following:

"2. The use of other observation units can 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 3 is 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 more years 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) In paragraph 4, the last subparagraph is 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) In point (d) (*'Form'*), paragraph 2 is 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) In point (g) ('Deadlines for data transmission'), paragraph 2 is 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 are replaced by references to Article 18 (2).

(7) Annex D ('Other services') is amended as follows:

(a) In point (b) (*'Observation unit*'), paragraph 2 is replaced by the following:

"2. The use of other observation units can 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 is 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 more years 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) In paragraph 4, the last subparagraph is 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) In point (d) (*'Form'*), paragraph 2 is 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) In point (e) (*'Reference period'*), last sentence is replaced by the following:

"The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(d) 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) In point (f) (*'Level of detail'*), paragraph 6 is 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 are 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[23]

As regards Regulation (EC) No 530/1999, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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 amended as follows:

(1) Articles 11 and 12 are replaced by the following:

"Article 11

Implementation measures

The 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),

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[23] OJ L 63, 12.3.1999, p. 6. Regulation as last amended by Regulation (EC) No 1893/2006 of the European Parliament and of the Council (OJ L 393, 31.12.2006, p. 1).

(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 periods 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), 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).

Article 12

Committee

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

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.

(*) OJ L 181, 28.6.1989, p. 47."

3.5. Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index[24]

As regards Regulation (EC) No 450/2003, power should in particular be conferred on the Commission 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 and to supplement it by the addition of new non-essential elements, they must be adopted in accordance with the

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[24] OJ L 69, 13.3.2003, p. 1. Regulation as last amended by Regulation (EC) No 1893/2006 of the European Parliament and of the Council (OJ L 393 31.12.2006, p. 1).

regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

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

(1) In Article 2, paragraph 4 is 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) In Article 3, paragraph 2 is 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 is 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 is 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 are replaced by the following:

"Article 11

Implementing measures

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

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

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

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

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

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

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

(g) 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), 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).

Article 12

Committee

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

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.

(*) OJ L 181, 28.6.1989, p. 47."

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[25]

As regards Regulation (EC) No 1552/2005, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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.

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[25] OJ L 255, 30.9.2005, p.1. Regulation last amended by Regulation (EC) No 1893/2006 of the European Parliament and of the Council (OJ L 393 31.12.2006, p. 1).

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

(1) In Article 5, paragraph 2 is 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 this definition, if such extension would enhance substantially 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) In Article 7, paragraph 3 is replaced by the following:

"3. Sampling and precision requirements, the sample sizes needed to meet these 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) In Article 8, paragraph 2 is 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) In Article 9, paragraph 4 is 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) In Article 10, paragraph 2 is 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 are replaced by the following:

"Article 13

Implementing measures

The implementing measures concerning the appropriate technical format and interchange standard of the electronically transmitted data shall be adopted in accordance with the procedure referred to in Article 14(2).

The measures necessary for the implementation of this Regulation, including measures to take account of economic and technical developments concerning the collection, transmission and processing of the data, shall be adopted in accordance with the procedure referred to in Article 14(3).

Article 14

Committee

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

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.

(*) OJ L 181, 28.6.1989, p. 47."

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)[26]

As regards Regulation (EC) No 2195/2002, power should in particular be conferred on the Commission to update the structure and codes of the CPV and to make technical adjustments to any of the annexes to this 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

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[26] OJ L 340, 16.12.2002, p.1. Regulation as last amended by Regulation (EC) No 2151/2003 (OJ L 329, 17.12.2003, p.1)

with the regulatory procedure with scrutiny provided for in Article 5(a) 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 must be able to use the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Regulation (EC) No 2195/2002 is amended as follows:

(1) Articles 2 and 3 are 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 use the urgent 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 (*), hereinafter referred to as "the Committee".

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.

(*) OJ L 185, 16.8.1971, p.15. Decision as amended by Decision 77/63/EEC (OJ L 13, 15.1.1977, p.15)."

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[27]

As regards Directive 2004/17/EC, powers should in particular be conferred on the Commission to make technical adjustments to certain passages of the instrument 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

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[27] OJ L 134, 30.4.2004, p 1.

2004/17/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5(a) of Decision 1999/468/EC.

On the grounds of efficiency and because of the time limits imposed by the procedures for calculation and publication laid down, 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 use the urgent 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 amended as follows:

(1) Article 68 is replaced by the following:

" Article 68

Committee

1. The Commission shall be assisted by the Committee instituted by Council Decision 71/306/EEC(*) (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, 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 two weeks.

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.

(*) OJ L 185, 16.8.1971, p.15. Decision as amended by Decision 77/63/EEC (OJ L 13, 15.1.1977, p.15)."

(2) Article 69 is amended as follows :

a) In paragraph 1, the first subparagraph is 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 Regulation, 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 use the urgent procedure referred to in Article 68(5)."

b) In paragraph 2, the first subparagraph is 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 Regulation, 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 use the urgent procedure referred to in Article 68(5)."

(3) Article 70 is replaced by the following:

"Article 70

Amendments

1. The Commission may amend, in accordance with the procedure provided for 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 this 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 this 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 Article 69(1) and (2), second subparagraph.

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 68(3). On imperative grounds of urgency, the Commission may use the urgent 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[28]

As regards Directive 2004/18/EC, power should in particular be conferred on the Commission to make technical adjustments to certain passages of the instrument 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 5(a) of Decision 1999/468/EC.

On the grounds of efficiency and because of the time limits imposed by the procedures for calculation and publication laid down, 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 use the urgent 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 amended as follows:

(1) Article 77 is replaced by the following:

[28] OJ L 134, 30.4.2004, p 114.

"Article 77

Committee

1. The Commission shall be assisted by the Committee instituted by Council Decision 71/306/EEC(*) (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, 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 two weeks.

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.

(*) OJ L 185, 16.8.1971, p.15. Decision as amended by Decision 77/63/EEC (OJ L 13, 15.1.1977, p.15)."

(2) Article 78 is amended as follows:

(a) In paragraph 1, the first subparagraph is 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 Regulation, 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 use the urgent procedure referred to in Article 77(5)."

(b) Paragraph 2 is replaced by the following:

"2. At the same time as the revision under paragraph 1, the Commission shall align:

(a) the thresholds established in (a) of the first subparagraph 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 thresholds established in (b) of the first subparagraph of Article 8, and in Article 67(1)(a) on the revised threshold applying to public service contracts concluded by the contracting authorities referred to in Annex IV;

(c) the threshold established in Article 67(1)(b) and (c) on the revised threshold applying to public service contracts awarded by the contracting authorities not included 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 77(4). On imperative grounds of urgency, the Commission may use the urgent procedure referred to in Article 77(5)."

(3) Article 79 is replaced by the following:

"Article 79

Amendments

1. The Commission may amend, in accordance with the procedure provided for 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, these prove 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, insofar as this does not change the material scope of this Directive, and the procedures for reference to particular positions of this nomenclature in the notices;

   (f) the reference numbers in the nomenclature set out in Annex II, insofar as this does not change the material scope of this Directive, and the procedures for reference in the notices to particular positions in this 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 Regulation, 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 use the urgent 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[29]

As regards Regulation (EEC) No 315/93, power should in particular be conferred on the Commission to establish maximum tolerances for specific contaminants. Since those measures are of general scope and are designed to amend non-essential elements of that Regulation 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.

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 use the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of these tolerances.

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

(1) In Article 2(3), the first subparagraph is replaced by the following:

"In order to protect public health and pursuant to paragraph 1, where necessary, the Commission may 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 use the urgent procedure referred to in Article 8(4).

(2) In Article 4(2), the words "Article 8" are replaced by the words "Article 8(2)".

(3) In the fourth subparagraph of Article 5(3), the words "Article 8" are replaced by the words "Article 8(2)".

(4) Article 8 is amended as follows:

(a) paragraph 3 is 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.";

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[29] OJ L 37, 13.2.1993, p. 1.

(b) the following paragraph 4 is 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[30]

As regards Directive 93/74/EEC, powers should in particular be conferred on the Commission to adopt general provisions regarding the application of the indications contained in the list of intended uses and 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 or to supplement it by the addition of 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. Consequently and on the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed 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 amended as follows :

(1) Article 6 is replaced by the following:

"Article 6

The Commission shall adopt:

(a) a list of intended uses as set out in the Annex not later than 30 June 1994 in accordance with the procedure referred to in Article 9(2). That list shall contain:

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

[30] OJ L 237, 22.9.1993, p. 23.

– 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 (a), including applicable tolerances;

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

The measures provided for in (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).

(2) In Article 8(2), the words "Article 9" are replaced by the words "Article 9(2)".

(3) In Article 9, paragraph 3 is replaced by the following:

"3. 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."

5.3. Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC[31]

As regards Directive 96/23/EC, power should in particular be conferred on the Commission to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of that Directive and to supplement it by the addition of 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 amended as follows:

(1) Article 6 is 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 adjust 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

[31] OJ L 125, 23.5.1996, p. 10. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).

listed in Annex I. 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 33(4).

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, account shall be taken of experience gained under existing national measures and 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 is amended as follows:

(a) In paragraph 1, the second and third subparagraphs are replaced by the following:

"Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the 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 procedure referred to in Article 33(2), to approve an amendment or addition to a plan previously approved pursuant to paragraph 2."

(b) In paragraph 2, the fifth subparagraph is replaced by the following:

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

(3) In Article 14(1), the third subparagraph is replaced by the following:

"A list of such designated laboratories shall be drawn up in accordance with the procedure laid down in Article 33(3)."

(4) In Article 15(1), the second subparagraph is 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) In Article 20(2), the sixth subparagraph is replaced by the following:

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

(6) In Article 21, the second subparagraph of paragraph 1 and paragraph 2 are replaced by the following:

"The Member State concerned shall take the measures necessary to take account of the results of these 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 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 procedure referred to in Article 33(3)."

(7) In Article 29, paragraph 2 is 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 procedure referred to in Article 33(3), at the request of a Member State or by the Commission on its own initiative."

(8) In Article 30(3), the first subparagraph is 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 that country, under the procedure referred to in Article 33(2), to benefit from the said agreements for the animals and products in question until the third country in question has made good its shortcomings. The suspension shall be revoked under the same procedure."

(9) Article 32 is deleted.

(10) Article 33 is 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 (*).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

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 Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

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.

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

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[32]

As regards Regulation (EC) No 258/97, power should in particular be conferred on the Commission to adopt data protection arrangements. Since those measures are of general scope and are designed to supplement Regulation (EC) No 258/97 by the addition of 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 amended as follows :

(1) In Article 1(3), the words "Article 13" are replaced by the words "Article 13(2)".

(2) In the second subparagraph of Article 3(4), the words "Article 13" are replaced by the words "Article 13(2)".

(3) In Article 4(5), the words "Article 13" are replaced by the words "Article 13(2)".

(4) In Article 7(1), the words "Article 13" are replaced by the words "Article 13(2)".

(5) In Article 8(3), the words "Article 13" are replaced by the words "Article 13(2)".

(6) Article 10 is 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

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

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) In Article 12(2), the words "Article 13" are replaced by the words "Article 13(2)".

(8) In Article 13, paragraph 3 is 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 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[33]

As regards Decision 2119/98/EC, power should in particular be conferred on the Commission to establish the communicable diseases and the criteria for selection of these 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 2119/98/EC and to supplement it by the addition of 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.

With a view to making the Community network operative and effective with regard to the epidemiological surveillance and to the achievement of uniform information within this framework, the communicable diseases to be covered by the network, as well as the criteria for the selection of these diseases and the epidemiological and microbiological surveillance methods, should be determined as soon as the disease is recognised. On the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of decisions determining the communicable diseases, the criteria for the selection of these diseases and the epidemiological and microbiological surveillance methods, as well as for the amendments to the Annex to Decision 2119/98/EC containing the list of categories of communicable diseases.

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 the 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 use the urgent 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 these diseases and the epidemiological and microbiological surveillance methods as well as for the amendments to the Annex to Decision 2119/98/EC containing the list of categories of communicable diseases.

Accordingly, Decision 2119/98/EC is amended as follows:

(1) Article 3 is amended as follows:

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[33] OJ L 268, 3.10.1998, p. 1. Decision as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(a) The introductory words are 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 second and third paragraphs are 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 use the urgent 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 procedure referred to in Article 7(2)."

(2) In Article 6, paragraph 5 is 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 procedure referred to in Article 7(2)."

(3) Article 7 is amended as follows:

a) Paragraph 3 is replaced by the following:

"3. 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."

b) The following paragraph 4 is 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 is 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 use the urgent 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[34]

As regards Directive 2000/13/EC, power should in particular be conferred on the Commission 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 and/or to supplement it by the addition of 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 the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the amendment of the lists of certain categories of ingredients.

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

(1) In Article 4, paragraph 3 is 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 is amended as follows :

(a) in paragraph 3a, second subparagraph, point (d) is 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) in paragraph 6, second subparagraph, the second indent is 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 this Annex based on advances in scientific and technical knowledge, 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(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,"

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[34] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2006/142/EC (OJ L 368, 23.12.2006, p. 110).

(c) in paragraph 7, the third subparagraph is 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) in paragraph 11, the third subparagraph is 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 (*). 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(4)".

(3) Article 7 is amended as follows :

(a) in paragraph 2, point (d) is replaced by the following:

"(d) in the cases determined by the Commission; determination of such cases, 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) in paragraph 3, point (d) is replaced by the following:

"(d) in the cases determined by the Commission; determination of such cases, 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) in paragraph 4, the third sentence is 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 is amended as follows :

(a) in paragraph 4, the third subparagraph is 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 is replaced by the following:

"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 is 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 16, paragraph 1 is 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, 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)."

(7) Article 20 is amended as follows :

(a) paragraph 3 is 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 4 is 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."

(8) Article 21 is replaced by the following:

"Article 21

If temporary measures prove necessary to facilitate the application of this Directive, they 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).

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

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[35]

As regards Directive 2001/37/EC, power should in particular be conferred on the Commission to adopt rules for the use of colour photographs or the illustrations on tobacco products and to adapt the provisions on the measurements 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 and to supplement it by the addition of 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.

Amendments to the measurements methodologies are measures of technical nature based on scientific advice and discussions at international level within the WHO Framework Convention on Tobacco Control and should be implemented within the EU legislation without delay. Therefore, on the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adaptation to scientific and technical progress of the measurements methods and the definitions relating thereto.

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

(1) The first subparagraph of the Article 5(3) is replaced by the following:

"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 is replaced by the following:

"Article 9

Adaptations

1. The adaptation to scientific and technical progress of the measurements methods laid down in Article 4 and the definitions relating thereto shall be decided by the Commission. Those measures, designed to amend non-essential

35 OJ L 194, 18.7.2001, p. 26.

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. 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 is replaced by the following:

"Article 10

Committee procedures

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.

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."

5.8. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[36]

As regards Directive 2001/95/EC, power should in particular be conferred on the Commission 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 that Directive, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[36] OJ L 11, 15.1.2002, p. 4.

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 amended as follows:

(1) In Article 4(1), point (a) is replaced by the following:

"(a) the requirements intended to ensure that products which conform to these 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) In Article 5(3), the second subparagraph is 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) In Article 12, paragraph 3 is replaced by the following:

"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 is replaced by the following:

"Article 15

"1. The Commission shall be assisted by a 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 laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

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 paragraphs 1 to 4 and 5 (b) and Article 7 of the 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[37]

As regards Regulation (EC) No 178/2002, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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 amended as follows :

(1) In Article 28(4), the second subparagraph is 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) In Article 29, paragraph 6 is replaced by the following:

"6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority. These 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).

[37] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

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

(3) In Article 36, paragraph 3 is replaced by the following:

"3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority. Those rules shall specify, in particular, 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 by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3)."

(4) In Article 58, paragraphs 2 and 3 are 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[38]

As regards Regulation (EC) No 1774/2002*,* power should in particular be conferred on the Commission 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 fertilizers and soil improvers; to define the conditions for the importation from third countries of pet food and raw material for pet food production as well as 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 that Regulation and to supplement it by the addition of 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 use the urgent 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

[38] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 829/2007 (OJ L 191, 21.7.2007, p. 1).

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 the amendments of the Annexes.

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

(1) In Article 3, paragraph 2 is 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. 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). Member States shall immediately inform the Commission of the use that they make of this possibility."

(2) Article 4 is amended as follows:

(a) In paragraph 2, point (e) is 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). These means may either supplement or replace those provided for in points (a) to (d) of this paragraph."

(b) In paragraph 4, the first sentence is 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 is amended as follows:

(a) Paragraph 2 is amended as follows:

(i) In point (c), point (i) is replaced by the following:

"(i) in the case of resulting proteinaceous material, used as an organic fertilizer 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) is 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) is 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) is 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) . These means or ways may either supplement or replace those provided for in points (a) to (f) of this paragraph."

(b) Paragraph 4 is 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) In Article 6(2), points (g), (h) and (i) are 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). These means or ways may either supplement or replace those provided for in points (a) to (h)."

(5) In Article 12, paragraph 5 is 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) In Article 16, paragraph 3 is amended as follows:

(a) Point (d) is 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 use the urgent procedure referred to in Article 33(4).

(b) In the second subparagraph, the first sentence is 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 use the urgent procedure referred to in Article 33(4)."

(7) In Article 20, paragraph 2 is replaced by the following:

"2. Member States shall ensure that organic fertilizers 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) In Article 22, paragraph 2 is replaced by the following:

"2. Rules for the implementation of this Article, including rules concerning control measures, shall be adopted in accordance with the procedure referred to in Article 33(2). Derogations from paragraph 1(a) of this Article may be granted by the Commission 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 by supplementing it, shall be adopted in

accordance with the regulatory procedure with scrutiny referred to in Article 33(3)."

(9) Article 23 is amended as follows:

(a) In paragraph 2, point d) is 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 is 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) In Article 25, paragraph 3 is replaced by the following:

"3. Detailed arrangements for implementing this Article, including rules concerning the frequency of checks and reference methods for microbiological analyses, 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)."

(11) In Article 26, paragraph 5 is replaced by the following:

"5. Detailed arrangements for implementing this Article, including rules concerning the frequency of checks and reference methods for microbiological analyses, 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)."

(12) In Article 28, the second paragraph is 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) In Article 32, paragraph 1 is 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. 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). On imperative grounds of urgency, the Commission may use the urgent procedure referred to in Article 33(4)."

(14) Article 33 is amended as follows:

(a) Paragraph 3 is 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 is 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."

(15) In Annex II, Chapter III, point 4 is replaced by the following:

"4. A model for the commercial document 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) In Annex III, Chapter II, Part B, point 11 is 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)."

(17) Annex V is amended as follows:

(a) In Chapter II, point 4 is 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) In Chapter V, point 5 is 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)."

(18) Annex VI is amended as follows:

(a) In Chapter I, Part C, point 8 is 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) In Chapter III, point 2(b) is replaced by the following:

"(b) in a continuous process at 140°C 2 bars (2000 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)."

(19) Annex VII is amended as follows:

(a) In Chapter II, Part C, point 13(b) is 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 is amended as follows:

(i) In Part A, point 1 is replaced by the following:

"1. 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) In Part B, point 6 is replaced by the following:

"6. 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) In Chapter VI, Part B, point 3(c) is 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) In Chapter VII, Part A, point 1 is 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 at (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) In Chapter VIII, Part A, point 1 is 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)."

(20) Annex VIII is amended as follows:

(a) Chapter IV, Part A, is amended as follows:

(i) In point 3(b)(ii), the fourth indent is replaced by the following:

"- any other treatment provided for 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 4 is replaced by the following:

"4. The specific conditions relating to imports of products for use *in vitro* diagnosis and laboratory reagents may be laid down by the Commission, where necessary. 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) In Chapter VI, Part A, point 2(e) is 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)."

(c) In Chapter VII, Part A, point 4(a)(iii) is 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 and amending Directive 2001/83/EC[39]

As regards Directive 2002/98/EC, power should in particular be conferred on the Commission to adapt the technical requirements set out in Annexes I to IV to technical and scientific

[39] OJ L 33, 8.2.2003, p. 30.

progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/98/EC and to supplement it by the addition of 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.

Regarding storage, transport, distribution, quality and safety of blood, as well as requirements applicable to autologous transfusions, discussions are currently ongoing within the Council of Europe. If progress is being made in this context and new internationally recognized conditions appear, the EU legislation should be adapted accordingly without delay. On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adaptation of the technical requirements related to storage, transport, distribution, quality and safety of blood, as well as requirements applicable to autologous transfusions, set out in Annexes I to IV, to scientific and technical progress.

In the event that scientific and technical developments indicate that additional information should be provided to or obtained from donors, in order to, for instance, 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 use the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adaptation 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, to scientific and technical progress.

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

(1) Article 28 is replaced by the following:

"Article 28

Committee Procedures

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) 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."

(2) Article 29 is amended as follows:

(a) The first paragraph is 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 use the urgent procedure referred to in Article 28(5) as regards technical requirements set out in Annexes III and IV."

(b) In the second paragraph, the introductory phrase is 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), (h) and (i) of the second paragraph, 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).

Technical requirements referred to in points (b), (c), (d), (e), (f) and (g), of the second paragraph, 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(4). On imperative grounds of urgency the Commission may use the urgent procedure referred to in Article 28(5) as regards technical requirements referred to in points (b), (c) and (d) 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[40]

As regards Regulation (EC) No 1831/2003, power should in particular be conferred on the Commission 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

[40] OJ L 268, 18.10.2003, p. 29.

to amend non-essential elements of Regulation (EC) No 1831/2003, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Additives for use in animal nutrition are substances, micro-organisms or preparations which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: satisfy the nutritional needs of animals, favourably affect the characteristics of feed or animal products, the colour of ornamental fish and birds, the environmental consequences of animal production, animal production, performance or welfare. In order to guarantee the improvements produced by the use of such additives and, consequently, an increase in the productivity and quality of animal production, access of additives to the market must be made easy and rapid. On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should therefore be curtailed for the adoption of those measures establishing additional feed additive categories and functional groups and for amendments to Annexes II , III and IV.

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

(1) Article 3(5), is 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(4)."

(2) Article 6(3) is 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(4)."

(3) In Article 7(5), the second subparagraph is replaced by the following:

"After the Authority has been consulted, further rules for the implementation of this Article may be established by the Commission. These 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. The implementing rules shall include provisions which allow for simplified procedures for the authorisation of additives which have been authorised for use in food. 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)."

(4) Article 16(6) is replaced by the following:

"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(4)."

(5) In Article 21, the third paragraph, is replaced by the following:

"Detailed rules for implementing Annex II and any amendments to that Annex shall be adopted in accordance with the 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(4)."

(6) Article 22 is amended as follows:

(a) paragraph 3 is 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 is 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."

5.13. 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[41]

As regards Regulation (EC) No 2065/2003, power should in particular be conferred on the Commission 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 by the addition of 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 amended as follows:

(1) Article 18 is replaced by the following:

[41] OJ L 309, 26.11.2003, p. 1.

"Article 18

Amendments

1. Amendments to the Annexes shall be adopted by the Commission following consultation of 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 procedure referred to in Article 19(2) following consultation of the Authority for scientific and/or technical assistance."

(2) In Article 19, paragraph 3 is 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[42]

As regards Regulation (EC) No 2160/2003*,* power should in particular be conferred on the Commission 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 that Regulation and to supplement it by the addition of 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 amended as follows:

(1) Article 4 is amended as follows:

(a) In paragraph 1, the second subparagraph is replaced by the following:

"The targets, and any amendments to them, 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) In paragraph 6, point (a) is replaced by the following:

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[42] OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 1237/2007, p. 5).

"(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 is 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) In Article 5, paragraph 6 is 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 point (c) of Article 4(6). 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) In Article 8, paragraph 1 is amended as follows:

(a) The introductory words are replaced by the following:

"At the initiative of the Commission or at the request of a Member State:"

(b) The following second subparagraph is 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) In Article 9, paragraph 4 is 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 is amended as follows:

(a) In paragraph 4, the second sentence is replaced by the following:

"Flocks and herds shall be tested for the zoonoses and zoonotic agents listed in Annex I, column 1, or, if necessary to achieve the objective of equivalent guarantees laid down in paragraph 1, such zoonoses and zoonotic agents as may be 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 14(3)."

(b) Paragraph 5 is replaced by the following:

"5. The Member State of final destination may be authorised, in accordance with the 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 is amended as follows:

(a) Paragraph 2 is 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 is 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) In Article 12(3), the third subparagraph is 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 is 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. 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)."

(9) In Article 14, paragraph 3 is 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) In Article 17, paragraph 2 is replaced by the following:

"2. Rules for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, 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)."

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[43]

As regards Directive 2004/23/EC*,* power should in particular be conferred on the Commission 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 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 that Directive and to supplement it by the addition of 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.

The use of tissues and cells for application in the human body carries a risk of disease transmission and other potential adverse effects in recipients. That risk can be reduced by careful donor selection and testing of each donation. In particular, due to scientific progress, new eligibility criteria to select donors and new requirement for laboratory tests could be developed and should, therefore, be implemented within the EU legislation without delay in order to exclude potential donors who might present a health risk to other people. On the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of decisions concerning the selection criteria for the donor of tissues and/or cells and the laboratory tests required for donors.

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[43] OJ L 102, 7.4.2004, p. 48.

Storage, transport and distribution of tissue and cells are a subject under discussion within the Council of Europe. Any progress made in this context giving rise to new internationally recognized conditions should be implemented within the EU legislation without delay. On the grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of decisions concerning tissue and cell processing, storage and distribution.

In the event that scientific and technical developments on selection criteria and laboratory tests for donors provide for a 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 use the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions concerning the selection criteria for the donor of tissues and/or cells and the laboratory tests required for donors.

Accordingly, Directive 2004/23/EC is amended as follows:

(1) Article 8 is amended as follows:

(a) paragraph 5 is replaced by the following:

"5. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with these 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 is 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 28 is amended as follows:

(a) The introductory phrase is 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 are added:

"1. Technical requirements referred to in points (a), (b), (c), (f), (g) and (i), 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. Technical requirements referred to in points (d), (e) and (h) ,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(4). On imperative grounds of urgency the Commission may use the urgent procedure referred to in Article 29(5) as regards technical requirements referred to in points (d) and (e) of Article 28."

(4) Article 29 is amended as follows:

(a) paragraph 3 is 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 4 and 5 are 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."

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[44]

As regards Regulation (EC) No 882/2004, power should in particular be conferred on the Commission 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, 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 that Regulation and to supplement it by the addition of 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 amended as follows :

(1) In Article 11, paragraph 4 is amended as follows :

(a) the introductory phrase is replaced by the following:

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[44] OJ L 165, 30.4.2004, p. 1; corrected version: OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

"The following implementing measures may be taken by the Commission:"

(b) the following second subparagraph is 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) In Article 20, paragraph 2 is 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) In Article 27(3), the second subparagraph is 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) In Article 30, paragraph 1 is amended as follows:

(a) the introductory phrase is 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 second and third 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 procedure referred to in Article 62(3)."

(5) In Article 32, paragraph 5 is 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."

(6) In Article 46(3), the second subparagraph is 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)."

(7) In Article 48, paragraph 1 is 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)."

(8) In Article 62, paragraph 4 is 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."

(9) In Article 63, paragraph 2 is replaced by the following:

"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)."

(10) Article 64 is 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 referred to in this Regulation may be updated in the event that CEN amends these 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 and repealing Directives 80/590/EEC and 89/109/EEC[45]

As regards Regulation (EC) No 1935/2004, power should in particular be conferred on the Commission to adopt specific measures for groups of materials and articles, Community authorisation of a substance, as well as its modification, suspension or revocation of this authorisation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1935/2004 and to supplement it by the addition of 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 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 these 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 as well as their modification, suspension or revocation.

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 use the urgent 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 amended as follows:

(1) Article 5 is amended as follows:

(a) In paragraph 1 the first subparagraph is 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 are added:

"The specific measures referred to in point (m) shall be adopted by the Commission in accordance with the procedure referred to in Article 23(2).

The specific measures referred to in points (f), (g), (h), (i), (j), (k), (l) and (n), measures designed to amend non-essential elements of this Regulation, shall be

[45] OJ L 338, 13.11.2004, p. 4.

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), 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(4)."

(c) Paragraph 2 is 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)."

(3) Article 11(3) is replaced by the following:

"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)."

(4) Article 12(6) is replaced by the following:

"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 use the urgent procedure referred to in Article 23(5)."

(5) Article 22 is 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)."

(6) Article 23 is amended as follows:

a) paragraph 3 is 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 4 and 5 are 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[46]

As regards Directive 96/98/EC, power should in particular be conferred on the Commission 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. Power should also be conferred on the Commission to apply, for the purposes of the 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, 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 amended as follows:

(1) In Article 7, paragraphs 5 and 6 are replaced by the following:

"5. Should the international organizations, 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 standardization organizations 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).

[46] OJ L 46, 17.2.1997, p. 25.

Article 5 shall apply to that equipment from the date of that transfer."

(2) In Article 13(2), the first indent is 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 procedure referred to in Article 18(2)."

(3) In Article 14, paragraph 5 is 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) In Article 17, the first paragraph is 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 is 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 (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission shall apply, having regard 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 5(a)(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 324, 29.11.2002, p. 1."

6.2. 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[47]

As regards Regulation (EC) 2099/2002, power should in particular be conferred on the Commission 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) 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) 2099/2002 is amended as follows:

(1) Article 3 is replaced by the following:

"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 5(a)(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 is replaced by the following:

[47] OJ L 324, 29.11.2002, p. 1

"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 by the procedure 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 regulatory procedure with scrutiny 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[48]

As regards Directive 2003/42/EC, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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 amended as follows:

(1) In Article 3, paragraph 2 is 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) In Article 7, paragraph 2 is 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 (*), 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. These measures, which can 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.

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[48] OJ L 167, 4.7.2003, p. 23

The individual measures shall be adopted in accordance with the procedure referred to in Article 10(2).

The general measures, which are measures designed to amend the 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.

(*) OJ L 145, 31.5.20001, p. 43."

(3) Article 10 is replaced by the following:

"Article 10

1. The Commission shall be assisted by the committee instituted by Article 12 of Council 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 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[49]

As regards Directive 2004/36/EC, power should in particular be conferred on the Commission 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 and to supplement it by the addition of 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 amended as follows:

(1) In Article 6, paragraph 3 is replaced by the following:

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[49] OJ L 143, 30.4.2004, p. 76.

"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. These 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 procedure referred to in Article 10(3).

The general measures, which are measures designed to amend the 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 10 is 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 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.

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

(*) OJ L 373, 31.12.1991, p. 4."

(3) Article 12 is 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[50]

As regards Regulation (EC) No 868/2004, power should in particular be conferred on the Commission 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 shall 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 amended as follows:

(1) In Article 5, paragraph 3, is 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 shall 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(3a)."

(2) Article 15 is replaced by the following:

"Article 15

Committee procedure

1. The Commission shall be assisted by the Committee instituted by Article 11 of Council Regulation (EEC) No 2408/92(*).

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.

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[50] OJ L 162, 30.4.2004, p. 1

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.

3a 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.

(*) OJ L 240, 24.8.1992, p. 8"

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[51]

As regards Directive 2004/54/EC, power should in particular be conferred on the Commission 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 amended as follows:

(1) Article 16 is 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 Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3)."

(2) Article 17 is replaced by the following:

"Article 17

Committee

1. The Commission shall be assisted by a committee.

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[51] OJ L 167, 30.4.2004, p. 39.

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, and repealing Article 9 of Directive 2004/36/EC[52]

As regards Regulation (EC) No 2111/2005, power should in particular be conferred on the Commission 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, and to supplement it by the addition of 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 amended as follows:

(1) Article 3(2) is 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 the 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 15 is 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 (the Committee).

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52 OJ L 344, 27.12.2005, p. 15.

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 5(a) (1) to (4) and (5) (b), and 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.

5. The Commission may consult the Committee on any other matter concerning the application of this Regulation."

Chronological Index

(16) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products – *Page 13.*

(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 – *Page 61.*

(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 – *Page 22.*

(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 – *Page 14.*

(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 – *Page 64.*

(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 – *Page 16.*

(22) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety – *Page 66.*

(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 – *Page 67.*

(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 – *Page 69.*

(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 – *Page 93.*

(26) Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV) – *Page 47.*

(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 and amending Directive 2001/83/EC – *Page 77.*

(28) Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index – *Page 41.*

(29) Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation – *Page 94.*

(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 – *Page 79.*

(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 – *Page 81.*

(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 – *Page 82.*

(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 – *Page 48.*

(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 – *Page 50.*

(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 – *Page 84.*

(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 – *Page 96.*

(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 – *Page 97.*

(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 – *Page 98.*

(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 – *Page 87.*

(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 and repealing Directives 80/590/EEC and 89/109/EEC – *Page 89.*

(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 – *Page 44.*

(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, and repealing Article 9 of Directive 2004/36/EC – *Page 99.*

(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 and amending Council Directives 91/689/EEC and 96/61/EC – *Page 25.*

(44) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC – *Page 27.*

(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 and amending Directive 2004/35/EC – *Page 28.*

(46) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) – *Page 18.*