



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.12.2007  
COM(2007) 824 final

2007/0293 (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 Two**

(presented by the Commission)

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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 Two**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 44(1), 71, 80(2), 95, 152(4)(b), 175(1), 179 and 285 thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the European Central Bank<sup>3</sup>,

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>4</sup>,

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<sup>5</sup> 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.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> OJ C [...], [...], p. [...].

<sup>3</sup> OJ C [...], [...], p. [...].

<sup>4</sup> OJ C [...], [...], p. [...].

<sup>5</sup> OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

- (2) In accordance with the joint statement of the European Parliament, the Council and the Commission<sup>6</sup> on Decision 2006/512/EC, for this new procedure to be applicable to 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*  
*The President*

*For the Council*  
*The President*

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<sup>6</sup> OJ C 255, 21.10.2006, p. 1.

## ANNEX

### 1. HUMANITARIAN AID

#### 1.1. Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid<sup>7</sup>

As regards Council Regulation (EC) No 1257/96, power should in particular be conferred on the Commission to adopt implementing Regulations for that Regulation. Since those measures are of general scope and are designed to supplement Regulation (EC) No 1257/96 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 1257/96 is amended as follows:

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

“Decisions to continue operations adopted by the emergency procedure shall be taken by the Commission, acting in accordance with the procedure laid down in Article 17(2) and within the limits set in the second indent of Article 15(2).”

(2) Article 15 is replaced by the following:

#### *“Article 15*

1. The Commission shall adopt implementing Regulations for this Regulation. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted according to the regulatory procedure with scrutiny referred to in Article 17(4).
2. Acting in accordance with the procedure laid down in Article 17(3), the Commission shall:
  - decide on Community financing for the humanitarian-aid protection operations referred to in Article 2(c),
  - decide to take direct Commission action or finance action by Member States' specialised agencies.
3. Acting in accordance with the procedure laid down in Article 17(2), the Commission shall:
  - approve global plans intended to provide a coherent framework for action in a given country or region where the scale and complexity of the humanitarian crisis is such that it seems likely to continue, and the budgets for those plans. In this context, the Commission and the Member

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<sup>7</sup> OJ L 163, 2.7.1996, p. 1.



States shall examine the priorities to be established in the implementation of these global plans,

- decide on projects in excess of ECU 2 million, without prejudice to Article 13.”

(3) Article 17 is replaced by the following:

*“Article 17*

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

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

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

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.”

## 2. ENTERPRISE

### 2.1. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers<sup>8</sup>

As regards Directive 75/324/EEC, power should in particular be conferred on the Commission to adopt the necessary technical adaptations to that Directive and the required amendments to adapt the Annex to technical progress. 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 75/324/EEC is amended as follows:

(1) Article 5 is replaced by the following:

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<sup>8</sup> OJ L 147, 9.6.1975, p. 40.

*“Article 5*

The Commission shall adopt the amendments required to adapt the Annex to this Directive to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(2)”.

(2) Article 7 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.

(3) In Article 10, paragraph 3 is replaced by the following:

“3. The Commission may adopt necessary technical adaptations of 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 7(2).

In that case, the Member State having adopted safeguard measures may maintain them until the entry into force of the adaptations.”

**2.2. Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses<sup>9</sup>**

As regards Directive 93/15/EEC, powers are conferred on the Commission in particular to adapt the Directive to take account of any future amendments to the United Nations recommendations and to set the conditions for the application of Article 14, second paragraph. Since those measures are of general scope and are designed to amend non-essential elements of Directive 93/15/EEC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 93/15/EEC is amended as follows:

(1) Article 13 is replaced by the following:

*“Article 13*

1. The Commission shall be assisted by a committee.

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

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<sup>9</sup> OJ L 121, 15.05.1993, p. 20.

3. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
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 Commission shall, in accordance with the procedure referred to in paragraph 3, adopt implementing measures in particular to take account of any future amendments to the United Nations recommendations.”

(2) The second paragraph of Article 14 is replaced by the following:

“Member States shall ascertain whether such undertakings possess a system for keeping track of explosives such that those holding explosives can be identified at any time. The Commission may adopt measures setting the conditions for the application of this paragraph. 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 13(4).”

### **2.3. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors<sup>10</sup>**

As regards Directive 2000/14/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 2000/14/EC is amended as follows:

(1) Article 18 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.

(2) The following Article 18a is inserted:

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<sup>10</sup> OJ L 162, 3.7.2000, p.1.

*“Article 18a*

The Commission shall adopt implementing measures for the adaptation to technical progress of Annex III, provided they do not have any direct impact on the measured sound power level of equipment listed in Article 12, in particular through the inclusion of references to relevant European standards.

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(2).”

(3) In Article 19, point (b) is replaced by the following:

“(b) assist the Commission in the adaptation to technical progress of Annex III”.

**2.4. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers<sup>11</sup>**

As regards Regulation (EC) No 2003/2003, power should in particular be conferred on the Commission to adapt its annexes to technical progress, to adapt the measuring, sampling and analysis methods, to adopt rules regarding control measures and to include new types of EC fertilisers. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2003/2003, 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 2003/2003 is amended as follows:

(1) In Article 29, paragraph 4 is replaced by the following:

“4. The Commission shall adapt and modernise the measuring, sampling and analysis methods and shall, wherever possible, use European Standards. 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 32(3). The same procedure shall apply to the adoption of implementing rules needed to specify the control measures provided for in this Article and in Articles 8, 26 and 27. Such rules shall in particular address the question of the frequency with which tests need to be repeated, as well as measures that are designed to ensure that the fertiliser put on the market is identical with the fertiliser tested.”

(2) Article 31 is amended as follows:

(a) Paragraph 1 is replaced by the following:

“1. The Commission shall adapt Annex I to include new types of fertilisers.”

(b) Paragraph 3 is replaced by the following:

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<sup>11</sup> OJ L 304, 21.11.2003, p. 1.

“3. The Commission shall adapt the Annexes to take account of technical progress.”

(c) The following paragraph 4 is added:

“4. The measures referred to in paragraphs 1 and 3, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).”

(3) Article 32 is replaced by the following:

*“Article 32*

*Committee procedure*

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.  
  
The time limit laid down in Article 5(6) of Decision 1999/468/EC shall be three months.
3. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.”

**2.5. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version)<sup>12</sup>**

As regards Directive 2004/9/EC, power should in particular be conferred on the Commission to adapt Annex I to technical progress and change the formula in Article 2(2). Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/9/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 2004/9/EC is amended as follows:

(1) Article 7 is replaced by the following:

*“Article 7*

1. The Commission shall be assisted by the Committee established by Article 29(1) of Directive 67/548/EEC(\*), hereinafter “the Committee”.

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<sup>12</sup> OJ L 50, 20.2.2004, p. 28.

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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be 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.

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(\*) OJ 196, 16.8.1967, p. 1, as amended by Council Regulation (EC) No 807/2003 of 14 April 2003, OJ L 122, 16.5.2003"

- (2) In Article 8, paragraph 2 is replaced by the following:

“2. The Commission shall adopt implementing measures for the following:

- (a) adaptation of the formula referred to in Article 2(2);
- (b) the adaptation of 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 7(3).”

**2.6. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)<sup>13</sup>**

As regards Directive 2004/10/EC, power should in particular be conferred on the Commission to adapt the Annex to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/10/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 2004/10/EC is amended as follows:

- (1) The following Article 3a is inserted:

*“Article 3a*

The Commission may adapt the Annex to technical progress, with regard to principles of GLP.

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<sup>13</sup> OJ L 50, 20.2.2004, p. 44.

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 4(2).”

- (2) Article 4 is replaced by the following:

*“Article 4*

1. The Commission shall be assisted by the Committee established by Article 29(1) of Directive 67/548/EEC(\*).
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.

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(\*) OJ 196, 16.8.1967, p. 1, as amended by Council Regulation (EC) No 807/2003 of 14 April 2003, OJ L 122, 16.5.2003.”

- (3) In Article 5(2) the third subparagraph is replaced by the following:

“The Commission may adopt implementing measures to introduce necessary technical adaptations of 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 4(2).

In the case referred to in the third subparagraph the Member State which adopted the safeguard measures may maintain them until the entry into force of those adaptations.”

**2.7. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors<sup>14</sup>**

As regards Regulation (EC) No 273/2004, power should in particular be conferred on the Commission to adopt measures for the implementation of the Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 273/2004, 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 273/2004 is amended as follows:

- (1) Article 14 is amended as follows:
- (a) the introductory sentence is replaced by the following:

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<sup>14</sup> OJ L 47, 18.2.2004, p. 1.

“Where necessary, the Commission shall adopt implementation measures concerning the following:”

(b) the following second and third paragraphs are added:

“The measures referred to in points (a) to (e) of the first paragraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

The measures referred to in point (f) of the first paragraph shall be adopted in accordance with the procedure referred to in Article 15(2)”

(2) Article 15 is replaced by the following:

*“Article 15*

*Committee*

1. The Commission shall be assisted by the Committee set up in Article 30 of Council Regulation (EC) No 111/2005(\*).
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The time limit laid down in Article 4(3) of Decision 1999/468/EC shall be 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.

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(\*) OJ L 22, 26.1.2005, p. 1.”

**2.8. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents<sup>15</sup>**

As regards Regulation (EC) No 648/2004, power should in particular be conferred on the Commission to adapt its annexes and to adopt any amendments or additions necessary for applying the rules of this Regulation to solvent-based detergents, where necessary. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 648/2004, 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 648/2004 is amended as follows:

(1) Article 12 is replaced by the following:

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<sup>15</sup> OJ L 104, 8.4.2004, p.1.



*“Article 12*

*Committee procedure*

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

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

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

- (2) Article 13 is replaced by the following:

*“Article 13*

*Adaptation of the Annexes*

1. The Commission shall adopt any amendments necessary for adapting the Annexes and shall, wherever possible, use European Standards.
2. The Commission shall adopt any amendments or additions necessary for applying the rules of this Regulation to solvent-based detergents.
3. The measures referred to in paragraphs 1 and 2, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).”

- (3) In Annex VII, point A, the antepenultimate paragraph is replaced by the following:

“If individual risk-based concentration limits for the fragrance allergens are subsequently established by the SCCNFP, the Commission shall propose the adoption of such limits to replace the limit of 0.01% mentioned above. 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 12(3).”

**2.9. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>16</sup>**

As regards Regulation (EC) No 726/2004, power should in particular be conferred on the Commission to adapt certain provisions and annexes, to adopt arrangements and principles and guidelines, and to lay down specific conditions of application. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 726/2004 and/or to supplement this Regulation 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 726/2004 is amended as follows:

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

“4. After the competent committee of the Agency has been consulted, the Commission may re-examine the Annex in the light of technical and scientific progress and may adopt any necessary amendments without extending the scope of the centralised procedure.

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 87(2a).”

(2) In Article 14(7), the third subparagraph is replaced by the following:

“The Commission shall adopt a Regulation laying down provisions for granting such authorisation. 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 87(2a).”

(3) In Article 16, paragraph 4 is replaced by the following:

“4. The Commission shall, after consulting the Agency, adopt appropriate provisions for the examination of variations to marketing authorisations in the form of a 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 87(2a).”

(4) Article 24 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

“The holder of the marketing authorisation for a medicinal product for human use shall ensure that all suspected serious unexpected adverse reactions and any suspected transmission via a medicinal product of any infectious agent occurring in

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<sup>16</sup> OJ L 136, 30. 4.2004, p. 1.

the territory of a third country are reported promptly to Member States and the Agency, and no later than 15 days following receipt of the information. The Commission shall adopt provisions for the reporting of suspected unexpected adverse reactions which are not serious, whether occurring in the Community or in a third country. 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 87(2a).”

(b) paragraph 4 is replaced by the following:

“4. The Commission may lay down provisions to amend paragraph 3 in view of experience gained with its operation. 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 87(2a).”

(5) Article 29 is replaced by the following:

*“Article 29*

The Commission may adopt any amendment which may be necessary to update the provisions of this Chapter in order to take account of scientific and technical progress. 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 87(2a).”

(6) In Article 41, paragraph 6 is replaced by the following:

“6. The Commission shall, after consulting the Agency, adopt appropriate provisions for the examination of variations to marketing authorisations in the form of a 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 87(2a).”

(7) Article 49 is amended as follows:

(a) in paragraph 2 the first subparagraph is replaced by the following:

“The holder of the marketing authorisation for a veterinary medicinal product shall ensure that all suspected serious unexpected adverse reactions, and adverse human reactions, and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country are reported promptly to the Member States and the Agency, and no later than 15 days following receipt of the information. The Commission shall adopt provisions for the reporting of suspected unexpected adverse reactions which are not serious, whether occurring in the Community or in a third country. Those measures, designed to amend non-essential elements of this regulation by supplementing it, shall be adopted in accordance with the procedure referred to in Article 87(2a).”

(b) paragraph 4 is replaced by the following:

“The Commission may lay down provisions to amend paragraph 3 in view of experience gained with its operation. Those measures, designed to amend non-essential elements of this regulation, shall be adopted in accordance with the procedure referred to in Article 87(2a).”

(8) Article 54 is replaced by the following:

*“Article 54*

The Commission may adopt any amendment which may be necessary to update the provisions of this Chapter in order to take account of scientific and technical progress. 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 87(2a).”

(9) In Article 70, paragraph 2 is replaced by the following:

“2. However, the Commission shall adopt provisions establishing the circumstances in which small and medium-sized enterprises may pay reduced fees, defer payment of the fee, or receive administrative assistance. 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 87(2a).”

(10) In Article 84(3), the first subparagraph is replaced by the following:

“At the Agency’s request, the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations. The maximum amounts as well as the conditions and methods for collection of these penalties 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 87(2a).”

(11) Article 87 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 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof”.

b) Paragraph 4 is deleted.

### 3. ENVIRONMENT

#### 3.1. Council Directive 82/883/EEC of 3 December 1982 on procedures for the surveillance and monitoring of environments concerned by waste from the titanium dioxide industry<sup>17</sup>

As regards Directive 82/883/EEC, power should in particular be conferred on the Commission to adapt the contents of the Annexes as regards parameters listed in the 'optional determination' column and reference methods of measurement to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 82/883/EEC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 82/883/EEC is amended as follows:

- (1) Article 9 is replaced by the following:

*“Article 9*

The Commission shall adopt the requisite amendments to adapt to scientific and technical progress the contents of the Annexes as regards parameters listed in the 'optional determination' column and reference methods of measurement.

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 11(2).”

- (2) Article 11 is replaced by the following:

*“Article 11*

1. The Commission shall be assisted by the committee on adaptation to technical progress.
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.”

#### 3.2. Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture<sup>18</sup>

As regards Directive 86/278/EEC, power should in particular be conferred on the Commission to adapt to technical and scientific progress provisions of the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 86/278/EEC, 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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<sup>17</sup> OJ L 378, 31.12.1982, p. 1.

<sup>18</sup> OJ L 181, 4.7.1986, p. 6.

Accordingly, Directive 86/278/EEC is amended as follows:

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

*“Article 13*

The Commission shall adapt to technical and scientific progress the provisions of the Annexes to the Directive, except for the parameters and values listed in Annexes I A, I B and I C, any factors likely to affect the evaluation of the values, and the parameters for analysis referred to in Annexes II A and II B.

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

- (2) Article 15 is replaced by the following:

*“Article 15*

1. The Commission shall be assisted by the Committee for adapting this Directive to technical and scientific progress.

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.”

**3.3. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste<sup>19</sup>**

As regards Directive 94/62/EC, power should in particular be conferred on the Commission to examine and, where necessary, review the illustrative examples for the definition of packaging and to determine the conditions under which concentration levels of heavy metals present in packaging or packaging components will not apply to some materials and product loops, the types of packaging exempted from the requirement regarding concentration levels and the technical measures necessary to deal with any difficulties encountered in applying the provisions of this Directive. Since those measures are of general scope and are designed to amend non-essential elements of Directive 94/62/EC or 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 94/62/EC is amended as follows:

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

“The Commission shall, as appropriate, examine and, where necessary, review the illustrative examples for the definition of packaging given in Annex I. As a priority, the following items shall be addressed: CD and video cases, flower pots, tubes and

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<sup>19</sup> OJ L 365, 31.12.1994, p. 10.

cylinders around which flexible material is wound, release paper of self-adhesive labels and wrapping paper. 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)."

(2) In Article 11, paragraph 3 is replaced by the following:

"3. The Commission shall determine the conditions under which the concentration levels referred to in paragraph 1 will not apply to recycled materials and to product loops which are in a closed and controlled chain, as well as the types of packaging which are exempted from the requirement referred to in paragraph 1, third indent.

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

(3) In Article 12, paragraph 3 is replaced by the following:

"3. In order to harmonise the characteristics and presentation of the data produced and to make the data of the Member States compatible, Member States shall provide the Commission with their available data by means of formats which shall be adopted on the basis of Annex III, in accordance with the regulatory procedure referred to in Article 21(2)."

(4) Article 19 is replaced by the following:

#### *"Article 19*

##### *Adaptation to scientific and technical progress*

(a) The amendments necessary for adapting to scientific and technical progress the identification system (as referred to in Article 8(2) and Article 10, second paragraph, last indent), and the formats relating to the database system (as referred to in Article 12(3) and Annex III) shall be adopted in accordance with the regulatory procedure referred to in Article 21(2).

(b) The Commission shall adopt the amendments necessary for adapting to scientific and technical progress the illustrative examples on the definition of packaging (as referred to 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 21(3)."

(5) In Article 20, paragraph 1 is replaced by the following:

"1. The Commission shall determine technical measures necessary to deal with any difficulties encountered in applying the provisions of this Directive in particular to inert packaging materials, put on the market in very small quantities (i.e. approximately 0.1% by weight) in the Community, primary packaging for medical devices and pharmaceutical products, small packaging

and luxury packaging. 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).”

(6) In Article 21, 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.”

### **3.4. Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels and amending Directive 93/12/EEC<sup>20</sup>**

As regards Directive 1999/32/EC, power should in particular be conferred on the Commission to establish criteria for the use of emission abatement technologies by ships of all flags in enclosed ports, harbours and estuaries in the Community and to adopt amendments necessary to make technical adaptations to some provisions in the light of scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 1999/32/EC or 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 1999/32/EC is amended as follows:

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

“3. Criteria shall be established by the Commission for the use of emission abatement technologies by ships of all flags in enclosed ports, harbours and estuaries in the Community. 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 9(2). The Commission shall communicate these criteria to the IMO.”

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

“4. Any amendments necessary to make technical adaptations to Article 2, points 1, 2, 3, 3a, 3b and 4, or Article 6(2) in the light of scientific and technical progress shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9(2). Such adaptations shall not result in any direct changes to the scope of this Directive or to limits on sulphur in fuel specified in this Directive.”

(3) Article 9 is replaced by the following:

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<sup>20</sup> OJ L 121, 11.5.1999, p. 13.



*“Article 9*

*Committee*

1. The Commission shall be assisted by a 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.”

**3.5. Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants<sup>21</sup>**

As regards Directive 2001/81/EC, power should in particular be conferred on the Commission to update the methodologies to be used in accordance with Annex III. Since those measures are of general scope and are designed to amend non-essential elements of that Directive, inter alia 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, Directive 2001/81/EC is amended as follows:

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

“4. Any updating of the methodologies to be used in accordance with Annex III, shall be adopted by the Commission. 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 13(3).”

- (2) 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.”

**3.6. Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC<sup>22</sup>**

As regards Directive 2003/87/EC, power should in particular be conferred on the Commission to adopt provisions necessary for the implementation of Article 11b(5), to adopt a Regulation for a standardised and secured system of registries including provisions concerning the use and identification of CERs and ERUs in the Community scheme and the monitoring of the level of such use, to amend Annex III as laid down in Article 22, to approve inclusion of activities and greenhouse gases not listed in Annex I, to draw up any necessary provisions relating to the mutual recognition of allowances under agreements with third countries, and to

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<sup>21</sup> OJ L 309, 27.11.2001, p. 22.

<sup>22</sup> OJ L 275, 25.10.2003, p. 32.

adopt standardised or accepted measures for monitoring of emissions of other greenhouse gases. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2003/87/EC or 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 2003/87/EC is amended as follows:

(1) In Article 11b, paragraph 7 is replaced by the following:

“7. Provisions for the implementation of paragraphs 3 and 4, particularly in respect of the avoidance of double counting, shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 23(2). The Commission shall adopt provisions for the implementation of paragraph 5 where the host party meets all eligibility requirements for JI project activities. 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 23(3).”

(2) In Article 19, paragraph 3 is replaced by the following:

“3. In order to implement this Directive, the Commission shall adopt a Regulation for a standardised and secured system of registries in the form of standardised electronic databases containing common data elements to track the issue, holding, transfer and cancellation of allowances, to provide for public access and confidentiality as appropriate and to ensure that there are no transfers incompatible with obligations resulting from the Kyoto Protocol. That Regulation shall also include provisions concerning the use and identification of CERs and ERUs in the Community scheme and the monitoring of the level of such use. 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 23(3).”

(3) Article 22 is replaced by the following :

*“Article 22*

*Amendments to Annex III*

The Commission may amend Annex III, with the exception of criteria (1), (5) and (7), for the period from 2008 to 2012 in the light of the reports provided for in Article 21 and of the experience of the application of 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 23(3).”

(4) 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.”

(5) In Article 24, paragraph 1 is replaced by the following:

“1. Taking into account all relevant criteria, in particular effects on the internal market, potential distortions of competition, the environmental integrity of the scheme and reliability of the planned monitoring and reporting system, Member States may from 2008 apply emission allowance trading in accordance with this Directive to:

- a) installations which are not listed in Annex I, provided that inclusion of such installations is approved by the Commission in accordance with the procedure referred to in Article 23(2), and
- b) activities and greenhouse gases which are not listed in Annex I, provided that inclusion of such activities and greenhouse gases is approved 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 23(3).

From 2005 Member States may under the same conditions apply emissions allowance trading to installations carrying out activities listed in Annex I below the capacity limits referred to in that Annex.”

(6) In Article 25, paragraph 2 is replaced by the following:

“2. Where an agreement referred to in paragraph 1 has been concluded, the Commission shall adopt any necessary provisions relating to the mutual recognition of allowances under that agreement. 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 23(3).”

(7) In Annex IV, the paragraph under the heading “Monitoring of emissions of other greenhouse gases” is replaced by the following:

“Standardised or accepted methods shall be used, developed by the Commission in collaboration with all relevant stakeholders. 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 23(3).”

**3.7. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC<sup>23</sup>**

As regards Regulation (EC) No 850/2004, power should in particular be conferred on the Commission to specify some concentration limits in the annexes, to amend annexes whenever a substance is listed in the Convention or the Protocol, to modify the existing entries and to adapt annexes to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 850/2004, they

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<sup>23</sup> OJ L 158, 30.4.2004, p. 7.

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 850/2004 is amended as follows:

(1) Article 7 is amended as follows:

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

“(a) waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Community legislation, provided that the content of the listed substances in the waste is below the concentration limits to be specified 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 17(3). Until such time as concentration limits are specified in accordance with such procedure, the competent authority of a Member State may adopt or apply concentration limits or specific technical requirements in respect of the disposal or recovery of waste under this subparagraph;”

(b) In paragraph 5, the first subparagraph is replaced by the following:

“Concentration limits in Annex V, part 2 shall be established by the Commission for the purposes of paragraph 4(b) of this Article. 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 14 is replaced by the following:

#### *“Article 14*

##### *Amendment of Annexes*

1. Whenever a substance is listed in the Convention or the Protocol, the Commission shall amend Annexes I, II and III accordingly where appropriate.

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 16(3).

2. Whenever a substance is listed in the Convention or the Protocol, the Commission shall amend Annex IV accordingly where appropriate.

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).

3. The Commission shall adopt modifications to the existing entries in Annexes I to III, including their adaptation to scientific and technical progress.

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 16(3).

4. The Commission shall adopt modifications to the existing entries in Annex IV and modifications to Annex V, including their adaptation to scientific and technical progress.

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).”

- (3) Article 16 is amended as follows:

- (a) Paragraph 1 is replaced by the following:

“1. The Commission shall be assisted by the Committee established by Article 29 of Council Directive 67/548/EEC(\*) for all matters under this Regulation except for those relating to waste.

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(\*) OJ 196, 16.8.1967, p. 1, as amended by Council Regulation (EC) No 807/2003 of 14 April 2003, OJ L 122, 16.5.2003.”

- (b) 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 17, 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.”

### **3.8. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air<sup>24</sup>**

As regards Directive 2004/107/EC, power should in particular be conferred on the Commission to adapt certain provisions and Annexes to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/107/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 2004/107/EC is amended as follows:

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<sup>24</sup> OJ L 23, 26.1.2005, p. 3.

(1) Article 4 is amended as follows:

(a) Paragraph 9 is replaced by the following:

“9. Irrespective of concentration levels, one background sampling point shall be installed every 100000 km<sup>2</sup> for the indicative measurement, in ambient air, of arsenic, cadmium, nickel, total gaseous mercury, benzo(a)pyrene and the other polycyclic aromatic hydrocarbons referred to in paragraph 8 and of the total deposition of arsenic, cadmium, mercury, nickel, benzo(a)pyrene and the other polycyclic aromatic hydrocarbons referred to in paragraph 8. Each Member State shall set up at least one measuring station; however, Member States may, by agreement, and in accordance with guidelines to be drawn up under the procedure referred to in Article 6(2), set up one or several common measuring stations, covering neighbouring zones in adjoining Member States, to achieve the necessary spatial resolution. Measurement of particulate and gaseous divalent mercury is also recommended. Where appropriate, monitoring shall be coordinated with the European Monitoring and Evaluation of Pollutants (EMEP) monitoring strategy and measurement programme. The sampling sites for these pollutants shall be selected in such a way that geographical variation and long-term trends can be identified. Sections I, II and III of Annex III shall apply.”

(b) Paragraph 15 is replaced by the following:

“15. Any amendments necessary to adapt the provisions of this Article and of Section II of Annex II and of Annexes III, IV and V to scientific and technical progress shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(3). They may not result in any direct or indirect changes to target values.”

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

“4. The Commission shall adopt, in accordance with the procedure referred to in Article 6(2), any detailed arrangements for forwarding the information to be provided under paragraph 1 of this Article.”

(3) In Article 6, 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) Annex V, point V is replaced by the following:

“V. Reference air quality modelling techniques

Reference air quality modelling techniques cannot be specified at present. The Commission may make amendments to adapt this point 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 6(3).”

### 3.9. Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste<sup>25</sup>

As regards Regulation (EC) No 1013/2006, power should in particular be conferred on the Commission to determine an issue as described in Article 11(3) of Regulation 1013/2006, to amend the annexes as laid down in Article 58 of Regulation 1013/2006 and to adopt additional measures as laid down in Article 59 of Regulation 1013/2006. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1013/2006 or to supplement Regulation (EC) No 1013/2006 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 1013/2006 is amended as follows:

- (1) In Article 11(3), the third subparagraph is replaced by the following:

“If there is no satisfactory solution, either Member State may refer the matter to the Commission. The issue shall then be determined in accordance with the regulatory procedure referred to in Article 59a(2).”

- (2) Article 58 is replaced by the following:

#### *“Article 58*

1. The Commission may amend the Annexes to take account of scientific and technical progress. 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 59a(3). In addition:
  - (a) Annexes I, II, III, IIIA, IV and V shall be amended to take account of changes agreed under the Basel Convention and the OECD Decision;
  - (b) unclassified wastes may be added to Annex IIIB, IV or V on a provisional basis pending a decision on their inclusion in the relevant Annexes to the Basel Convention or to the OECD Decision;
  - (c) following the submission of a request by a Member State, mixtures of two or more wastes listed in Annex III may be considered for inclusion in Annex IIIA in the cases referred to in Article 3(2) on a provisional basis pending a decision on their inclusion in the relevant Annexes to the Basel Convention or to the OECD Decision. Annex IIIA may contain the proviso that one or more of the entries therein shall not apply for exports to countries to which the OECD Decision does not apply;
  - (d) the exceptional cases referred to in Article 3(3) shall be determined and, where necessary, such waste shall be added to Annexes IVA and V and deleted from Annex III;

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<sup>25</sup> OJ L 190, 12.7.2006, p. 1.

- (e) Annex V shall be amended to reflect agreed changes to the list of hazardous waste adopted in accordance with Article 1(4) of Directive 91/689/EEC;
  - (f) Annex VIII shall be amended to reflect relevant international conventions and agreements.
2. When amending Annex IX, the Committee established by Council Directive 91/692/EEC shall be fully associated with the deliberations.”
- (3) Article 59 is replaced by the following:

*“Article 59*

*Additional measures*

1. The Commission may adopt, in accordance with the regulatory procedure referred to in Article 59a(2), the following additional measures related to the implementation of this Regulation:
- (a) guidelines for the application of Article 12(1)(g);
  - (b) guidelines on the application of Article 15 in relation to the identification and tracking of waste undergoing substantial changes in the interim recovery or disposal operation;
  - (c) guidelines for the cooperation of competent authorities with regard to illegal shipments as referred to in Article 24;
  - (d) technical and organisational requirements for the practical implementation of electronic data interchange for the submission of documents and information in accordance with Article 26(4);
  - (e) further guidance concerning the use of languages referred to in Article 27;
  - (f) further clarification of the procedural requirements of Title II as regards their application to exports, imports and transit of waste from, to, and through the Community;
  - (g) further guidance concerning undefined legal terms.
2. The Commission may adopt implementing measures concerning the following:
- (a) a method for calculating the financial guarantee or equivalent insurance as set out in Article 6;
  - (b) further conditions and requirements in relation to pre-consented recovery facilities as referred to in Article 14.



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 59a(3)."

- (4) The following Article 59a is inserted:

*"Article 59a*

*Committee procedure*

1. The Commission shall be assisted by the committee set up in Article 18(1) of Directive 2006/12/EC(\*).
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limit laid down in Article 5(6) of Decision 1999/468/EC shall be 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.

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(\* ) OJ L 114, 27.4.2006, p. 9."

- (5) Article 63 is amended as follows:

- (a) in paragraph 2, the third subparagraph is replaced by the following:

"With the exception of glass waste, paper waste and waste pneumatic tyres, this period may be extended until no later than 31 December 2012 in accordance with the regulatory procedure referred to in Article 59a(2)"

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

"This period may be extended until no later than 31 December 2012 in accordance with the procedure referred to in Article 59a(2)."

- (c) paragraph 5 is amended as follows:

- (i) the third subparagraph is replaced by the following:

"This period may be extended until no later than 31 December 2015 in accordance with the regulatory procedure referred to in Article 59a(2)."

- (ii) the fifth subparagraph is replaced by the following:

"This period may be extended until no later than 31 December 2015 in accordance with the regulatory procedure referred to in Article 59a(2)."

#### 4. EUROSTAT

##### 4.1. Council Regulation (EEC) No 3924/91 of 19 December 1991 on the establishment of a Community survey of industrial production<sup>26</sup>

As regards Regulation (EEC) No 3924/91, power should in particular be conferred on the Commission to establish and update the list of products concerned by that Regulation. Power should also be conferred on it to adopt detailed rules as regards representativeness and periodicity for certain products and to establish the arrangements for survey contents and implementing measures, including the measures for adjustment to technical progress concerning collection of data and the processing of the results. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EEC) No 3924/91, 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 (EEC) No 3924/91 is amended as follows:

(1) In Article 2, paragraph 6 is replaced by the following:

“6. The Prodcom list, the information actually collected for each heading and the other implementing procedures of this Regulation shall be established and updated 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 10(3).”

(2) Article 3 is amended as follows:

a) In paragraph 2 the words “in Article 10” are replaced by the words “in Article 10(2)”.

b) Paragraph 5 is replaced by the following:

“5. Detailed rules for applying this Article, including measures for adjustment to technical progress, shall be adopted, as necessary, 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 10(3).”

(3) Article 4 is replaced by the following:

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<sup>26</sup> OJ L 374, 31.12.1991, p.1. Regulation last amended by Regulation (EC) No 1893/2006 of the European Parliament and of the Council (OJ L 393, 30.12.2006, p. 1).

#### *“Article 4*

##### *Survey periods*

The survey shall cover an annual period of one calendar year.

However, for certain headings in the Prodcom list, monthly or quarterly surveys may be decided 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 10(3).”

- (4) In Article 5, paragraph 1 is replaced by the following:
- “1. The required information shall be collected by the Member States using survey questionnaires the content of which shall comply with the arrangements defined 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 10(3).”
- (5) In Article 6 and in Article 7(2) the words “in Article 10” are replaced by the words “in Article 10(2)”.
- (6) Articles 9 and 10 are replaced by the following:

#### *“Article 9*

##### *Implementing measures*

The measures for adjustment to technical progress concerning collection of data and the processing of the results shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be laid down in accordance with the regulatory procedure with scrutiny referred to in Article 10(3). Other measures for implementing this Regulation shall be adopted by the Commission in accordance with the procedure referred to in Article 10(2).

#### *Article 10*

##### *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, Article 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

3. Where reference is made to this paragraph, Articles 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 181, 28.6.1989, p. 47.”

#### **4.2. Council Directive 96/16/EC of 19 March 1996 on statistical surveys of milk and milk products<sup>27</sup>**

As regards Directive 96/16/EC, power should in particular be conferred on the Commission to adopt the definitions for the agricultural holdings among which Member States must conduct surveys of the production of milk and its use, determine the list of milk products covered by the surveys and lay down standard definitions to be used for communicating the results to the Commission. Since those measures are of general scope and are designed to supplement Directive 96/16/EC by adding 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 96/16/EC is amended as follows:

- (1) Article 1(2) is replaced by the following:
  - "2) shall carry out annual surveys of the production of milk and its use among agricultural holdings as defined by the Commission; the measures defining agricultural holdings, 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 3(2) and (3) are replaced by the following:
  - "2. The list of milk products covered by the surveys 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 7(3).
  3. The standard definitions to be used for communicating the results for the various products shall be drawn up 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 7(3)."
- (3) In Article 4(2) and Article 6(1), the words "in Article 7" are replaced by "in Article 7(2)".

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<sup>27</sup> OJ L 78, 28.3.1996, p. 27. Directive as last amended by Directive 2003/107/EC of the European Parliament and of the Council (OJ L 7, 13.1.2004, p. 40).

- (4) Article 7 is replaced by the following:

*"Article 7*

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics set up by Council Decision 72/279/EEC(\*).
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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be 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.

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(\* ) OJ L 179, 7.8.1972, p. 1."

**4.3. Directive 2001/109/EC of the European Parliament and of the Council of 19 December 2001 concerning the statistical surveys to be carried out by the Member States in order to determine the production potential of plantations of certain species of fruit trees<sup>28</sup>**

As regards Directive 2001/109/EC, power should in particular be conferred on the Commission to amend the list of species of fruit trees and the table of species surveyed in the Member States, to adopt the detailed rules for the application of certain articles and to determine the boundaries of the production areas to be adopted for Member States. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/109/EC and to supplement the 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 2001/109/EC is amended as follows:

- (1) The third subparagraph of Article 1(2) is replaced by the following:

"The list of said species and the said table may be amended by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(2)."

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<sup>28</sup> OJ L 13, 16.1.2002, p. 21. Directive as last amended by Directive 2006/110/EC (OJ L 363, 20.12.2006, p. 418).

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

"2. Detailed rules for applying this Article 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 8(2)."

(3) Article 3(4) is replaced by the following:

"4. Detailed rules for applying this Article 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 8(2)."

(4) Article 4(2) is replaced by the following:

"2. The results referred to in paragraph 1 shall be supplied for each production area. The boundaries of the production areas to be adopted for Member States 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 8(2)."

(5) Article 8 is replaced by the following:

*"Article 8*

1. The Commission shall be assisted by the Standing Committee on Agricultural Statistics set up by Council Decision 72/279/EEC(\*).
2. Where reference is made to this paragraph, Article 5a(1) to (4) and 5(a), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(\* ) OJ L 179, 7.8.1972, p.1."

**4.4. Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics<sup>29</sup>**

As regards Regulation (EC) No 91/2003, power should in particular be conferred on the Commission to adapt the definitions and adopt additional provisions, to adapt the content of the annexes and to define the guidelines for the reports on the quality and comparability of the results. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 91/2003 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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<sup>29</sup> OJ L 14, 21.1.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1192/2003 (OJ L 167, 4.7.2003, p. 13).

Accordingly, Regulation (EC) No 91/2003 is amended as follows:

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

"2. The definitions referred to in paragraph 1 may be adapted, and additional definitions needed to ensure harmonisation of statistics 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 11(3)."

(2) Article 4 is amended as follows:

a) Paragraph 2 is replaced by the following:

"2. Annexes B and D set out simplified reporting requirements, which may be used by Member States as alternatives to the normal detailed reporting set out in Annexes A and C, for undertakings for which the total volume of goods or passenger transport is less than 500 million tonne-km or 200 million passenger-km respectively. These thresholds may be adapted 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 11(3)."

b) Paragraph 5 is replaced by the following:

"5. The contents of the Annexes may be adapted 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 11(3)."

(3) Article 10 is replaced by the following:

#### *"Article 10*

##### *Implementing procedures*

1. The arrangements for transmission of the data to Eurostat shall be made in accordance with the procedure specified in Article 11(2).
2. The Commission shall adopt the following implementing measures:
  - a) adaptation of the thresholds for simplified reporting (Article 4);
  - b) adaptation of the definitions and adoption of additional definitions (Article 3(2));
  - c) adaptation of the contents of the annexes (Article 4);
  - d) definition of the guidelines for the reports on the quality and comparability of the results (Articles 8 and 9).

Those measures, designed to amend or supplement non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3)."

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

*"Article 11*

*Committee*

1. The Commission shall be assisted by the Statistical Programme Committee instituted 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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(a), 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 181, 28.6.1989, p. 47."

- (5) In point 5 of Annex H, and in Annex J, the words "in Article 11(2)" are replaced by "in Article 11(3)".

**4.5. Regulation (EC) No 437/2003 of the European Parliament and of the Council of 27 February 2003 on statistical returns in respect of the carriage of passengers, freight and mail by air<sup>30</sup>**

As regards Regulation (EC) No 437/2003, power should in particular be conferred on the Commission to amend the definitions in the Regulation, to adopt additional provisions and to adapt the content of the annexes thereto. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 437/2003, 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 437/2003 is amended as follows:

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<sup>30</sup> OJ L 66, 11.3.2003, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1.)



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

"2. Each Member State shall collect all data set out in Annex I for all Community airports in its territory with traffic in excess of 150 000 passenger units annually.

A list of Community airports covered by the first subparagraph shall be drawn up by the Commission and, if necessary, updated. 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 11(3)."

(2) Article 5 is replaced by the following:

*"Article 5*

*Accuracy of statistics*

The collection of data shall be based on complete returns, unless other standards of accuracy are 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 11(3)."

(3) Article 7(2) is replaced by the following:

"2. The results shall be transmitted according to the data files shown in Annex I. The files shall be specified by the Commission. 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 11(3).

The medium to be used for transmission shall be specified by the Commission in accordance with the procedure laid down in Article 11(2)."

(4) Article 10 is replaced by the following:

*"Article 10*

*Implementing arrangements*

1. The following implementing measures shall be adopted in accordance with the procedure referred to in Article 11(2):

- description of the data codes and the medium to be used for transmission of results to the Commission (Article 7),
- dissemination of statistical results (Article 8).

2. The Commission shall adopt the following implementing measures:
  - adaptation of the specifications in the Annexes to this Regulation,
  - adaptation of the data collection characteristics (Article 3),
  - the list of Community airports covered by Article 3(2),
  - accuracy of statistics (Article 5),
  - description of the data files (Article 7).

Those measures, designed to amend or supplement non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3)."

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

*"Article 11*

*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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be three months.
3. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(a), 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 181, 28.6.1989, p. 47."

**4.6. Regulation (EC) No 48/2004 of the European Parliament and of the Council of 5 December 2003 on the production of annual Community statistics on the steel industry for the reference years 2003-2009<sup>31</sup>**

As regards Regulation (EC) No 48/2004, powers should in particular be conferred on the Commission to establish and update the list of characteristics concerned by that Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 48/2004, inter alia by supplementing it by the addition of new non-

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<sup>31</sup> OJ L 7, 13.1.2004, p. 1.

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 48/2004 is amended as follows:

(1) Article 7 is replaced by the following:

*“Article 7*

*Implementing measures*

1. The measures for the implementation of this Regulation concerning transmission formats and the first transmission period shall be adopted in accordance with the procedure referred to in Article 8(2).
2. The measures for the implementation of this Regulation concerning any alteration to the list of characteristics, provided that no significant additional burden is imposed upon the Member States, 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).”

(2) In Article 8, 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. INTERNAL MARKET**

### **5.1. Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids<sup>32</sup>**

As regards Directive 2004/25/EC, power should be conferred on the Commission to adopt rules for the application of Article 6(3) on the contents of the offer document. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia by supplementing it or 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 2004/25/EC provided for a time restriction concerning the implementing powers conferred on the Commission. In their joint statement on Decision 2006/512/EC amending Decision 1999/468/EC, the European Parliament, the Council and the Commission have stated that Decision 2006/512/EC provides a horizontal and satisfactory solution to the European Parliament's wish to scrutinise the implementation of instruments adopted under the co-decision procedure and that, accordingly, implementing powers should be conferred on the

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<sup>32</sup> OJ L 142, 30.4.2004, p. 12.

Commission without time limit. Following the introduction of the regulatory procedure with scrutiny, the provision establishing that time restriction in Directive 2004/25/EC should be deleted.

Accordingly, Directive 2004/25/EC is amended as follows:

- (1) In Article 6, paragraph 4 is replaced by the following:
  - “4. The Commission shall adopt rules for the application of paragraph 3. 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 18(2).”
- (2) Article 18 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. HEALTH AND CONSUMER PROTECTION**

### **6.1. Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs<sup>33</sup>**

As regards Directive 79/373/EEC, power should in particular be conferred on the Commission to adopt exceptions to the prescriptions on the packaging of feedingstuffs and to amend the Annex. Since those measures are of general scope and are designed to amend non-essential elements of Directive 79/373/EEC and to supplement the 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 79/373/EEC is amended as follows:

- (1) Article 4(2) is replaced by the following:
  - "2. The Commission shall adopt exceptions to the principle of paragraph 1 to be authorised at Community level. 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 13(3), provided that the identity and quality of the compound feedingstuffs concerned are ensured."
- (2) Article 10 is replaced by the following:

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<sup>33</sup> OJ L 86, 6.4.1979, p. 30.

## *"Article 10*

In the light of advances in scientific and technical knowledge:

- a) categories grouping several feed materials shall be established not later than 22 January 1991 in accordance with the procedure laid down in Article 13(2);
- b) methods of calculating the energy value of compound feedingstuffs may be established in accordance with the procedure laid down in Article 13(2);
- c) amendments to the Annex shall be adopted by the Commission; those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3)."

(3) Article 13(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."

### **6.2. Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>34</sup>**

As regards Directive 82/471/EEC, power should in particular be conferred on the Commission to adopt amendments and to lay down the criteria required to define the products included in the Directive. Since those measures are of general scope and are designed to amend non-essential elements of Directive 82/471/EEC and to supplement the 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. On grounds of urgency, the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to the Directive must be used.

Accordingly, Directive 82/471/EEC is amended as follows:

(1) Article 6 is amended as follows:

(a) Paragraph 1 is replaced by the following:

- "1. Amendments to be made to the Annex as a result of developments in scientific or technical knowledge shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3). In the case of the products referred to in Sections 1.1 and 1.2 of the Annex, the Commission shall consult the Scientific Committee for Animal Nutrition and the Scientific Committee for Food.

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<sup>34</sup> OJ L 213, 21.7.1982, p. 8.

However, in the case of products obtained from yeasts of the 'Candida' variety and cultivated on n-alkanes, referred to in Article 4(1), the Commission shall adopt a position within two years of notification of this Directive, after consulting the Scientific Committee for Animal Nutrition and the Scientific Committee for Food."

(b) Paragraph 3 is replaced by the following:

"3. Criteria making it possible to define the products included in this Directive, particularly the criteria of composition and purity and the physico-chemical and biological properties, may be adopted by the Commission in the light of scientific and technical knowledge. 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 13(3)."

(2) In the second subparagraph of Article 7(2), "Article 13" is replaced by "Article 13(2)".

(3) Article 8(3) is replaced by the following:

"3. If the Commission considers that amendments to this Directive are necessary to alleviate the difficulties referred to in paragraph 1 and to ensure the protection of human or animal health, it shall adopt such measures. 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 13(4). The Member State that has adopted safeguard measures may in that event retain them until the amendments have entered into force."

(4) Article 13 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), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof."

(5) Article 14 is deleted.

**6.3. Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC<sup>35</sup>**

As regards Directive 96/25/EC, power should in particular be conferred on the Commission to lay down and amend the list of materials whose circulation or use for animal nutrition purposes is restricted or prohibited and to amend the annex in the light of advances in scientific and technical knowledge. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/25/EC and to supplement the 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.

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 amendment of the list of materials whose circulation or use for animal nutrition purposes is restricted or prohibited.

On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny must be curtailed for the adoption of amendments to the annex in the light of advances in scientific and technical knowledge.

Accordingly, Directive 96/25/EC is amended as follows:

(1) The second indent of Article 5(1)(g) is replaced by the following:

"- Community measures included on a list to be drawn up 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 13(3)."

(2) Article 11 is replaced by the following:

*"Article 11*

1. A numerical coding system for the listed feed materials based on glossaries concerning the origin, part of the product/by-product used, processing and maturity/quality of the feed materials enabling feed to be identified at international level — in particular by name and description — may be adopted in accordance with the procedure referred to in Article 13(2).
2. The list of materials whose circulation or use for animal nutrition purposes is restricted or prohibited shall be drawn up by the Commission in order to ensure their compliance with Article 3. 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 13(3).

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<sup>35</sup> OJ L 125, 23.5.1996, p. 35.

3. The list referred to paragraph 2 shall be amended by the Commission in the light of advances in scientific and technical knowledge. 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 13(3). On imperative grounds of urgency, the Commission may use the urgent procedure referred to in Article 13(5) with a view to adopting those measures.
4. Amendments to be made to the Annex as a result of developments in scientific or technical knowledge shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(4)."

(3) Article 13 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 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."

#### **6.4. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed<sup>36</sup>**

As regards Directive 2002/32/EC, power should in particular be conferred on the Commission to amend Annexes I and II and adapt them in the light of developments in scientific and technical knowledge, and to lay down additional criteria for detoxification processes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/32/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.

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<sup>36</sup> OJ L 140, 30.5.2002, p. 10.



When, on imperative grounds of urgency, the time limits normally applicable 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 Annexes I and II in the light of developments in scientific and technical knowledge.

Accordingly, Directive 2002/32/EC is amended as follows:

(1) The first subparagraph of Article 7(2) is replaced by the following:

"An immediate decision shall be taken as to whether Annexes I and II should be amended. 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 11(4)."

(2) Article 8(1) and (2) are replaced by the following:

"1. The Commission shall adapt Annexes I and II in the light of developments in scientific and technical knowledge. 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 11(3). On imperative grounds of urgency, the Commission may use the urgent procedure referred to in Article 11(4) with a view to adopting those amendments.

2. Furthermore the Commission:

- shall periodically adopt consolidated versions of Annexes I and II incorporating any adaptations made pursuant to paragraph 1, in accordance with the procedure provided for in Article 11(2),

- may define acceptability criteria for detoxification processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes. 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 11(3)."

(3) Article 11 is replaced by the following:

#### *"Article 11*

1. The Commission shall be assisted by the Standing Committee for Feedingstuffs set up by Article 1 of Decision 70/372/EEC(\*).

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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be 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.

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(\* ) OJ L 170, 3.8.1970, p.1."

(4) Article 12 is deleted.

**6.5. Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movements of pet animals and amending Council Directive 92/65/EEC<sup>37</sup>.**

As regards Regulation (EC) No 998/2003, power should in particular be conferred on the Commission to amend the list of species of animals set out in Part C of Annex I and the lists of countries and territories set out in Parts B and C of Annex II. Since those measures are of general scope and are designed to amend non-essential elements of that Regulation, 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 adoption of the list of certain third countries.

Accordingly, Regulation (EC) No 998/2003 is amended as follows:

(1) Article 10 is amended as follows:

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

“The list of third countries provided for in part C of Annex II shall be drawn up by the Commission [before the date provided for in the second paragraph of Article 25]. To be included on that list, a third country must first demonstrate its status with regard to rabies and that.”

(b) The following second subparagraph is added:

“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 24(5).”

(2) Article 19 is replaced by the following:

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<sup>37</sup> OJ L 146, 13.6.2003, p. 1.

*“Article 19*

Part C of Annex I and parts B and C of Annex II may be amended by the Commission to take account of developments in the situation within Community territory or in third countries as regards diseases affecting the species of animals covered by this Regulation, in particular rabies, and, if need be, limit, for the purposes of this Regulation, the number of animals which can be moved. 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 24(4)”.

- (3) Article 21 is replaced by the following:

*“Article 21*

Any transitional implementing provisions may be adopted by the Commission to permit the changeover from the current arrangements to the arrangements established by 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 24(4)”

- (4) Article 24 is amended as follows:

- a) 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.”

- b) The following paragraph 5 is added:

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

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

**6.6. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC<sup>38</sup>**

As regards Directive 2003/99/EC, power should in particular be conferred on the Commission to establish coordinated monitoring programmes concerning zoonoses and zoonotic agents. 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

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<sup>38</sup> OJ L 325, 12.12.2003, p. 31.

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 urgency, it is necessary to apply the urgent procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to Annex I to Directive 2003/99/EC in order to add zoonoses and zoonotic agents to, or delete them from, the lists provided for therein.

Accordingly, Directive 2003/99/EC is amended as follows:

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

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

“Annex I may be amended by the Commission to add zoonoses or zoonotic agents to, or delete them from, the lists therein, taking account in particular of the following criteria:”

(b) The following second subparagraph is added:

“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(4).”

(2) In Article 5, paragraph 1 is replaced by the following:

“1. If data collected through routine monitoring in accordance with Article 4 are not sufficient, coordinated monitoring programmes concerning one or more zoonoses and/or zoonotic agents may be established by the Commission, especially when specific needs are identified, to assess risks or to establish baseline values related to zoonoses or zoonotic agents at the level of Member States or at Community level. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).”

(3) Article 11 is replaced by the following:

#### *“Article 11*

##### *Amendments to the Annexes and transitional or implementing measures*

Annexes II, III and IV may be amended by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Any appropriate transitional or implementing measures may be adopted in accordance with the procedure referred to in Article 12(2).”

(4) Article 12 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), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.”

**6.7. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs<sup>39</sup>**

As regards Regulation (EC) No 852/2004, power should in particular be conferred on the Commission to adopt provisions relating to specific hygiene rules and to the approval of establishments, and to grant derogations from Annexes I and II subject to certain conditions. Since those measures are of general scope and are designed to amend non-essential elements of this 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 852/2004 is amended as follows:

(1) Article 4(4) is replaced by the following:

"4. The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods 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)."

(2) Point (c) of Article 6(3) is replaced by the following:

"(c) by a decision adopted by the Commission; 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 14(3)."

(3) Article 13 is amended as follows:

a) Paragraph 1 is amended as follows:

i) the introductory clause is replaced by the following:

"Annexes I and II may be adapted or updated by the Commission taking into account:"

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<sup>39</sup> OJ L 139, 30.4.2004, p. 1.

ii) the following second subparagraph is added:

"Those measures, designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3)."

b) Paragraph 2 is replaced by the following:

"2 Derogations from Annexes I and II may be granted by the Commission, in particular in order to facilitate the implementation of Article 5 for small businesses, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of 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 14(3)."

(4) Article 14(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."

**6.8. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>40</sup>**

As regards Regulation (EC) No 853/2004, power should in particular be conferred on the Commission to adopt provisions relating to the general obligations of food business operators and to the special guarantees for placing food on the market in Sweden or Finland, and to allow derogations from the annexes subject to certain conditions. Since those measures are of general scope and are designed to amend non-essential elements of this 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 853/2004 is amended as follows:

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

"Food business operators shall not use any substance other than potable water — or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water — to remove surface contamination from products of animal origin, unless use of the substance has been 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 12(3)."

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<sup>40</sup> OJ L 139, 30.4.2004, corrected version in OJ L 226, 25.6.2004, p. 22.

(2) Article 8(3) is replaced by the following:

"3.

- a) The requirements of paragraphs 1 and 2 may be updated by the Commission to take account in particular of changes to Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004. 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).
- b) In accordance with the procedure referred to in Article 12(2), the rules laid down in paragraph 2 of this Article in respect of any of the foodstuffs referred to in paragraph 1 of this Article may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned."

(3) Article 10 is amended as follows:

(a) Paragraph 1 is amended as follows:

i) the introductory clause is replaced by the following:

"Annexes II and III may be adapted or updated by the Commission taking into account:"

ii) the following second subparagraph is added:

"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)."

(b) Paragraph 2 is replaced by the following:

"2. Exemptions from Annex II and III may be granted by the Commission, provided that they do not affect the achievement of the objectives 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 12(3)."

(4) The introductory clause of Article 11 is replaced by the following:

"Without prejudice to the generality of Article 9 and Article 10(1), implementing measures may be laid down in accordance with the procedure referred to in Article 12(2), or amendments to Annex II or III, measures designed to amend non-essential elements of this Regulation, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3)."

(5) Article 12(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."

**6.9. Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>41</sup>**

As regards Regulation (EC) No 854/2004, powers should be conferred on the Commission to amend or adapt the annexes thereto. Since those measures are of general scope and are designed to amend non-essential elements of that Regulation, 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 854/2004 is amended as follows:

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

"1. Annexes I, II, III, IV, V and VI may be amended or supplemented by the Commission to take account of scientific and technical progress. 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 19(3).

2. Exemptions from Annexes I, II, III, IV, V and VI may be granted by the Commission, provided that they do not affect the achievement of the objectives of 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 19(3)."

(2) The introductory clause of Article 18 is replaced by the following:

"Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down in accordance with the procedure referred to in Article 19(2), or amendments to Annexes I, II, III, IV, V or VI, measures designed to amend non-essential elements of this Regulation, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3), to specify:"

(3) Article 19(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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<sup>41</sup> OJ L 139, 30.4.2004, corrected version in OJ L 226, 25.6.2004, p. 83.



**6.10. Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene<sup>42</sup>**

As regards Regulation (EC) No 183/2005, power should in particular be conferred on the Commission to define the microbiological criteria and targets to be met by feed business operators, to adopt measures for the approval of establishments, to amend Annexes I, II and III, and to grant derogations from those annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 183/2005 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.

Accordingly, Regulation (EC) No 183/2005 is amended as follows:

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

"The criteria and targets referred to in points (a) and (b) shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 31(3)."

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

"3) approval is required by a Regulation adopted by the Commission; this 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 31(3)."

(3) Article 27 is replaced by the following:

*"Article 27*

*Amendments to Annexes I, II and III*

Annexes I, II and III may be amended to take account of:

- a) the development of codes of good practice;
  - b) the experience gained from the implementation of HACCP-based systems pursuant to Article 6;
  - (c) technological developments;
  - (d) scientific advice, particularly new risk assessments;
  - (e) the setting of feed safety targets;
- and

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<sup>42</sup> OJ L 35, 8.2.2005, p. 1.

- (f) the development of requirements relating to specific operations.

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 31(3)."

- (4) Article 28 is replaced by the following:

*"Article 28*

*Derogations from Annexes I, II and III*

Derogations from Annexes I, II and III may be granted by the Commission for particular reasons, provided that such derogations do not affect the achievement of the objectives of 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 31(3)."

- (5) Article 31(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."

**7. ENERGY AND TRANSPORT**

**7.1. Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport<sup>43</sup>**

As regards Regulation (EEC) No 3821/85, 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 Regulation (EEC) No 3821/85, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EEC) No 3821/85 is amended as follows:

- (1) Article 5(2) is replaced by the following:

"The system's security must comply with the technical requirements laid down in Annex IB. The Commission shall ensure that the said Annex stipulates that recording equipment may not be granted EC component type-approval until the whole system (the recording equipment itself, driver card and electrical gearbox connections) has demonstrated its capacity to resist attempts to tamper with or alter the data on driving times. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred

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<sup>43</sup> OJ L 370, 31.12.1985, p. 8.

to in Article 18(2). The tests necessary to establish this shall be carried out by experts familiar with up-to-date tampering techniques."

(2) Article 17(1) is replaced by the following:

"1. The amendments required to adjust the annexes to technical progress, which are 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(2)."

(3) Article 18 is replaced by the following:

*"Article 18*

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this 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."

**7.2. Council Directive 97/70/EC of 11 December 1997 setting up a harmonised safety regime for fishing vessels of 24 metres in length and over<sup>44</sup>**

As regards Directive 97/70/EC, power should in particular be conferred on the Commission to adopt provisions for the harmonised interpretation of provisions of the Annex to the Torremolinos Protocol and for the implementation of the Directive. The Commission should also be empowered to amend certain provisions of the Directive and of the annexes thereto in order to apply, for the purpose of the Directive, subsequent amendments to the Torremolinos Protocol which entered into force after the adoption of the Directive. Since those measures are of general scope and are designed to amend non-essential elements of Directive 97/70/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 97/70/EC is amended as follows:

(1) In Article 4(4)(b), the words "in Article 9" are replaced by "in Article 9(2)".

(2) In Article 8, the first subparagraph is replaced by the following:

"The following adaptations, which are 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 9(3):

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<sup>44</sup> OJ L 34, 9.2.1998, p. 1.

- a) provisions may be adopted and incorporated for:
  - a harmonised interpretation of provisions of the Annex to the Torremolinos Protocol which have been left to the discretion of the administrations of individual contracting parties, as far as necessary to ensure their consistent implementation in the Community,
  - the implementation of this Directive without broadening its scope.
- b) Articles 2, 3, 4, 6 and 7 of this Directive may be adapted and its Annexes may be amended in order to apply, for the purpose of this Directive, subsequent amendments to the Torremolinos Protocol which have entered into force after the adoption of this Directive."

(3) Article 9 is replaced by the following:

*"Article 9*

*Committee*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) set up 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 shall apply, having regard to the provisions of Article 8 thereof.  
  
The time limit laid down in Article 5(6) of Decision 1999/468/EC shall be two months.
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

**7.3. Council Directive 1999/35/EC of 29 April 1999 on a system of mandatory surveys for the safe operation of regular ro-ro ferry and high-speed passenger craft services<sup>45</sup>**

As regards Directive 1999/35/EC, power should in particular be conferred on the Commission to adapt the Annexes, definitions and references to Community instruments and instruments of the International Maritime Organisation (IMO) in order to bring them into line with Community or IMO measures which have subsequently entered into force. The Commission should also be empowered to amend the annexes in order to improve the regime established by the Directive. Since those measures are of general scope and are designed to amend non-

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<sup>45</sup> OJ L 138, 1.6.1999, p. 1.

essential elements of Directive 1999/35/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 1999/35/EC is amended as follows:

- (1) In Article 4(1)(d), last sentence, Article 11(6) and (8), and Article 13(3), second and last sentences, the words "in Article 16" are replaced by "in Article 16(2)".
- (2) Article 16 is replaced by the following:

*"Article 16*

*Committee*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) set up by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council(\*).
2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

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

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

- (3) Article 17 is replaced by the following:

*"Article 17*

*Amendment procedure*

The Annexes to this Directive, the definitions, the references to Community instruments and references to IMO instruments may be amended to the extent necessary to bring them into line with Community or IMO measures which have entered into force, but without broadening the scope of this Directive.

The Annexes may also be amended when it is necessary to improve the arrangements established by this Directive, but without broadening its scope.

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 16(3).

The amendments to the international instruments referred to in Article 2 may be excluded from the scope of this Directive pursuant to Article 5 of Regulation (EC) No 2099/2002."

**7.4. Regulation (EC) No 417/2002 of the European Parliament and of the Council of 18 February 2002 on the accelerated phasing-in of double hull or equivalent design requirements for single hull oil tankers and repealing Council Regulation (EC) No 2978/94<sup>46</sup>**

As regards Regulation (EC) No 417/2002, power should in particular be conferred on the Commission to amend certain references to the relevant regulations in MARPOL 73/78 and to Resolutions MEPC 111(50) and 94(46) in order to bring the references into line with amendments to these regulations and resolutions adopted by the IMO, in so far as such amendments do not broaden the scope of this Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 417/2002, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 417/2002 is amended as follows:

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

*"Article 10*

*Committee procedure*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) set up by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council(\*).
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.

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

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<sup>46</sup> OJ L 64, 7.3.2002, p. 1.

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

"The Commission may amend the references in the Articles of this Regulation to the regulations of Annex I of MARPOL 73/78 and to Resolutions MEPC 111(50) and 94(46), as amended by MEPC Resolutions 99(48) and 112(50), in order to bring the references into line with amendments to these regulations and resolutions adopted by the IMO, in so far as such amendments do not broaden the scope 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 10(2)."

**7.5. Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships<sup>47</sup>**

As regards Regulation (EC) No 782/2003, power should in particular be conferred on the Commission to introduce a harmonised survey and certification regime for certain ships, to take certain measures as regards ships sailing under the flag of a third State, to lay down port State control procedures, and to amend certain references and annexes to take account of developments at international level, in particular in the International Maritime Organisation (IMO), or to improve the effectiveness of the Regulation in the light of experience. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 782/2003, 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 782/2003 is amended as follows:

- (1) Article 6 is amended as follows:

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

"If necessary, the Commission may establish a harmonised survey and certification regime for these ships. 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 9(2)."

- b) Paragraph 3 is replaced by the following:

"3. If the AFS-Convention has not entered into force by [1 January 2007], the Commission shall adopt appropriate measures in order to allow ships flying the flag of a third State to demonstrate their compliance with Article 5. 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 9(2)."

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<sup>47</sup> OJ L 115, 9.5.2003, p. 1.

- (2) In Article 7, the second subparagraph is replaced by the following:

"If the AFS-Convention has not entered into force by [1 January 2007], the Commission shall establish appropriate procedures for these controls. 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 9(2)."

- (3) Article 8 is replaced by the following:

*"Article 8*

In order to take account of developments at international level and in particular in the International Maritime Organisation (IMO), or to improve the effectiveness of this Regulation in the light of experience, the Commission may amend the references to the AFS-Convention, to the AFS-Certificate, to the AFS-Declaration and to the AFS-Statement of Compliance and/or the Annexes to this Regulation, including relevant IMO guidelines in relation to Article 11 of the AFS-Convention. 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 9(2)."

- (4) Article 9 is replaced by the following:

*"Article 9*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) set up by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council(\*).
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.

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

**7.6. Directive 2004/8/EC of the European Parliament and of the Council of 11 February 2004 on the promotion of cogeneration based on a useful heat demand in the internal energy market<sup>48</sup> and amending Directive 92/42/EEC**

As regards Directive 2004/8/EC, power should in particular be conferred on the Commission to review harmonised efficiency reference values for separate production of electricity and heat, to adapt the threshold values set out in Article 13 to technical progress, and to establish and adapt to technical progress the detailed guidelines for the implementation and application of Annex II of Directive 2004/8/EC, including the determination of the power to heat ratio. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/8/EC and to supplement it by the addition of new non-essential elements,

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<sup>48</sup> OJ L 52, 21.2.2004, p. 50.



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

Accordingly, Directive 2004/8/EC is amended as follows:

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

"2. The Commission shall review the harmonised efficiency reference values for separate production of electricity and heat referred to in paragraph 1, for the first time on 21 February 2011, and every four years thereafter, to take account of technological developments and changes in the distribution of energy sources. Any measures resulting from this review, designed to amend the non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2)."

(2) Article 13 is replaced by the following:

### *"Article 13*

#### *Review*

1. The Commission shall adapt the threshold values used for calculation of electricity from cogeneration referred to in Annex II(a) to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).
2. The Commission shall adapt the threshold values used for calculation of efficiency of cogeneration production and primary energy savings referred to in Annex III(a) to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).
3. The Commission shall adapt the guidelines for determining the power to heat ratio referred to in Annex II(d) to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2)."

(3) Article 14 is replaced by the following:

*"Article 14*

*Committee*

1. The Commission shall be assisted by a 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."
- (4) In Annex II, point (e) is replaced by the following:
- "(e) The Commission shall establish detailed guidelines for the implementation and application of Annex II, including the determination of the power to heat ratio. 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 14(2)."

**7.7. Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community<sup>49</sup>**

As regards Directive 2004/52/EC, power should in particular be conferred on the Commission to adapt the annex, to take decisions as regard the definition of the European electronic toll service by [1 July 2006] and, if they are not taken by that date, to set a new date. The Commission should also be empowered to take technical decisions relating to the realisation of the European electronic toll service. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/52/EC 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 2004/52/EC is amended as follows:

- (1) Article 4(2), (4), (5) and (6) are replaced by the following:
  - "2. Where appropriate, this Annex may be modified for technical reasons. 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 5(2).
  4. The decisions relating to the definition of the European electronic toll service shall be taken by the Commission by [1 July 2006]. 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 5(2). Such decisions shall only be taken if all the conditions, evaluated on the basis of appropriate studies, are in place to enable interoperability to work from all points of view, including technical, legal and commercial.

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<sup>49</sup> OJ L 166, 30.4.2004, p. 124.

5. If the decisions referred to in paragraph 4 are not taken by [1 July 2006], the Commission shall set a new date by which such decisions are to be taken. That measure, designed to amend a non-essential element of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5(2).
6. Technical decisions relating to the realisation of the European electronic toll service shall be taken 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 5(2)."

(2) Article 5 is replaced by the following:

*"Article 5*

*Committee*

1. The Commission shall be assisted by an Electronic Toll Committee (hereinafter "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."

**7.8. Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security<sup>50</sup>**

As regards Regulation (EC) No 725/2004, power should in particular be conferred on the Commission to decide whether amendments to the Annexes, which concern certain special measures to enhance maritime security of the International Convention for the Safety of Life at Sea, and of the International Code for the security of ships and of port facilities, that apply automatically to international traffic should also apply to ships operating domestic services and the port facilities serving them. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 725/2004, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Regulation (EC) No 725/2004 lays down security requirements and measures and is based on international instruments that are subject to amendment. On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adaptation of its Annexes.

Accordingly, Regulation (EC) No 725/2004 is amended as follows:

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<sup>50</sup> OJ L 129, 29.4.2004, p. 6.

(1) In Article 10, paragraph 2 is replaced by the following:

“2. The Commission shall decide integration of amendments to the international instruments referred to in Article 2 in respect of ships operating domestic services and the port facilities serving them to which this Regulation applies, in so far as they constitute a technical update of the provisions of the SOLAS Convention and the ISPS Code. 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 11(4). The procedure for checking conformity established in paragraph 5 shall not apply in these cases.”

(2) Article 11 is replaced by the following:

*“Article 11*

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

3. Where reference is made to this paragraph, Articles 6 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The periods laid down in Article 6(b) and (c) respectively of Decision 1999/468/EC shall be one month.

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

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

**7.9. Regulation (EC) No 789/2004 of the European Parliament and of the Council of 21 April 2004 on the transfer of cargo and passenger ships between registers within the Community and repealing Council Regulation (EEC) No 613/91<sup>51</sup>**

As regards Regulation (EC) No 789/2004, power should in particular be conferred on the Commission to amend certain definitions in order to take account of developments at international level, in particular in the International Maritime Organisation (IMO), and to improve the effectiveness of the Regulation in the light of experience and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 789/2004, 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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<sup>51</sup> OJ L 138, 30.04.2004, p. 19.

Accordingly, Regulation (EC) No 789/2004 is amended as follows:

(1) Article 7 is replaced by the following:

*"Article 7*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) set up by Article 3 of Regulation (EC) No 2099/2002 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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be two months.

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

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

(2) Article 9(1) is replaced by the following:

"1. In order to take account of developments at international level, in particular in the International Maritime Organisation (IMO), and to improve the effectiveness of this Regulation in the light of experience and technical progress, the Commission may amend the definitions in Article 2 insofar as such amendments do not broaden the scope of the 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 7(3)."

**7.10. Directive 2005/44/EC of the European Parliament and of the Council of 7 September 2005 on harmonised river information services (RIS) on inland waterways in the Community<sup>52</sup>**

As regards Directive 2005/44/EC, power should in particular be conferred on the Commission to adapt the annexes to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2005/44/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 2005/44/EC is amended as follows:

(1) Article 10 is replaced by the following:

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<sup>52</sup> OJ L 255, 30.9.2005, p. 152.

*"Article 10*

*Amendment procedure*

Annexes I and II may be amended in the light of the experience gained from the application of this Directive and adapted to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(4)."

- (2) Article 11 is replaced by the following:

*"Article 11*

*Committee*

1. The Commission shall be assisted by the Committee instituted by Article 7 of Directive 91/672/EEC(\*).
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 time limit laid down in Article 5(6) of Decision 1999/468/EC shall be 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 Commission shall regularly consult representatives of the sector.

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(\*) OJ L 373, 31.12.1991, p. 29. "

**7.11. Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security<sup>53</sup>**

As regards Directive 2005/65/EC, power should in particular be conferred on the Commission to adapt the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2005/65/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Directive 2005/65/EC lays down security requirements and measures and is based on international instruments that are subject to amendment. On grounds of efficiency, the normal

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<sup>53</sup> OJ L 310, 25.11.2005, p. 28.

time limits for the regulatory procedure with scrutiny should be curtailed for the adaptation of its Annexes.

Accordingly, Directive 2005/65/EC is amended as follows:

(1) Articles 14 and 15 of Directive 2005/65/EC are replaced by the following:

*“Article 14*

*Adaptations*

The Commission may amend Annexes I to IV without broadening the scope of 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 15(2).

*Article 15*

*Committee*

1. The Commission shall be assisted by the committee set up by Regulation (EC) No 725/2004.
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.

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

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