

Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two

REGULATION (EC) No 219/2009 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 March 2009

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

Adaptation to the regulatory procedure with scrutiny — Part 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,

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

Having regard to the opinion of the European Central Bank⁽²⁾,

After consulting the Committee of the Regions,

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

Whereas:

- (1) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁴⁾ has been amended by Decision 2006/512/EC⁽⁵⁾, which introduced the regulatory procedure with scrutiny for the adoption of 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 with new non-essential elements.
- (2) In accordance with the statement of the European Parliament, the Council and the Commission⁽⁶⁾ concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny 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 adjusted in accordance with the applicable procedures.
- (3) Since the amendments made to instruments for this purpose are technical in nature and concern committee procedure only, they do not, in the case of directives, need to be transposed by the Member States,

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 shall be understood to be references to those provisions as adapted by this Regulation.

Article 3

This Regulation shall enter into force on the 20th 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.

ANNEX

1. HUMANITARIAN AID

Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid⁽⁷⁾

As regards Regulation (EC) No 1257/96, the Commission should be empowered to adopt implementing measures for that Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1257/96, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1257/96 is hereby amended as follows:

1. in Article 13, the fourth paragraph shall be replaced by the following:

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

2. Article 15 shall be replaced by the following:

Article 15

- 1 The Commission shall adopt implementing measures for 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 17(4).

- 2 Acting in accordance with the regulatory procedure referred to 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 management procedure referred to in Article 17(2), the Commission shall:

- approve global plans intended to provide for actions 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 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 shall be 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 period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 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⁽⁸⁾

As regards Directive 75/324/EEC, the Commission should be empowered 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 Directive 75/324/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 75/324/EEC is hereby amended as follows:

1. Article 5 shall be replaced by the following:
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 hereby amended as follows:

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

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

- (b) paragraph 3 shall be deleted;

3. in Article 10, paragraph 3 shall be 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.

- ^{F1}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

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Textual Amendments

- F1** Deleted by [Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses \(recast\) \(Text with EEA relevance\)](#).

- 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⁽⁹⁾.

As regards Directive 2000/14/EC, the Commission should be empowered to adopt implementing measures for the adaptation to technical progress of Annex III. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2000/14/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 2000/14/EC is hereby amended as follows:

1. Article 18 shall be amended as follows:
 - (a) paragraph 2 shall be replaced by the following:
 2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof;
 - (b) paragraph 3 shall be deleted;
2. the following Article shall be inserted:

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) shall be 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⁽¹⁰⁾

As regards Regulation (EC) No 2003/2003, the Commission should be empowered 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 hereby amended as follows:

1. in Article 29, paragraph 4 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 hereby amended as follows:
 - (a) paragraph 1 shall be replaced by the following:
 1. The Commission shall adapt Annex I to include new types of fertilisers.;
 - (b) paragraph 3 shall be replaced by the following:
 3. The Commission shall adapt the Annexes to take account of technical progress.;
 - (c) the following paragraph shall be 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 shall be 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 period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
- 3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 2.5. 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)⁽¹¹⁾

As regards Directive 2004/9/EC, the Commission should be empowered 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 hereby amended as follows:

1. Article 6(3) shall be replaced by the following:
3. If the Commission considers that amendments to this Directive are necessary in order to resolve the matters referred to in paragraph 1, it shall adopt those amendments.

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. Article 7 shall be replaced by the following:
Article 7

1 The Commission shall be assisted by the Committee established by Article 29(1) of Council Directive 67/548/EEC⁽¹²⁾, hereinafter “the Committee”.

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

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

3 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. Article 8(2) shall be replaced by the following:
2. The Commission shall adopt implementing measures for the following:
 - a the 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)⁽¹³⁾

As regards Directive 2004/10/EC, the Commission should be empowered to adapt Annex I 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 hereby amended as follows:

1. the following Article shall be inserted:
Article 3a

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

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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 shall be replaced by the following:

Article 4

- 1 The Commission shall be assisted by the Committee established by Article 29(1) of Council Directive 67/548/EEC⁽¹⁴⁾.

- 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. in Article 5(2) the third subparagraph shall be 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⁽¹⁵⁾

As regards Regulation (EC) No 273/2004, the Commission should be empowered to adopt implementing measures. 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 hereby amended as follows:

1. Article 14 is hereby amended as follows:

- (a) the introductory sentence shall be replaced by the following:

Where necessary, the Commission shall adopt implementing measures concerning the following.;

- (b) the following paragraphs shall be 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 management procedure referred to in Article 15(2).;

2. Article 15 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Article 15

Committee procedure

1 The Commission shall be assisted by the Committee set up by Article 30 of Council Regulation (EC) No 111/2005⁽¹⁶⁾.

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

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

3 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.

2.8. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents⁽¹⁷⁾

As regards Regulation (EC) No 648/2004, the Commission should be empowered to adapt its annexes and to adopt any amendments or additions necessary for applying the rules of that 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 hereby amended as follows:

1. Recital 27 shall be deleted;
2. Article 12 shall be replaced by the following:

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

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

3. Article 13 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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).;
4. in Annex VII, point A, the sixth paragraph shall be 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⁽¹⁸⁾

As regards Regulation (EC) No 726/2004, the Commission should be empowered to adapt certain provisions and annexes, to adopt new provisions, 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 726/2004 is hereby amended as follows:

1. Article 3(4) shall be replaced by the following:
4. After the competent committee of the Agency has been consulted, the Commission may adapt the Annex to 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 shall be replaced by the following:

The Commission shall adopt a Regulation laying down provisions for granting such authorisation. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).;
3. Article 16(4) shall be 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 hereby amended as follows:

- (a) in paragraph 2, the first subparagraph shall be 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 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 shall be 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 shall be 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. Article 41(6) shall be 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 hereby amended as follows:

- (a) in paragraph 2 the first subparagraph shall be 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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 shall be 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 procedure referred to in Article 87(2a).;

8. Article 54 shall be 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. Article 70(2) shall be 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 shall be 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 hereby amended as follows:

(a) the following paragraph shall be inserted:

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

(b) paragraph 4 shall be 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⁽¹⁹⁾

As regards Directive 82/883/EEC, the Commission should be empowered 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. 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 hereby amended as follows:

1. Article 9 shall be 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 shall be replaced by the following:
Article 11

- 1 The Commission shall be assisted by the committee.

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

- 3.2. 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⁽²⁰⁾

As regards Directive 86/278/EEC, the Commission should be empowered to adapt to technical and scientific progress the 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.

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

1. Article 13 shall be 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 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Article 15

- 1 The Commission shall be assisted by the Committee.
- 2 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 3.3. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste⁽²¹⁾

As regards Directive 94/62/EC, the Commission should be empowered 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 94/62/EC is hereby amended as follows:

1. in Article 3(1), the fourth subparagraph shall be 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 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. Article 11(3) shall be 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 the third indent of paragraph 1.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).;
3. Article 12(3) shall be 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 in formats which shall be adopted on the basis of Annex I II, in accordance with the regulatory procedure referred to in Article 21(2).;
4. Article 19 shall be replaced by the following:

Article 19

Adaptation to scientific and technical progress

- 1 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).
- 2 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. Article 20(1) shall be replaced by the following:
 1. The Commission shall determine the technical measures necessary to deal with any difficulties encountered in applying the provisions of this Directive, in particular, to inert packaging materials placed 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. Article 21(3) shall be replaced by the following:
 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- ^{F2}3.4. Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels

Textual Amendments

- F2** Deleted by [Directive \(EU\) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels \(codification\)](#).

- 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⁽²²⁾

As regards Directive 2001/81/EC, the Commission should be empowered 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 with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/81/EC is hereby amended as follows:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

1. Article 7(4) shall be 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. Article 13(3) shall be replaced by the following:
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 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⁽²³⁾

As regards Directive 2003/87/EC, the Commission should be empowered to adopt provisions necessary for the implementation of Article 11b(5), to adopt guidelines for the monitoring and reporting of emissions, 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 adopt standardised or accepted methods 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2003/87/EC is hereby amended as follows:

1. in Article 11b, paragraph 7 shall be 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 of this Article 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 14(1), the first sentence shall be replaced by the following:
The Commission shall adopt guidelines for the monitoring and reporting of emissions resulting from the activities listed in Annex I of greenhouse gases specified in relation to those 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).;
3. Article 19(3) shall be 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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

confidentiality as appropriate and to ensure that there are no transfers which are incompatible with the 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).;

4. Article 22 shall be 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).;

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

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

6. Article 24 shall be amended as follows:

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

1. Taking into account all relevant criteria, in particular the effects on the internal market, potential distortions of competition, the environmental integrity of the scheme and the 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 regulatory procedure referred to in Article 23(2), and
- b activities and greenhouse gases which are not listed in Annex I, provided that the inclusion of such activities and greenhouse gases is approved 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 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.;

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

3. The Commission may, on its own initiative, or shall, on request by a Member State, adopt monitoring and reporting guidelines for emissions from activities, installations and greenhouse gases which are not listed in

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Annex I if the monitoring and reporting of these emissions can be carried out with sufficient accuracy.

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. Article 25(2) shall be 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).;

8. in Annex IV, the paragraph under the heading ‘Monitoring of emissions of other greenhouse gases’ shall be 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)..

F³3.7. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants

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Textual Amendments

F3 Deleted by [Regulation \(EU\) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants \(recast\) \(Text with EEA relevance\).](#)

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⁽²⁴⁾

As regards Directive 2004/107/EC, the Commission should be empowered 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 hereby amended as follows:

1. Article 4 shall be amended as follows:

(a) paragraph 9 shall be replaced by the following:

9. Irrespective of concentration levels, one background sampling point shall be installed every 100 000 km² 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 regulatory 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 shall be 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. Article 5(4) shall be replaced by the following:

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

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

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

4. Annex V, point V shall be 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⁽²⁵⁾

As regards Regulation (EC) No 1013/2006, the Commission should be empowered to amend the annexes as laid down in Article 58 of Regulation (EC) No 1013/2006 and to adopt certain additional measures as laid down in Article 59 of Regulation (EC) No 1013/2006. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1013/2006, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1013/2006 is hereby amended as follows:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

1. in Article 11(3), the third subparagraph shall be 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 shall be replaced by the following:

Article 58

Amendment of Annexes

- 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;
 - 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 of 23 December 1991 standardising and rationalising reports on the implementation of certain Directives relating to the environment⁽²⁶⁾ shall be fully associated with the deliberations.;
3. Article 59 shall be 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);

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- 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 recommendations 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 shall be inserted:

Article 59a

Committee procedure

1 The Commission shall be assisted by the committee set up by 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 period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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

5. Article 63 shall be amended as follows:

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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

(c) paragraph 5 shall be amended as follows:

(i) the third subparagraph shall be 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 shall be 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⁽²⁷⁾

As regards Regulation (EEC) No 3924/91, the Commission should be empowered to update the list of products concerned by that Regulation. It should also be empowered 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 the 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 with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EEC) No 3924/91 is hereby amended as follows:

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

6. The Prodcom list and the information actually collected for each heading shall be 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 shall be amended as follows:

(a) in paragraph 2 the words ‘in accordance with the procedure laid down in Article 10’ shall be replaced by the words ‘in accordance with the management procedure referred to in Article 10(2).’;

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

5. Detailed rules for applying paragraph 3, including measures for the 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 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Article 4

Survey periods

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

However, for certain headings in the Prodcom list, the Commission may decide that monthly or quarterly surveys are to be conducted. 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. Article 5(1) shall be 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. Article 6 shall be replaced by the following:

Article 6

Processing of results

Member States shall process the completed questionnaires referred to in Article 5(1) or the information from other sources referred to in Article 5(3) in accordance with the detailed rules adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;

6. in Article 7(2) the words ‘in accordance with the procedure laid down in Article 10’ shall be replaced by the words ‘in accordance with the management procedure referred to in Article 10(2)’;
7. Article 9 shall be deleted;
8. Article 10 shall be replaced by the following:

Article 10

Committee procedure

- 1 The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom⁽²⁸⁾.
- 2 Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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.

4.2. Council Directive 96/16/EC of 19 March 1996 on statistical surveys of milk and milk products⁽²⁹⁾

As regards Directive 96/16/EC, the Commission should be empowered to adopt the definitions for the agricultural holdings among which Member States must conduct surveys of the production of milk and its use, adopt the list of milk products covered by the surveys and draw up standard definitions to be used when communicating the results to the Commission. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/16/EC by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/16/EC is hereby amended as follows:

1. in Article 1, point 2 shall be 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) shall be 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 when 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 5(2) and Article 6(1), the words ‘in accordance with the procedure laid down in Article 7’ shall be replaced by the words ‘in accordance with the regulatory procedure referred to in Article 7(2).’;
4. Article 7 shall be replaced by the following:
Article 7
- 1 The Commission shall be assisted by the Standing Committee on Agricultural Statistics set up by 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 period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
- 3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- ^{F4}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
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Textual Amendments

- F4** Deleted by [Regulation \(EU\) No 1337/2011 of the European Parliament and of the Council of 13 December 2011 concerning European statistics on permanent crops and repealing Council Regulation \(EEC\) No 357/79 and Directive 2001/109/EC of the European Parliament and of the Council \(Text with EEA relevance\).](#)

- ^{F5}4.4. Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics
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Textual Amendments

- F5** Deleted by [Regulation \(EU\) 2018/643 of the European Parliament and of the Council of 18 April 2018 on rail transport statistics \(recast\).](#)

- 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⁽³⁰⁾

As regards Regulation (EC) No 437/2003, the Commission should be empowered to establish standards of accuracy, specify data files and adopt certain implementing measures. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 437/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 437/2003 is hereby amended as follows:

1. Article 5 shall be 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).;

2. Article 7(2) shall be 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. 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).

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

The medium to be used for transmission shall be specified by the Commission in accordance with the regulatory procedure referred to in Article 11(2).;

3. Article 10 shall be replaced by the following:

Article 10

Implementing measures

- 1 The following implementing measures shall be adopted in accordance with the regulatory procedure referred to in Article 11(2):
- the list of Community airports covered by Article 3(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),
 - accuracy of statistics (Article 5),
 - description of the data files (Article 7),

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).;

4. Article 11 shall be replaced by the following:

Article 11

Committee procedure

- 1 The Commission shall be assisted by the Statistical Programme Committee established by 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 set at 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..
- 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⁽³¹⁾

As regards Regulation (EC) No 48/2004, the Commission should be empowered to 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*,

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 48/2004 is hereby amended as follows:

1. Article 7 shall be 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 regulatory procedure referred to in Article 8(2).
- 2 The measures for the implementation of this Regulation concerning the updating of the list of characteristics, 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), provided that no significant additional burden is imposed upon the Member States.;
2. Article 8(3) shall be replaced by the following:
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. INTERNAL MARKET

Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids⁽³²⁾

As regards Directive 2004/25/EC, the Commission should be empowered to adopt rules for the application of Article 6(3) to the contents of the offer document. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/25/EC, 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 statement concerning 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 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 hereby amended as follows:

1. Article 6(4) shall be replaced by the following:
4. The Commission may adopt rules modifying the list in paragraph 3. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2).;
2. Article 18 shall be amended as follows:
 - (a) paragraph 2 shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

(b) paragraph 3 shall be deleted.

6. HEALTH AND CONSUMER PROTECTION

6.1. Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs⁽³³⁾

As regards Directive 79/373/EEC, the Commission should be empowered 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 79/373/EEC is hereby amended as follows:

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

Article 10

In the light of advances in scientific and technical knowledge, the Commission shall:

- (a) establish categories grouping several feed materials;
- (b) adopt methods of calculating the energy value of compound feedingstuffs;
- (c) adopt amendments to the Annex.

All the above 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).;

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

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

6.2. Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition⁽³⁴⁾

As regards Directive 82/471/EEC, the Commission should be empowered 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 by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision

1999/468/EC. On the grounds of urgency, it is necessary to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to the Directive.

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

1. Article 6 is hereby amended as follows:
 - (a) paragraph 1 shall be 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.

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 shall be 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 laid down 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), the words ‘the procedure laid down in Article 13’ shall be replaced by the words ‘the regulatory procedure referred to in Article 13(2).’;
3. Article 8(3) shall be 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 urgency procedure 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 shall be amended as follows:
 - (a) paragraph 3 shall be replaced by the following:
 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

(b) the following paragraph shall be added:

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

5. Article 14 shall be deleted.

6.3. Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials⁽³⁵⁾

As regards Directive 96/25/EC, the Commission should be empowered to draw up 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency 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 hereby amended as follows:

1. the second indent of Article 5(1)(g) shall be 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 shall be 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 regulatory 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).
 - 3 The list referred to in 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, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3). On imperative

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

grounds of urgency, the Commission may have recourse to the urgency 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 shall be amended as follows:

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

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

- (b) the following paragraphs shall be added:

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

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

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

- 6.4. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed⁽³⁶⁾

As regards Directive 2002/32/EC, the Commission should be empowered 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the time limits normally applicable for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency 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 hereby amended as follows:

1. the first subparagraph of Article 7(2) shall be replaced by the following:
2. 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 urgency procedure referred to in Article 11(4).;
2. Article 8(1) and (2) shall be 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-

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 have recourse to the urgency 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 regulatory procedure referred to 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 shall be replaced by the following:

Article 11

- 1 The Commission shall be assisted by the Standing Committee for Feedingstuffs set up by Article 1 of Council Decision 70/372/EEC⁽³⁷⁾.

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

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

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

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

4. Article 12 shall be deleted.

- F⁶6.5. 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

Textual Amendments

- F6** Deleted by [Regulation \(EU\) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation \(EC\) No 998/2003 \(Text with EEA relevance\)](#).

- 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⁽³⁸⁾

As regards Directive 2003/99/EC, the Commission should be empowered 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 Directive 2003/99/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of urgency, it is necessary to apply the urgency 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 hereby amended as follows:

1. in Article 4, paragraph 4 shall be amended as follows:
 - (a) the introductory phrase shall be 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 subparagraph shall be added:

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the urgency procedure referred to in Article 12(4).;
2. Article 5(1) shall be 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 shall be 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).

Transitional measures of general scope designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 12(2).;

4. Article 12 shall be amended as follows:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- (a) paragraph 3 shall be replaced by the following:
 - 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;
- (b) the following paragraph shall be added:
 - 4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

As regards Regulation (EC) No 852/2004, the Commission should be empowered 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 Regulation (EC) No 852/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 852/2004 is hereby amended as follows:

- 1. Article 4(4) shall be 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. Article 6(3)(c) shall be 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 12 shall be replaced by the following:

Article 12

Transitional measures of general scope designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).;

- 4. Article 13 shall be amended as follows:
 - (a) paragraph 1 shall be amended as follows:
 - (i) the introductory sentence shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

(ii) the following subparagraph shall be 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 shall be replaced by the following:

2. Derogations from Annexes I and II may be granted by the Commission, in particular 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).;

5. Article 14(3) shall be replaced by the following:

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

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⁽⁴⁰⁾

As regards Regulation (EC) No 853/2004, the Commission should be empowered 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 Regulation (EC) No 853/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 853/2004 is hereby amended as follows:

1. in Article 3(2), the first sentence shall be 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).;

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

3.

a The requirements of paragraphs 1 and 2 may be updated by the Commission, in particular to take account of changes in Member States' control programmes or of the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004. Those measures, designed to amend non-

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 regulatory 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 9 shall be replaced by the following:

Article 9

Transitional measures of general scope designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 12(2).;

- 4. Article 10 is hereby amended as follows:

- (a) paragraph 1 shall be amended as follows:

- (i) the introductory wording shall be replaced by the following:

Annexes II and III may be adapted or updated by the Commission taking into account.;

- (ii) the following subparagraph shall be 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 shall be 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).;

- 5. the introductory wording of Article 11 shall be replaced by the following:

Without prejudice to the general application of Article 9 and Article 10(1), implementing measures may be laid down in accordance with the regulatory procedure referred to in Article 12(2), and amendments to Annex II or III, as 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).;

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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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⁽⁴¹⁾

As regards Regulation (EC) No 854/2004, the Commission should be empowered to amend or adapt the annexes thereto and to adopt transitional measures, in particular further specifications of the requirements laid down in the provisions of that Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 854/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 854/2004 is hereby amended as follows:

1. Article 16 shall be replaced by the following:
Article 16

Transitional measures of general scope designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 19(2).;

2. Article 17(1) and (2) shall be 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).;
 3. the introductory wording of Article 18 shall be replaced by the following:

Without prejudice to the general application of Article 16 and Article 17(1), implementing measures may be laid down in accordance with the regulatory procedure referred to in Article 19(2), and amendments to Annexes I, II, III, IV, V or VI, as 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;
 4. Article 19(3) shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

As regards Regulation (EC) No 183/2005, the Commission should be empowered 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

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

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

The criteria and targets referred to in points (a) and (b) shall be defined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 31(3).;
2. in Article 10, point (3) shall be 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 shall be 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
- (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).;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

4. Article 28 shall be 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) shall be replaced by the following:

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

7. ENERGY AND TRANSPORT

- ^{F7}7.1. Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport

.....

Textual Amendments

- F7** Deleted by [Regulation \(EU\) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation \(EEC\) No 3821/85 on recording equipment in road transport and amending Regulation \(EC\) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport \(Text with EEA relevance\).](#)

- 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⁽⁴³⁾

As regards Directive 97/70/EC, the Commission should be empowered 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 hereby amended as follows:

1. in Article 4(4)(b), the words ‘in accordance with the procedure laid down in Article 9’ shall be replaced by the words ‘in accordance with the regulatory procedure referred to in Article 9(2).’;
2. in Article 8, the first subparagraph shall be replaced by the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

The following adaptations, 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):

- (a) provisions may be adopted and incorporated for:
 - a harmonised interpretation of those 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 shall be replaced by the following:

Article 9

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⁽⁴⁴⁾.
- 2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁴⁵⁾ shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at two months.
- 3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 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⁽⁴⁶⁾

As regards Directive 1999/35/EC, the Commission should be empowered 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-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 hereby amended as follows:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

1. in Article 4(1)(d), last sentence, Article 11(6) and (8) and Article 13(3), second and last sentences, the words ‘the procedure laid down in Article 16’ shall be replaced by the words ‘the regulatory procedure referred to in Article 16(2).’;
2. Article 16 shall be replaced by the following:

Article 16

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⁽⁴⁷⁾.
- 2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 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.;
3. Article 17 shall be 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 adapted 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 adapted 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.

- ^{F8}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

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Textual Amendments

- F8** Deleted by [Regulation \(EU\) No 530/2012 of the European Parliament and of the Council of 13 June 2012 on the accelerated phasing-in of double-hull or equivalent design requirements for single-hull oil tankers \(recast\)](#).

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⁽⁴⁸⁾

As regards Regulation (EC) No 782/2003, the Commission should be empowered to establish 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 establish port State control procedures, and to amend certain references and annexes to take account of developments at international level, in particular in the IMO, or to improve the effectiveness of that 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 hereby amended as follows:

1. Article 6 shall be amended as follows:
 - (a) in paragraph 1(b), the second subparagraph shall be 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 shall be 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).;
2. in Article 7, the second paragraph shall be 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. 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).;
3. Article 8 shall be 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 the Annexes to this Regulation, including relevant IMO

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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 shall be replaced by the following:

Article 9

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⁽⁴⁹⁾.

- 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.

- ^{F9}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

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Textual Amendments

- F9** Deleted by [Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC \(Text with EEA relevance\)](#).

- 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⁽⁵⁰⁾

As regards Directive 2004/52/EC, the Commission should be empowered to adapt the annex and to take decisions relating to the definition of the European electronic toll service. 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2004/52/EC is hereby amended as follows:

1. Article 4 shall be amended as follows:
 - (a) paragraph 2 shall be replaced by the following:
 2. Where appropriate, the Annex may be adapted 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).;
 - (b) paragraphs 4, 5 and 6 shall be replaced by the following:

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4. The decisions relating to the definition 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). 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 conditions.

5 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 shall be replaced by the following:

Article 5

Committee procedure

- 1 The Commission shall be assisted by an Electronic Toll 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⁽⁵¹⁾

As regards Regulation (EC) No 725/2004, the Commission should be empowered 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, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Regulation (EC) No 725/2004 lays down security requirements and measures and is based on international instruments that are subject to amendment. Where, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC.

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

1. Article 10(2) shall be replaced by the following:
2. The Commission shall decide on the 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

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Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(4); on imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 11(5). The procedure for checking conformity established in paragraph 5 of this Article shall not apply in these cases.;

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

3. The Commission may adopt provisions in order to define harmonised procedures for the application of the mandatory provisions of the ISPS Code, without broadening the scope 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 11(4).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 11(5).;

3. Article 11 shall be replaced by the following:

Article 11

Committee procedure

1 The Commission shall be assisted by a committee.

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

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

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..

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⁽⁵²⁾

As regards Regulation (EC) No 789/2004, the Commission should be empowered 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.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

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

1. Article 7 shall be replaced by the following:

Article 7

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⁽⁵³⁾.
- 2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 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.;
2. Article 9(1) shall be 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⁽⁵⁴⁾

As regards Directive 2005/44/EC, the Commission should be empowered 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 hereby amended as follows:

1. Article 10 shall be replaced by the following:

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 shall be replaced by the following:

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Article 11

Committee procedure

1 The Commission shall be assisted by the Committee set up by Article 7 of Council Directive 91/672/EEC of 16 December 1991 on the reciprocal recognition of boatmasters' certificates for the carriage of goods and passengers by inland waterway⁽⁵⁵⁾.

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

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

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

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

5 The Commission shall regularly consult representatives of the sector.

7.11. Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security⁽⁵⁶⁾

As regards Directive 2005/65/EC, the Commission should be empowered to adapt the Annexes thereto. 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. Where, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adaptation of its Annexes.

Accordingly, Articles 14 and 15 of Directive 2005/65/EC shall be replaced by the following:

Article 14

Adaptations

The Commission may adapt 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).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 15(3).

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

Article 15

Committee procedure

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.

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

Chronological index

- (1) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers
- (2) Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feeding stuffs
- (3) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition
- (4) 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
- (5) Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport
- (6) 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
- (7) Council Regulation (EEC) No 3924/91 of 19 December 1991 on the establishment of a Community survey of industrial production
- (8) 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
- (9) European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste
- (10) Council Directive 96/16/EC of 19 March 1996 on statistical surveys of milk and milk products
- (11) Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials
- (12) Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid
- (13) 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
- (14) Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels

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- (15) 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
- (16) 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
- (17) Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants
- (18) 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
- (19) 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
- (20) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed
- (21) Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics
- (22) 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
- (23) 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
- (24) 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
- (25) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers
- (26) 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
- (27) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents
- (28) 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
- (29) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors
- (30) 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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- (31) 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)
- (32) 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)
- (33) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
- (34) Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security
- (35) 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
- (36) 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
- (37) Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids
- (38) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants
- (39) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
- (40) 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
- (41) 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
- (42) 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
- (43) 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
- (44) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
- (45) 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
- (46) Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC)
No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- (47) Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- (1) OJ C 224, 30.8.2008, p. 35.
- (2) OJ C 117, 14.5.2008, p. 1.
- (3) Opinion of the European Parliament of 23 September 2008 (not yet published in the Official Journal) and Council Decision of 16 February 2009.
- (4) OJ L 184, 17.7.1999, p. 23.
- (5) OJ L 200, 22.7.2006, p. 11.
- (6) OJ C 255, 21.10.2006, p. 1.
- (7) OJ L 163, 2.7.1996, p. 1.
- (8) OJ L 147, 9.6.1975, p. 40.
- (9) OJ L 162, 3.7.2000, p. 1.
- (10) OJ L 304, 21.11.2003, p. 1.
- (11) OJ L 50, 20.2.2004, p. 28.
- (12) OJ 196, 16.8.1967, p. 1.';
- (13) OJ L 50, 20.2.2004, p. 44.
- (14) OJ 196, 16.8.1967, p. 1.';
- (15) OJ L 47, 18.2.2004, p. 1.
- (16) OJ L 22, 26.1.2005, p. 1.'
- (17) OJ L 104, 8.4.2004, p. 1.
- (18) OJ L 136, 30.4.2004, p. 1.
- (19) OJ L 378, 31.12.1982, p. 1.
- (20) OJ L 181, 4.7.1986, p. 6.
- (21) OJ L 365, 31.12.1994, p. 10.
- (22) OJ L 309, 27.11.2001, p. 22.
- (23) OJ L 275, 25.10.2003, p. 32.
- (24) OJ L 23, 26.1.2005, p. 3.
- (25) OJ L 190, 12.7.2006, p. 1.
- (26) OJ L 377, 31.12.1991, p. 48.';
- (27) OJ L 374, 31.12.1991, p. 1.
- (28) OJ L 181, 28.6.1989, p. 47.'
- (29) OJ L 78, 28.3.1996, p. 27.
- (30) OJ L 66, 11.3.2003, p. 1.
- (31) OJ L 7, 13.1.2004, p. 1.
- (32) OJ L 142, 30.4.2004, p. 12.
- (33) OJ L 86, 6.4.1979, p. 30.
- (34) OJ L 213, 21.7.1982, p. 8.
- (35) OJ L 125, 23.5.1996, p. 35.
- (36) OJ L 140, 30.5.2002, p. 10.
- (37) OJ L 170, 3.8.1970, p. 1.';
- (38) OJ L 325, 12.12.2003, p. 31.
- (39) OJ L 139, 30.4.2004, p. 1.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC)
No 219/2009 of the European Parliament and of the Council. (See end of Document for details)

- (40) OJ L 139, 30.4.2004, p. 55.
- (41) OJ L 139, 30.4.2004, p. 206.
- (42) OJ L 35, 8.2.2005, p. 1.
- (43) OJ L 34, 9.2.1998, p. 1.
- (44) OJ L 324, 29.11.2002, p. 1.
- (45) OJ L 184, 17.7.1999, p. 23.’
- (46) OJ L 138, 1.6.1999, p. 1.
- (47) OJ L 324, 29.11.2002, p. 1.’;
- (48) OJ L 115, 9.5.2003, p. 1.
- (49) OJ L 324, 29.11.2002, p. 1.’
- (50) OJ L 166, 30.4.2004, p. 124.
- (51) OJ L 129, 29.4.2004, p. 6.
- (52) OJ L 138, 30.4.2004, p. 19.
- (53) OJ L 324, 29.11.2002, p. 1.’;
- (54) OJ L 255, 30.9.2005, p. 152.
- (55) OJ L 373, 31.12.1991, p. 29.’
- (56) OJ L 310, 25.11.2005, p. 28.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 219/2009 of the European Parliament and of the Council.