ANNEX

1. ENTERPRISE

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

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

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

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

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

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

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

3. Article 14 shall be replaced by the following:

Article 14

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

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

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

Article 14a

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

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

5. Article 15 shall be amended as follows:

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

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

(b) paragraph 3 shall be deleted;

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

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

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

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

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

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

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

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

1. Article 7 shall be replaced by the following:

Article 7

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

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

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

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

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

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

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

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

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

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

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

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

5. Article 13 shall be replaced by the following:

Article 13

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

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

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

1. Where a Member State considers that:

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

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

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

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

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

1.3. **Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity**[(4)]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. the following Article shall be inserted:

Article 15a

Regulatory procedure with scrutiny

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. the following Article shall be inserted:

Article 10a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Article 20 shall be replaced by the following:

Article 20

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

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

4. Article 21 shall be replaced by the following:

Article 21

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

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

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

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

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

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

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

1. **[**[X1]. . . . .

2. . . . .**]**

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

> However, the 10-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated by the Commission.
>
> That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

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

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

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

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

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

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

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

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

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

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

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

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

Member States may continue to apply national provisions until either:

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

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

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

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

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

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

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

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

11. Article 79 shall be replaced by the following:

Article 79

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

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

12. Article 88 shall be replaced by the following:

Article 88

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

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

13. Article 89 shall be amended as follows:

(a) the following paragraph shall be inserted:

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

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

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

Editorial Information

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

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

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

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

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

1. Article 8 shall be replaced by the following:

Article 8

Specific measures

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

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

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

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

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

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

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

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

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

3. Article 22 shall be amended as follows:

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

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

(b) paragraph 4 shall be deleted.

(**1**) OJ L 59, 27.2.1998, p. 1.

(**2**) OJ L 331, 7.12.1998, p. 1.

(**3**) OJ L 184, 17.7.1999, p. 23.';

(**4**) OJ L 91, 7.4.1999, p. 10.

(**5**) OJ L 18, 22.1.2000, p. 1.

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

(**7**) OJ L 184, 17.7.1999, p. 23.'.

(**8**) OJ L 121, 1.5.2001, p. 34.

(**9**) OJ L 311, 28.11.2001, p. 67.'

(**10**) OJ L 311, 28.11.2001, p. 1.

(**11**) OJ L 157, 9.6.2006, p. 24.

Changes to legislation:
Regulation (EC) No 596/2009 of the European Parliament and of the Council, Division 1. is up to date with all changes known to be in force on or before 28 September 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation partial repeal by EUDN 2013/1082 Decision
- Regulation partial repeal by EUDR 2014/24 Directive
- Regulation partial repeal by EUDR 2014/25 Directive
- Regulation partial repeal by EUDR 2014/40 Directive
- Regulation partial repeal by EUDR 2014/53 Directive
- Regulation partial repeal by EUDR 2014/90 Directive
- Regulation partial repeal by EUR 2011/1169 Regulation
- Regulation partial repeal by EUR 2014/376 Regulation
- Regulation partial repeal by EUR 2014/536 Regulation