ANNEX

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[(1)]

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

. . . . . .

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[(2)].

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[(3)]

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:

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)[(4)]

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.

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, Division 2.. (See end of Document for details)*

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[5], 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)[6]

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.

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[7].

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[8]

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:

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[9].

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.

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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[(10)]

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:

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[11]

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

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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 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.

(**1**) OJ L 147, 9.6.1975, p. 40.

(**2**) OJ L 162, 3.7.2000, p. 1.

(**3**) OJ L 304, 21.11.2003, p. 1.

(**4**) OJ L 50, 20.2.2004, p. 28.

(**5**) OJ 196, 16.8.1967, p. 1.';

(**6**) OJ L 50, 20.2.2004, p. 44.

(**7**) OJ 196, 16.8.1967, p. 1.';

(**8**) OJ L 47, 18.2.2004, p. 1.

(**9**) OJ L 22, 26.1.2005, p. 1.'

(**10**) OJ L 104, 8.4.2004, p. 1.

(**11**) OJ L 136, 30.4.2004, p. 1.

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