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

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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 outstanding changes not yet made to Regulation (EC) No 596/2009 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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.

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ANNEX

1. ENTERPRISE

1.1. **Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery**[(7)]

As regards Directive 97/68/EC, 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

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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[8]**

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[9] 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.

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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.