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#### INFORMATION NOTE

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From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

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Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union

- Outcome of the European Parliament's first reading  
(Strasbourg, 15 to 18 April 2019)

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## I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure<sup>1</sup>, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

In this context, the rapporteur, József SZÁJER (EPP, HU), presented a compromise amendment (amendment number 585) to the proposal for a Regulation on behalf of the Committee on Legal Affairs. This amendment had been agreed during the informal contacts referred to above. The rapporteur also tabled amendment number 586, suggesting to take note of the statement by the Commission annexed to the resolution, and amendment number 587, suggesting to approve the joint statement by the Parliament, the Council and the Commission, annexed to the resolution.

## II. VOTE

When it voted on 17 April 2019, the plenary adopted the compromise amendment (amendment number 585) to the proposal for a Regulation, as well as amendments number 586 and 587. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto<sup>2</sup>.

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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<sup>1</sup> OJ C 145, 30.6.2007, p. 5.

<sup>2</sup> The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics***. The symbol "■" indicates deleted text.

## **Adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 TFEU - part I \*\*\*I**

**European Parliament legislative resolution of 17 April 2019 on the proposal for a regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (COM(2016)0799 – C8-0524/2016 – 2016/0400A(COD))**

### **(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2016)0799),
- having regard to Article 294(2) and Article 33, Article 43(2), Article 53(1), Article 62, Article 64(2), Article 91, Article 100(2), Article 114, Article 153(2)(b), Article 168(4) (a), Article 168(4)(b), Article 172, Article 192(1), Article 207, Article 214(3), and Article 338(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0524/2016),
- having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
- having regard to Article 294(3) and Article 33, Article 43(2), Article 53(1), Article 62, Article 91, Article 100(2), Article 114, Article 153(2)(b), Article 168(4)(b), Article 172, Article 192(1), Article 207(2), Article 214(3), and Article 338(1) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 1 June 2017<sup>1</sup>,
- having regard to the opinion of the Committee of the Regions of 1 December 2017<sup>2</sup>,
- having regard to the letters of the Committee on Employment and Social Affairs, the Committee on the Environment, Public Health and Food Safety, the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection,
- having regard to the decision by the Conference of Presidents of 7 March 2019 to authorise the Committee on Legal Affairs to split the above-mentioned Commission proposal and to draw up two separate legislative reports on the basis thereof,
- having regard to the provisional agreement approved by the committee responsible under Rule 69f(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 27 February 2019 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

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<sup>1</sup> OJ C 288, 31.8.2017, p. 29.

<sup>2</sup> OJ C 164, 8.5.2018, p. 82.

- having regard to the report of the Committee on Legal Affairs (A8-0190/2019),
  - having regard to Rules 59 and 39 of its Rules of Procedure,
  - having regard to the report of the Committee on Legal Affairs and also the opinions and position in the form of amendments of the Committee on Economic and Monetary Affairs, the Committee on the Environment, Public Health and Food Safety, the Committee on Transport and Tourism and the Committee on Agriculture and Rural Development (A8-0020/2018),
1. Adopts its position at first reading hereinafter set out;
  2. Approves the joint statement by Parliament, the Council and the Commission annexed to this resolution;
  3. Takes note of the Commission statement annexed to this resolution;
  4. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

**Position of the European Parliament adopted at first reading on 17 April 2019 with a view to the adoption of Regulation (EU) 2019/... of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 33, Article 43(2), Article 53(1), Article 62, ■ Article 91, Article 100(2), Article 114, Article 153(2)(b), ■ Article 168(4)(b), Article 172, Article 192(1), Article 207(2), Article 214(3), and Article 338(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>3</sup>,

Having regard to the opinion of the Committee of the Regions<sup>4</sup>,

Acting in accordance with the ordinary legislative procedure<sup>5</sup>,

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<sup>3</sup> OJ C 288, 31.8.2017, p. 29.

<sup>4</sup> OJ C 164, 8.5.2018, p. 82.

<sup>5</sup> Position of the European Parliament of 17 April 2019.

Whereas:

- (1) The Treaty of Lisbon ***modified the legal framework governing the powers conferred on the Commission by the legislator, introducing*** a distinction between powers delegated to the Commission to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act (delegated acts), and the powers conferred on the Commission to adopt acts to ensure uniform conditions for implementing legally binding Union acts (implementing acts).
- (2) ***Legislative acts adopted before the entry into force of the Treaty of Lisbon confer powers on the Commission to adopt measures under*** the regulatory procedure with scrutiny established by Article 5a of Council Decision 1999/468/EC<sup>6</sup>.
- (3) Earlier proposals relating to the alignment of legislation referring to the regulatory procedure with scrutiny with the legal framework introduced by the Treaty of Lisbon **█** were withdrawn<sup>7</sup> due to the stagnation of the interinstitutional negotiations.

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<sup>6</sup> Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

<sup>7</sup> **█** OJ C 80, 7.2.2015, p. 17.

- (4) The European Parliament, the Council and the Commission subsequently agreed on a new framework for delegated acts in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>8</sup>, and acknowledged the need to align all existing legislation to the legal framework introduced by the Treaty of Lisbon. In particular, they agreed on the need to give high priority to the prompt alignment of all basic acts which still refer to the regulatory procedure with scrutiny. The Commission gave a commitment to prepare a proposal for that alignment by the end of 2016.
- (5) The majority of empowerments in basic acts which provide for the use of the regulatory procedure with scrutiny fulfil the criteria in Article 290(1) of the Treaty on the Functioning of the European Union (TFEU) and should be adapted to that provision.
- (6) Other empowerments in basic acts which provide for the use of the regulatory procedure with scrutiny fulfil the criteria in Article 291(2) TFEU and should be adapted to that provision.

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<sup>8</sup> OJ L 123, 12.5.2016, p. 1.

- (7) Where implementing powers are conferred on the Commission, those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>9</sup>.
- (8) In *a limited number of* basic acts which currently provide for the use of the regulatory procedure with scrutiny the respective empowerments *are no longer needed* and should therefore be deleted.
- (9) *Point 31 of the Interinstitutional Agreement of 13 April 2016 on Better Law-Making states that, on condition that the Commission provides objective justifications based on the substantive link between two or more empowerments contained in a single legislative act, and unless the legislative act provides otherwise, empowerments may be bundled. Consultations in the preparation of delegated acts also serve to indicate which empowerments are considered to be substantially linked. In such cases, any objection by the European Parliament or the Council will indicate clearly to which empowerment it specifically relates. In a limited number of basic acts listed in the Annex to this Regulation, a clear provision concerning adoption of separate delegated acts for different delegated powers has been included in the basic act.*

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<sup>9</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).



- (10) This Regulation should not affect pending procedures in which the committee has already delivered its opinion in accordance with Article 5a of Decision 1999/468/EC before the entry into force of this Regulation.
- (11) Since the adaptations and amendments to be made concern procedures at Union level only, they do not, in the case of directives, need to be transposed by the Member States.
- (12) The acts concerned should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

## Article 1

The acts listed in the Annex are amended as set out therein.

## Article 2

This Regulation shall not affect pending procedures in which a committee has already delivered its opinion in accordance with Article 5a of Decision 1999/468/EC.

## Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at,

*For the European Parliament*

*For the Council*

*The President*

*The President*

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## ANNEX



### I. COMMUNICATION NETWORKS, CONTENT AND TECHNOLOGY



1. Regulation (EC) No 733/2002 of the European Parliament and of the Council of 22 April 2002 on the implementation of the .eu Top Level Domain<sup>10</sup>

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<sup>10</sup> OJ L 113, 30.4.2002, p. 1.

In order to set out the conditions for the implementation of the .eu country code Top Level Domain (ccTLD) established by Regulation (EC) No 733/2002, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement that Regulation with the criteria and the procedure for the designation of the Registry, and with public policy rules concerning the implementation and functions of the .eu Top Level Domain (TLD) and the public policy principles on registration. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 733/2002 is amended as follows:

(1) in Article 3(1), point (a) of the first subparagraph is replaced by the following:

"(a) adopt delegated acts in accordance with Article 5a *in order to supplement this Regulation by* establishing the criteria and the procedure for the designation of the Registry.

Where, in the case of establishing the criteria and the procedure for the designation of the Registry, imperative grounds of urgency so require, the procedure provided for in Article 5b shall apply to delegated acts adopted pursuant to this Article;"

(2) Article 5 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

"After consulting the Registry, the Commission is empowered to adopt delegated acts in accordance with Article 5a ***in order to supplement this Regulation by*** setting out public policy rules on the implementation and function of the .eu TLD and public policy principles on registration.";

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

"Where a Member State or the Commission within 30 days of publication raises an objection to an item included in a notified list, the Commission is empowered to adopt delegated acts in accordance with Article 5a in order to remedy the situation ***by supplementing this Regulation.***";

(3) the following Articles ■ are inserted:

"Article 5a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 3(1) and Article 5(1) and (2) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 3(1) and Article 5(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.



6. A delegated act adopted pursuant to Article 3(1) and Article 5(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 5b

#### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 5a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(4) in Article 6, paragraphs 3 and 4 are deleted.

2. Decision No 626/2008/EC of the European Parliament and of the Council of 30 June 2008 on the selection and authorisation of systems providing mobile satellite services (MSS)<sup>11</sup>

In order to ensure uniform conditions for the implementation of Decision No 626/2008/EC, implementing powers should be conferred on the Commission concerning appropriate modalities for coordinated application of the rules on enforcement. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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<sup>11</sup> OJ L 172, 2.7.2008, p. 15.

Accordingly, Decision No 626/2008/EC is amended as follows:

(1) in Article 9, paragraph 3 is replaced by the following:

"3. The Commission may adopt, by means of implementing acts, measures defining any appropriate modalities for coordinated application of the rules on enforcement referred to in paragraph 2 of this Article, including rules for the coordinated suspension or withdrawal of authorisations for breaches of the common conditions provided for in Article 7(2). Those implementing acts shall be adopted in accordance with the procedure referred to in Article 10(3).";

(2) in Article 10, paragraph 4 is deleted.

## II. HUMANITARIAN AID AND CIVIL PROTECTION

Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid<sup>12</sup>

Since its adoption in 1996, no measures have ever had to be adopted by the Commission in accordance with the regulatory procedure with scrutiny in order to amend non-essential elements of Regulation (EC) No 1257/96. There does not seem to be any foreseeable need to do so in the future. The possibility of adopting implementing measures in accordance with the regulatory procedure with scrutiny should therefore be removed from Regulation (EC) No 1257/96, without there being a need to *give any empowerment to* the Commission

■ .

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

- (1) in Article 15, paragraph 1 is deleted;
- (2) in Article 17, paragraph 4 is deleted.

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<sup>12</sup> OJ L 163, 2.7.1996, p. 1.

### III. EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

#### I

1. Council Directive 89/654/EEC of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>13</sup>

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<sup>13</sup> *OJ L 393, 30.12.1989, p.1.*

In order to take account of technical harmonisation and standardisation of the design, manufacture or construction of parts of workplaces, technical progress, changes in international regulations or specifications and knowledge with regard to the workplaces, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to ***make strictly*** technical ***amendments to the Annexes*** to Directive 89/654/EEC. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and ***the*** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Council Decision of 22 July 2003<sup>14</sup>, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 89/654/EEC is amended as follows:

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

"Article 9

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article **9a** *to make strictly technical amendments to* the Annexes, in order to take account of technical harmonisation and standardisation of the design, manufacture or construction of parts of workplaces, technical progress, changes in international regulations or specifications and knowledge with regard to workplaces.

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<sup>14</sup> *Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).*

Where, in *duly justified and exceptional cases involving imminent, direct and serious* risks to workers' *and other persons' physical health and safety*, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.



2. The power to adopt delegated acts referred to in Article 9 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this **amending Regulation**]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 9 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 9 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 9b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 9a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

2. Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>15</sup>

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and knowledge with regard to personal protective equipment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly* technical *amendments to* the Annexes to Directive 89/656/EEC. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>15</sup> OJ L 393, 30.12.1989, p. 18.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 89/656/EEC is amended as follows:

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

"Article 9

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 9a *to make strictly* technical *amendments to* the Annexes, **■** in order to take account of technical harmonisation and standardisation relating to personal protective equipment, technical progress, changes in international regulations or specifications and knowledge in the field of personal protective equipment.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 9 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 9 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 9 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.



## Article 9b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 9a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

3. Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>16</sup>

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<sup>16</sup> OJ L 156, 21.6.1990, p. 9.

In order to take account of technical progress, changes in international regulations or specifications and knowledge with regard to manual handling of loads where there is a risk particularly of back injury to workers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to **make strictly technical amendments to** the Annexes to Directive 90/269/EEC **█** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making **█** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and **the** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 90/269/EEC is amended as follows:

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

"Article 8

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 8a *to make strictly* technical *amendments to* the Annexes, in order to take account of technical progress, changes in international regulations or specifications and knowledge in the field of the manual handling of loads.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 8b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles are inserted:

"Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 8 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 8b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 8a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."



4. Council Directive 90/270/EEC of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>17</sup>

In order to take account of technical progress, changes in international regulations or specifications and knowledge with regard to display screen equipment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to **make strictly technical amendments to** the Annex to Directive 90/270/EEC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>17</sup> OJ L 156, 21.6.1990, p. 14.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 90/270/EEC is amended as follows:

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

"Article 10

Amendments to the Annex

The Commission is empowered to adopt delegated acts in accordance with Article 10a *to make strictly technical amendments to* the Annex, **■** in order to take account of technical progress, developments in international regulations or specifications and knowledge in the field of display screen equipment.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article. ";

(2) the following *Articles* ■ are inserted:

"Article 10a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 10 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 10 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 10 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 10b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 10a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

5. Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels<sup>18</sup>

In order to take account of technical progress or changes in international regulations or specifications and new findings with regard to medical treatment on board vessels, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly technical amendments to* the Annexes to Directive 92/29/EEC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>18</sup> OJ L 113, 30.4.1992, p. 19.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 92/29/EEC is amended as follows:

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

"Article 8

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 8a **to make strictly technical amendments to** the Annexes, **■** in order to take account of technical progress or changes in international regulations or specifications and new findings concerning medical treatment on board vessels.



Where, in *duly justified and exceptional cases involving* imminent, *direct and serious risks to workers' and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 8b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 8 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 8b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 8a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

6. Council Directive 92/57/EEC of 24 June 1992 on the implementation of minimum safety and health requirements at temporary or mobile construction sites (eighth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>19</sup>

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and knowledge with regard to temporary or mobile construction sites, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to **make strictly technical amendments to Annex IV to Directive 92/57/EEC** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and **the** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>19</sup> OJ L 245, 26.8.1992, p. 6.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 92/57/EEC is amended as follows:

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

"Article 13

Amendments to Annex IV

The Commission is empowered to adopt delegated acts in accordance with Article 13a *to make strictly* technical *amendments to* Annex IV, **■** in order to take account of technical harmonisation and standardisation regarding temporary or mobile construction sites, as well as technical progress, changes in international regulations or specifications and knowledge in the field of temporary or mobile construction sites.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 13a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 13 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 13 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.



4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 13 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 13b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 13a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

7. Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>20</sup>

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and knowledge with regard to safety and health signs at work, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly technical amendments to* the Annexes to Directive 92/58/EEC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>20</sup> OJ L 245, 26.8.1992, p. 23.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 92/58/EEC is amended as follows:

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

"Article 9

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 9a *to make strictly technical amendments to* the Annexes, **■** in order to take account of technical harmonisation and standardisation concerning the design and manufacture of safety and/or health signs or devices at work, as well as technical progress, changes in international regulations or specifications and advances in knowledge in the field of safety and/or health signs or devices at work.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article. "

(2) the following Articles ■ are inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 9 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 9 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 9 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 9b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 9a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."





8. Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work<sup>21</sup>

In order to achieve adequate protection of young people at work and to take account of technical progress, changes in international *rules* or specifications and *advances in knowledge*, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly technical amendments to* the Annex to Directive 94/33/EC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>21</sup> OJ L 216, 20.8.1994, p. 12.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 94/33/EC is amended as follows:

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

"Article 15

Amendments to the Annex

The Commission is empowered to adopt delegated acts in accordance with Article 15a *to make strictly technical amendments to* the Annex, **■** in the light of technical progress, changes in international rules or specifications and advances in knowledge concerning the protection of young people at work.";

(2) the following Article ■ is inserted:

"Article 15a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 15 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 15 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

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\* OJ L 123, 12.5.2016, p. 1."

9. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>22</sup>

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<sup>22</sup> OJ L 131, 5.5.1998, p. 11.

In order to achieve adequate protection of workers from risks to their health and safety and to take account of technical harmonisation and standardisation, technical progress, changes in international standards or specifications and new findings concerning chemical agents, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to ***make strictly technical amendments to*** the Annexes to Directive 98/24/EC **█**, and to supplement that Directive by establishing or revising indicative occupational exposure limit values. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making **█**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and ***the*** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 98/24/EC is amended as follows:

- (1) in Article 3(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 12a *in order to supplement this Directive by establishing or revising the* indicative occupational exposure limit values *referred to in the first subparagraph of this paragraph*, taking into account the availability of measurement techniques.

Member States shall keep workers' and employers' organisations informed of indicative occupational exposure limit values set at Union level.

Where, in *duly justified and exceptional cases involving imminent, direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency **█** require *action in a very short timeframe*, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this *Article.*";

(2) in Article 12, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 12a *to make strictly technical amendments to* the Annexes, █ in order to take account of technical harmonisation and standardisation concerning chemical agents, as well as technical progress, changes in international standards or specifications and new findings with regard to chemical agents.

Where, in *duly justified and exceptional cases involving imminent, direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency █ require *action in a very short timeframe*, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";



(3) the following Articles ■ are inserted:

"Article 12a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 3(2) and Article 12(1) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 3(2) and Article 12(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 3(2) and Article 12(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

#### Article 12b

#### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

10. Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>23</sup>

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<sup>23</sup> OJ L 177, 6.7.2002, p. 13.

In order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment and workplaces, technical progress, changes in harmonised European standards or specifications and new findings concerning mechanical vibration, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to ***make strictly technical amendments*** to the Annex to Directive 2002/44/EC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and ***the*** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 2002/44/EC is amended as follows:

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

"Article 11

Amendments to the Annex

The Commission is empowered to adopt delegated acts in accordance with Article 11a *to make strictly technical amendments to* the Annex, **■** in order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment and workplaces, technical progress, changes in harmonised European standards or specifications and new findings concerning mechanical vibration.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.



4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

## Article 11b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

- (3) Article 12 is deleted.

11. Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>24</sup>

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<sup>24</sup> OJ L 42, 15.2.2003, p. 38.

In order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment and workplaces, technical progress, changes in harmonised European standards or specifications and new findings concerning noise, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly* technical *amendments to* Directive 2003/10/EC. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 2003/10/EC is amended as follows:

- (1) Article 12 is replaced by the following:

"Article 12

Amendments to the Directive

The Commission is empowered to adopt delegated acts in accordance with Article 12a *to make strictly* technical *amendments to* this Directive in order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment and workplaces, technical progress, changes in harmonised European standards or specifications and new findings concerning noise.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles are inserted:

"Article 12a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 12 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 12 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 12 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.



## Article 12b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 13 is deleted.

12. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)<sup>25</sup>

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<sup>25</sup> OJ L 158, 30.4.2004, p. 50.

In order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens or mutagens, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly technical amendments to* Annex II to Directive 2004/37/EC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 2004/37/EC is amended as follows:

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

"Article 17

Amendment of Annex II

The Commission is empowered to adopt delegated acts in accordance with Article 17a *to make strictly* technical *amendments to* Annex II, **■** in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens or mutagens.

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency **■** require *action in a very short timeframe*, the procedure provided for in Article 17b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 17a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 17 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 17 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

#### Article 17b

#### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 17a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

13. Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>26</sup>

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<sup>26</sup> OJ L 114, 27.4.2006, p. 38.



In order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces, technical progress, changes in harmonised European standards or international specifications and new scientific findings concerning occupational exposure to optical radiation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to ***make strictly technical amendments to*** the Annexes to Directive 2006/25/EC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and ***the*** Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 2006/25/EC is amended as follows:

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

"Article 10

Amendment of the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 10a *to make strictly technical amendments to* the Annexes, **■** in order to take account of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces, technical progress, changes in harmonised European standards or international specifications and new scientific findings concerning occupational exposure to optical radiation. *Those amendments shall not result in a modification of the exposure limit values set out in the Annexes.*

Where, in *duly justified and exceptional cases involving* imminent, *direct and serious* risks to workers' *and other persons' physical* health and safety, imperative grounds of urgency ■ require *action in a very short timeframe*, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles ■ are inserted:

"Article 10a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 10 shall be conferred on the Commission for *a* period of *five years* from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 10 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 10 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

#### Article 10b

##### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 10a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council. █

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 11 is deleted.

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14. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work<sup>27</sup>

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<sup>27</sup> OJ L 330, 16.12.2009, p. 28.

In order to take account of technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex I to Directive 2009/148/EC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 2009/148/EC is amended as follows:

- (1) Article 9 is deleted;
- (2) in Article 18, paragraph 2 is replaced by the following:

"2. An assessment of each worker's state of health must be available prior to the beginning of exposure to dust arising from asbestos or materials containing asbestos at the place of work.

That assessment shall include a specific examination of the chest. Annex I gives practical recommendations to which the Member States may refer for the clinical surveillance of workers. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending Annex I, ■ to adapt it to technical progress.



Where, in *duly justified and exceptional cases involving imminent, direct and serious* risks to workers' *and other persons' physical* health and safety ▯ , imperative grounds of urgency ▯ require *action in a very short timeframe*, the procedure provided for in Article 18b shall apply to delegated acts adopted pursuant to this *Article*.

A new assessment must be available at least once every three years for as long as exposure continues.

An individual health record shall be established in accordance with national laws and/or practices for each worker referred to in the first subparagraph.";

(3) the following Articles ■ are inserted:

"Article 18a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 18(2) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 18(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 18(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

#### Article 18b

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 18a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

#### IV. ENERGY



Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters<sup>28</sup>

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<sup>28</sup> OJ L 342, 22.12.2009, p. 46.

In order to make the necessary technical adaptations to Regulation (EC) No 1222/2009 the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Regulation to adapt them to technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 1222/2009 is amended as follows:

(1) Article 11 is replaced by the following:

"Article 11

Amendments and adaptations to technical progress

The Commission is empowered to adopt delegated acts in accordance with Article 12a amending this Regulation in respect of the following:

- (a) introduction of information requirements with respect to wet grip grading of C2 and C3 tyres, provided that suitable harmonised testing methods are available;
- (b) adaptation, where relevant, of grip grading to the technical specificities of tyres primarily designed to perform better in ice and/or snow conditions than a normal tyre with regard to their ability to initiate, maintain, or stop vehicle motion;
- (c) adaptation of Annexes I to V to technical progress.";

(2) the following Article ■ is inserted:

"Article 12a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for *a* period of **five years** from ... *[date of entry into force of this **amending Regulation**]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*



3. The delegation of power referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 13 is deleted.

## V. ENVIRONMENT

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1. European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations<sup>29</sup>

In order to ensure that the specifications for bottom loading equipment laid down in Directive 94/63/EC are revised where appropriate and to adapt the Annexes to technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making ■ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>29</sup> OJ L 365, 31.12.1994, p. 24.

Accordingly, Directive 94/63/EC is amended as follows:

- (1) in Article 4(1), the sixth subparagraph is replaced by the following:

"All terminals with loading facilities for road tankers shall be equipped with at least one gantry which meets the specifications for bottom loading equipment laid down in Annex IV. The Commission shall re-examine those specifications at regular intervals and is empowered to adopt delegated acts in accordance with Article 7a amending Annex IV in the light of the result of that re-examination.";

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

"Article 7

Adaptation to technical progress

The Commission is empowered to adopt delegated acts in accordance with Article 7a amending the Annexes to adapt them to technical progress, with the exception of the limit values laid down in point 2 of Annex II.";

(3) the following Article ■ is inserted:

"Article 7a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 4(1) and Article 7 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 4(1) and Article 7 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 4(1) and Article 7 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

- (4) Article 8 is deleted.

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2. Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise<sup>30</sup>

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<sup>30</sup> OJ L 189, 18.7.2002, p. 12.

In order to adapt Directive 2002/49/EC to technical and scientific progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2002/49/EC is amended as follows:



(1) Article 6 is amended as follows:

(a) paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 12a amending Annex II in order to establish common assessment methods for the determination of Lden and Lnight.";

(b) in paragraph 3, the following second subparagraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 12a amending Annex III in order to establish common assessment methods for the determination of harmful effects.";

- (2) Article 12 is replaced by the following:

"Article 12

Adaptation to technical and scientific progress

The Commission is empowered to adopt delegated acts in accordance with Article 12a amending point 3 of Annex I and Annexes II and III to adapt them to technical and scientific progress.";

- (3) the following Article ■ is inserted:

"Article 12a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6(2) and (3) and Article 12 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 6(2) and (3) and Article 12 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 6(2) and (3) and Article 12 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1";

(4) in Article 13, paragraph 3 is deleted;

(5) in Annex III, the second sentence of the introductory wording is replaced by the following:

"The dose-effect relations introduced by future revisions of this Annex will concern in particular:".

3. Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC<sup>31</sup>

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<sup>31</sup> OJ L 143, 30.4.2004, p. 87.

In order to ensure the use of up-to-date analytical methods for determining compliance with volatile organic compounds content limit values, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex III to Directive 2004/42/EC to adapt it to technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2004/42/EC is amended as follows:

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

"Article 11

Adaptation to technical progress

The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annex III to adapt it to technical progress.";

- (2) the following Article ■ is inserted:

"Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.



4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016. p.1.";

(3) in Article 12, paragraph 3 is deleted.

**I**

4. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC<sup>32</sup>

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<sup>32</sup> OJ L 33, 4.2.2006, p. 1.

In order to adapt Regulation (EC) No 166/2006 to technical progress and to the evolution of international law, and to ensure better reporting, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes II and III to that Regulation to adapt them to scientific or technical progress or as a result of the adoption by the Meeting of the Parties to the Protocol of any amendment of the Annexes to the UNECE Protocol on Pollutant Release and Transfer Registers, as well as to supplement that Regulation by initiating reporting on releases of relevant pollutants from one or more diffuse sources. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 166/2006 is amended as follows:

(1) in Article 8, paragraph 3 is replaced by the following:

“3. Where it determines that no data on the releases from diffuse sources exist, the Commission is empowered to adopt delegated acts in accordance with Article 18a *in order to supplement this Regulation by initiating* reporting on releases of relevant pollutants from one or more diffuse sources using, where appropriate, internationally approved methodologies.”;

(2) Article 18 is replaced by the following:

"Article 18

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 18a to amend Annexes II and III for the following purposes:

- (a) to adapt them to scientific or technical progress;
- (b) to adapt them as a result of the adoption by the Meeting of the Parties to the Protocol of any amendment to the Annexes to the Protocol.”;

(3) the following Article ■ is inserted:

"Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 8(3) and Article 18 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 8(3) and Article 18 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 8(3) and Article 18 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

(4) in Article 19, paragraph 3 is deleted.

5. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006<sup>33</sup>

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<sup>33</sup> OJ L 353, 31.12.2008, p. 1.

In order to ensure that Regulation (EC) No 1272/2008 is regularly updated, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission:

- to amend Annex VI to that Regulation to harmonise the classification and labelling of substances;
- to amend *Annex VIII to further harmonise the information* relating to emergency health response *and preventative measures*;
- to amend certain provisions of that Regulation and Annexes I to VIII to that Regulation in order to adapt them to technical and scientific progress.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.



Accordingly, Regulation (EC) No 1272/2008 is amended as follows:

(1) in Article 37, paragraph 5 is replaced by the following:

"5. The Commission shall without undue delay adopt delegated acts in accordance with Article 53a, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, where appropriate, the specific concentration limits or M-factors.

A corresponding entry shall be included in Table 3.2 of Part 3 of Annex VI subject to the same conditions, until 31 May 2015.

Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.";

(2) in Article 45, paragraph 4 is replaced by the following:

"4. *The Commission is empowered to adopt delegated acts in accordance with Article 53a amending Annex VIII to further harmonise the information relating to emergency health response and preventative measures*, following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) **■** .";

(3) in Article 53, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 53a amending Article 6(5), Article 11(3), Articles 12 and 14, point (b) of Article 18(3), Article 23, Articles 25 to 29, the second and third subparagraphs of Article 35(2) and Annexes I to VIII in order to adapt them to technical and scientific progress, taking due account of the further development of the GHS, in particular any UN amendments relating to the use of information on similar mixtures, and considering the developments in internationally recognised chemical programmes and of the data from accident databases.

Where imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.";

(4) the following Articles ■ are inserted:

"Article 53a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 37(5), Article 45(4) and Article 53(1) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Articles 37(5), Article 45(4) and Article 53(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 37(5), Article 45(4) and Article 53(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 53b

#### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 53a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council. ";

***Article 53c***

***Separate delegated acts for different delegated powers***

***The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.***

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\* OJ L 123, 12.5.2016, p.1.";

- (5) in Article 54, paragraphs 3 and 4 are deleted.
6. Directive 2009/126/EC of the European Parliament and of the Council of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations<sup>34</sup>

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<sup>34</sup> OJ L 285, 31.10.2009, p. 36.

In order to ensure consistency with relevant standards drawn up by the European Committee for Standardisation (CEN), the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend certain provisions of Directive 2009/126/EC in order to adapt them to technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2009/126/EC is amended as follows:

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

"Article 8

Technical adaptations

The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Articles 4 and 5 to adapt them to technical progress where necessary to ensure consistency with any relevant standard drawn up by the European Committee for Standardisation (CEN).

The delegation of power referred to in the first paragraph shall not apply to the petrol vapour capture efficiency and vapour/petrol ratio specified in Article 4 and the time periods specified in Article 5.";



(2) the following Article is inserted:

"Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 8 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 8 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 9 is deleted.

## VI. EUROSTAT

1. Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains<sup>35</sup>

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<sup>35</sup> OJ L 393, 30.12.2006, p.1.

In order to adapt Regulation (EC) No 1893/2006 to technological and economic developments and to align NACE Rev. 2 with other economic and social classifications, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex I to that Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 1893/2006 is amended as follows:

(1) Article 6 is amended as follows:

(a) the title is replaced by the following:

"Delegated and implementing acts";

(b) paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending Annex I to take account of technological or economic developments or to align it with other economic and social classifications.";

(2) the following Article ■ is inserted:

"Article 6a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6(2) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this **amending Regulation**]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *three* months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(3) in Article 7, paragraph 3 is deleted.

**I**

2. Regulation (EC) No 451/2008 of the European Parliament and of the Council of 23 April 2008 establishing a new statistical classification of products by activity (CPA) and repealing Council Regulation (EEC) No 3696/93<sup>36</sup>

In order to adapt Regulation (EC) No 451/2008 to technological or economic developments and align it with other economic and social classifications, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annex to that Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>36</sup> OJ L 145, 4.6.2008, p. 65.



Accordingly, Regulation (EC) No 451/2008 is amended as follows:

(1) Article 6 is amended as follows:

(a) the title is replaced by the following:

"Delegated and implementing acts";

(b) paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending the Annex ■ to take account of technological or economic developments *or* to align it with other economic and social classifications.

When exercising that power, the Commission shall ensure that the delegated acts do not impose a significant additional burden or cost on the Member States or on the respondents.";

(2) the following Article ■ is inserted:

"Article 6a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6(2) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *three* months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) in Article 7, paragraph 3 is deleted.

## VII. INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

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1. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products<sup>37</sup>

In order to adapt Directive 76/211/EC to technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I and II to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making ■ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>37</sup> OJ L 46, 21.2.1976, p. 1.

Accordingly, Directive 76/211/EEC is amended as follows:

- (1) Article 6 is replaced by the following:

"Article 6

The Commission is empowered to adopt delegated acts in accordance with Article 6a amending Annexes I and II to adapt them to technical progress.";

- (2) the following Article ■ is inserted:

"Article 6a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

■

3. The delegation of power referred to in Article 6 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 6 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

2. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors<sup>38</sup>

In order to adapt Directive 2000/14/EC to technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex III to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>38</sup> OJ L 162, 3.7.2000, p. 1.



Accordingly, Directive 2000/14/EC is amended as follows:

- (1) in Article 18, paragraph 2 is deleted;
- (2) Article 18a is replaced by the following:

"Article 18a  
Amendments to Annex III

The Commission is empowered to adopt delegated acts in accordance with Article 18b amending Annex III to adapt it to technical progress. Those delegated acts shall 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.";

- (3) the following Article ■ is inserted:

"Article 18b  
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 18a shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 18a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 18a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

(4) in Article 19, point (b) is deleted.

■

3. 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)<sup>39</sup>

In order to adopt the necessary technical adaptation to Directive 2004/9/EC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission:

- to amend that Directive in order to resolve disagreements in relation to GLP compliance;
- to amend the endorsement formula in that Directive;
- to amend Annex I to that Directive to take account of technical progress.

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<sup>39</sup> OJ L 50, 20.2.2004, p. 28.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive **2004/9/EC** is amended as follows:

(1) in Article 6, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending this Directive in order to resolve the matters referred to in paragraph 1. ***Amendments to Annex I shall not change its nature of providing guidance for compliance monitoring procedures for GLP and for the conduct of test facility inspections and study audits.***";

(2) the following Article ■ is inserted:

"Article 6a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 6(3) and Article 8(2) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 6(3) and Article 8(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 6(3) and Article 8(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) in Article 7, paragraph 3 is deleted;
- (4) in Article 8, paragraph 2 is replaced by the following:
- "2. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending:
- (a) the formula in Article 2(2);
- (b) Annex I, to take account of technical progress."

I



4. Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC<sup>40</sup>

In order to take into account new developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the indicative list of safety components in Annex V to Directive 2006/42/EC. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>40</sup> OJ L 157, 9.6.2006, p. 24.

In order to ensure uniform conditions for the implementation of Directive 2006/42/EC, implementing powers should be conferred on the Commission concerning necessary measures to deal with potentially hazardous machinery. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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

- (1) in the second paragraph of Article 2, the second subparagraph of point (c) is replaced by the following:

"An indicative list of safety components is set out in Annex V.";

- (2) in Article 8, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex V to update the indicative list of safety components.";

- (3) in Article 9(3), the second and third subparagraphs are replaced by the following:

"Taking due account of the results of that consultation, the Commission shall adopt the necessary measures by implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 22(3).";

(4) the following Article ■ is inserted:

"Article 21a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 8(1) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 8(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 8(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

- (5) in Article 22, paragraph 3 is replaced by the following:

- "3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council\* shall apply.

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\* Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13)."

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5. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control<sup>41</sup>

In order to ensure that the necessary technical adaptations are made to Directive 2009/34/EC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive to adapt them to technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>41</sup> OJ L 106, 28.4.2009, p. 7.

As far as the empowerment in Article 5(3) is concerned, which provides that Member States which have granted limited EC pattern approval are to apply for adjustment to technical progress of Annexes I and II, such limited EC pattern approvals no longer exist. The empowerment in Article 5(3) should therefore be deleted.

Accordingly, Directive 2009/34/EC is amended as follows:

- (1) in Article 5, paragraph 3 is deleted;
- (2) Article 16 is replaced by the following:

"Article 16

The Commission is empowered to adopt delegated acts in accordance with Article 16a amending Annexes I and II to adapt them to technical progress.";

(3) the following Article ■ is inserted:

"Article 16a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 16 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***



3. The delegation of power referred to in Article 16 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 16 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (4) Article 17 is deleted.

■

6. Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community<sup>42</sup>

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<sup>42</sup> OJ L 146, 10.6.2009, p. 1.

In order to ensure that the list of defence-related products set out in the Annex to Directive 2009/43/EC strictly corresponds to the Common Military List of the European Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend that Annex and to amend that Directive as regards the circumstances in which Member States may exempt transfers of defence-related products from the obligation of prior authorisation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2009/43/EC is amended as follows:

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

- "3. The Commission is empowered to adopt delegated acts in accordance with Article 13a, at the request of a Member State or on its own initiative, amending paragraph 2, in order to include cases where:
- (a) the transfer takes place under conditions which do not affect public policy or public security;
  - (b) the obligation of prior authorisation has become incompatible with international commitments of the Member States subsequent to the adoption of this Directive;
  - (c) it is necessary for intergovernmental cooperation, as referred to in Article 1(4).";

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

"Article 13

Amendment of the Annex

The Commission is empowered to adopt delegated acts in accordance with Article 13a amending the list of defence-related products set out in the Annex, so that it strictly corresponds to the Common Military List of the European Union.

Where imperative grounds of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.";

- (3) the following Articles **■** are inserted:

"Article 13a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 4(3) and Article 13 shall be conferred on the Commission for a period of **five years** from ... [date of entry into force of this **amending Regulation**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
  
3. The delegation of power referred to in Article 4(3) and Article 13 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 4(3) and Article 13 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

## Article 13b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 13a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

- (4) Article 14 is deleted.

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7. Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC<sup>43</sup>

In order to adapt Regulation (EC) No 79/2009 to technical progress as regards the safety of hydrogen powered vehicle, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement that Regulation with technical requirements for such vehicles as well as with administrative provisions, templates for administrative documents and models for markings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>43</sup> OJ L 35, 4.2.2009, p. 32.

Accordingly, Regulation (EC) No 79/2009 is amended as follows:

(1) Article 12 is replaced by the following:

“Article 12

Delegated powers

The Commission is empowered to adopt delegated acts in accordance with Article 12a **in order to supplement this Regulation in** the light of technical progress **by establishing**:

- (a) detailed rules for the test procedures set out in Annexes II to V;
- (b) detailed rules concerning the requirements for the installation of hydrogen components and systems set out in Annex VI;
- (c) detailed rules concerning the requirements for the safe and reliable functioning of hydrogen components and systems set out in Article 5;

- (d) specifications for requirements relating to any of the following:
  - (i) the use of pure hydrogen or a mixture of hydrogen and natural gas/biomethane;
  - (ii) new forms of hydrogen storage or usage;
  - (iii) the impact protection of vehicles with regard to the integrity of hydrogen components and systems;
  - (iv) integrated system safety requirements, covering at least the detection of leakage and requirements relating to purge gas;
  - (v) electrical isolation and electric safety;
- (e) administrative provisions for the EC type-approval of vehicles, with regard to hydrogen propulsion, and hydrogen components and systems;

- (f) rules on the information to be provided by manufacturers for the purposes of the type-approval and inspection referred to in Article 4(4) and (5);
  - (g) detailed rules for the labelling or other means of clear and rapid identification of hydrogen-powered vehicles referred to in point 16 of Annex VI;  
  
and
  - (h) other measures necessary for the application of this Regulation.";
- (2) the following Article ■ is inserted:

“Article 12a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 12 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this amending Regulation]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 12 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 12 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 13 is deleted.

8. Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC<sup>44</sup>

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<sup>44</sup> OJ L 216, 20.8.2009, p. 76.

In order to adapt Directive 2009/81/EC to rapid technical, economic and regulatory developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the threshold amounts for contracts in order to align them to those laid down in Directive 2014/25/EU of the European Parliament and of the Council<sup>45</sup>, to amend the references to the Common Procurement Vocabulary (CPV nomenclature) and to amend certain reference numbers in the CPV nomenclature and the procedures for reference in notices to certain headings in the CPV nomenclature. As the technical details and characteristics of the devices for electronic receipt should be kept up to date with technological developments, it is also necessary to empower the Commission to amend the technical details and characteristics of devices for electronic receipt. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>45</sup> Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).



Accordingly, Directive 2009/81/EC is amended as follows:

(1) the following Articles ■ are inserted:

"Article 66a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 68(1) and Article 69(2) shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 68(1) and Article 69(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 68(1) and Article 69(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 66b

#### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 66a (6). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(2) in Article 67, paragraphs 3 and 4 are deleted.

(3) Article 68(1) is amended as follows:

(a) the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 66a amending the thresholds as provided for in the first subparagraph.";

(b) the following subparagraph is added:

"Where it is necessary to revise the thresholds as provided for in the first subparagraph, and time constraints prevent the use of the procedure set in Article 66a and therefore imperative grounds of urgency so require, the procedure provided for in Article 66b shall apply to delegated acts adopted pursuant to this paragraph.";

(4) in Article 69, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 66a amending:

- (a) the reference numbers in the CPV nomenclature set out in Annexes I and II, insofar as this does not change the material scope of this Directive, and the procedures for reference in the notices to particular headings in the CPV nomenclature within the categories of services listed in those Annexes;
- (b) the technical details and characteristics of the devices for electronic receipt referred to in points (a), (f) and (g) of Annex VIII."



## VIII. JUSTICE AND CONSUMERS

1. Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>46</sup>

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<sup>46</sup> OJ L 348, 28.11.1992, p. 1.

In order to take account of technical progress, changes in international regulations or specifications and new findings, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to *make strictly technical amendments to* Annex I to Directive 92/85/EEC **■** . It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and *the* Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

*In accordance with the Decision of 22 July 2003, the Commission is assisted by the Advisory Committee on Safety and Health at Work in the preparation, implementation and evaluation of activities in the fields of safety and health at work.*

Accordingly, Directive 92/85/EEC is amended as follows:

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

"Article 13

*Amendments to Annex I*

The Commission is empowered to adopt delegated acts in accordance with Article 13a **to make strictly technical amendments to** Annex I, in order to take account of technical progress, changes in international regulations or specifications and new findings.

Where, in **duly justified and exceptional cases involving** imminent, **direct and serious** risks to **workers' and other persons' physical health and safety**, imperative grounds of urgency require **action in a very short timeframe**, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this **Article.**";



(2) the following **■** are inserted:

"Article 13a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 13 shall be conferred on the Commission for *a* period of **five years** from ... [date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 13 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016 on Better Law-Making* **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 13 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 13b

##### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 13a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1."

2. Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers and repealing Council Directive 87/102/EEC<sup>47</sup>

In order to update Directive 2008/48/EC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend that Directive to add additional assumptions for the calculation of the annual percentage rate of charge or to modify the existing assumptions. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>47</sup> OJ L 133, 22.5.2008, p. 66.

Accordingly, Directive 2008/48/EC is amended as follows:

(1) in Article 19, paragraph 5 is replaced by the following:

"5. Where necessary, the additional assumptions set out in Annex I may be used in calculating the annual percentage rate of charge.

If the assumptions set out in this Article and in Part II of Annex I do not suffice to calculate the annual percentage rate of charge in a uniform manner or are no longer adapted to the commercial situations in the market, the Commission is empowered to adopt delegated acts in accordance with Article 24a amending this Article and *Part II of* Annex I to add the necessary additional assumptions for the calculation of the annual percentage rate of charge or to modify the existing ones.";

(2) the following Article ■ is inserted:

"Article 24a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 19(5) shall be conferred on the Commission for *a* period of **five years** from... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 19(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 19(5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 25 is deleted.



## IX. MOBILITY AND TRANSPORT

### I

1. Council Directive 95/50/EC of 6 October 1995 on uniform procedures for checks on the transport of dangerous goods by road<sup>48</sup>

In order to adapt Directive 95/50/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive, in particular to take account of amendments to Directive 2008/68/EC of the European Parliament and of the Council<sup>49</sup>. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>48</sup> OJ L 249, 17.10.1995, p. 35.

<sup>49</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

Accordingly, Directive 95/50/EC is amended as follows:

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

"Article 9a

The Commission is empowered to adopt delegated acts in accordance with Article 9aa amending the Annexes in order to adapt them to scientific and technical progress in the fields covered by this Directive, in particular to take account of amendments to Directive 2008/68/EC of the European Parliament and of the Council\*.

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\* Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).";

- (2) the following Article ■ is inserted:

"Article 9aa

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 9a shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 9a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 9a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 9b is deleted.

**I**

2. Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC<sup>50</sup>

In order to adapt Directive 2002/59/EC to the evolution of Union and international law and to the experience gained in its implementation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend:

- the references to Union and International Maritime Organisation (IMO) instruments in that Directive, in order to bring them into line with provisions of Union or international law,
- certain definitions in that Directive, in order to bring them into line with other provisions of Union or international law;
- Annexes I, III and IV to that Directive in the light of technical progress and experience gained with that Directive.

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<sup>50</sup> OJ L 208, 5.8.2002, p. 10.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive [2002/59/EC](#) is amended as follows:

(1) Article 27 is replaced by the following:

"Article 27

Amendments

1. ***Within the scope of this Directive as defined in Article 2, the*** Commission is empowered to adopt delegated acts in accordance with Article 27a amending references to Union and IMO instruments in this Directive and the definitions in Article 3 and the Annexes in order to bring them into line with provisions of Union or international law which have been adopted or amended or which have entered into force **■** .

2. *Within the scope of this Directive as defined in Article 2, the Commission is empowered to adopt delegated acts in accordance with Article 27a amending Annexes I, III and IV in the light of technical progress and experience gained with this Directive* ■ .";

(2) the following Article ■ is inserted:

"Article 27a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 27 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this **amending Regulation**]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.



6. A delegated act adopted pursuant to Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(3) Article 28 is deleted.

3. Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships<sup>51</sup>

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<sup>51</sup> OJ L 324, 29.11.2002, p. 1.

In order to update the list of Union acts referring to the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) in Regulation (EC) No 2099/2002, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend that Regulation to include a reference to the Union acts conferring powers on the COSS that have entered into force. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 2099/2002 is amended as follows:

- (1) in Article 3, paragraph 3 is deleted;
- (2) Article 7 is replaced by the following:

"Article 7

Powers of COSS and amendments

COSS shall exercise the powers conferred on it by virtue of the Union maritime legislation in force.

The Commission is empowered to adopt delegated acts in accordance with Article 7a amending point 2 of Article 2 in order to include a reference to the Union acts conferring powers on COSS that have entered into force following the adoption of this Regulation.";

(3) the following Article ■ is inserted:

"Article 7a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 7 shall be conferred on the Commission for a ■ period of *five years* from ... [date of entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 7 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 7 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1."

4. Directive [2003/25/EC](#) of the European Parliament and of the Council of 14 April 2003 on specific stability requirements for ro-ro passenger ships<sup>52</sup>

In order to adapt Directive [2003/25/EC](#) to technical progress, to developments at international level and to experience gained in its implementation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>52</sup> [OJ L 123, 17.5.2003, p. 22.](#)

Accordingly, Directive 2003/25/EC is amended as follows:

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

"Article 10

Amendment of Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the Annexes in order to take account of developments at international level, in particular in the IMO, and to improve the effectiveness of this Directive in the light of experience and technical progress.";

- (2) the following Article ■ is inserted:

"Article 10a

Exercise of the delegation

1. The power to adopt delegated acts referred to in Article 10 is conferred on the Commission subject to the conditions laid down in this Article.



2. The power to adopt delegated acts referred to in Article 10 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this **amending Regulation**]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 10 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in *the Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 10 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 11 is deleted.

5. Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers, amending Council Regulation (EEC) No 3820/85 and Council Directive 91/439/EEC and repealing Council Directive 76/914/EEC<sup>53</sup>

In order to adapt Directive 2003/59/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I and II to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making<sup>54</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>53</sup> OJ L 226, 10.9.2003, p. 4.

Accordingly, Directive 2003/59/EC is amended as follows:

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

"Article 11

Adaptation to scientific and technical progress

The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes I and II in order to adapt them to scientific and technical progress.";

- (2) the following Article ■ is inserted:

"Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 12 is deleted.

**I**

6. Regulation (EC) No 785/2004 of the European Parliament and of the Council of 21 April 2004 on insurance requirements for air carriers and aircraft operators<sup>54</sup>

In order to adapt Regulation (EC) No 785/2004 to the evolution of international law, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend certain values in that Regulation in the light of amendments to international agreements. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>54</sup> OJ L 138, 30.4.2004, p. 1.

Accordingly, Regulation (EC) No 785/2004 is amended as follows:

(1) in Article 6, paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the values referred to in paragraphs 1, 2 and 3 of this Article where amendments to the relevant international agreements make this necessary.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the values referred to in paragraph 1 of this Article where amendments to the relevant international agreements make this necessary.";



(3) the following Article ■ is inserted:

"Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 6(5) and Article 7(2) shall be conferred on the Commission for *a* period of **five years** from ... [*date of entry into force of this amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 6(5) and Article 7(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 6(5) and Article 7(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (4) in Article 9, paragraph 3 is deleted.

7. Regulation (EC) No 789/2004 of the European Parliament and of the Council of 21 April 2004 on the transfer of cargo and passenger ships between registers within the Community and repealing Council Regulation (EEC) No 613/91<sup>55</sup>

In order to adapt Regulation (EC) No 789/2004 to developments at international level, in particular in the International Maritime Organisation, and to improve the effectiveness of that Regulation in the light of experience and technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend certain definitions in that Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>55</sup> OJ L 138, 30.4.2004, p. 19.

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

- (1) in Article 7, paragraph 3 is deleted;
- (2) in Article 9, paragraph 1 is replaced by the following:

"1. *Within the scope of this Regulation as defined in Article 3, the* Commission is empowered to adopt delegated acts in accordance with Article 9a amending the definitions in Article 2 in order to take account of developments at international level, in particular in the IMO, and to improve the effectiveness of this Regulation in the light of experience and technical progress ■ .";

(3) the following Article ■ is inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 9(1) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this **amending Regulation**]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 9(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 9(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1."

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8. Directive 2005/44/EC of the European Parliament and of the Council of 7 September 2005 on harmonised river information services (RIS) on inland waterways in the Community<sup>56</sup>

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<sup>56</sup> OJ L 255, 30.9.2005, p. 152.



In order to adapt Directive 2005/44/EC to technical progress and to take into account experience gained from its application, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I and II to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2005/44/EC is amended as follows:

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

"Article 10

Amendments to Annexes I and II

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending Annexes I and II in the light of the experience gained from the application of this Directive and in order to adapt those Annexes to technical progress.";

- (2) the following Article ■ is inserted:

"Article 10a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 10 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 10 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 10 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(3) in Article 11, paragraph 4 is deleted.

9. Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security<sup>57</sup>

In order to update the technical measures necessary to ensure port security on a regular basis, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I to IV to Directive 2005/65/EC. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>57</sup> OJ L 310, 25.11.2005, p. 28.

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

- (1) Article 14 is replaced by the following:

"Article 14

Amendments to Annexes I to IV

The Commission is empowered to adopt delegated acts in accordance with Article 14a amending Annexes I to IV in order to adapt them to the experience gained in their implementation without broadening the scope of this Directive.

Where, in the case of amendments required to adapt Annexes I to IV, imperative grounds of urgency so require, the procedure provided for in Article 14b shall apply to delegated acts adopted pursuant to this Article.";

- (2) the following Articles ■ are inserted:

"Article 14a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 14 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 14 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 14 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.



## Article 14b

### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 14a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 15 is deleted.

10. Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier, and repealing Article 9 of Directive 2004/36/EC<sup>58</sup>

In order to adapt Regulation (EC) No 2111/2005 to scientific and technical progress and to specify further the applicable procedures, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annex to that Regulation and to supplement that Regulation with detailed rules in respect of certain procedures. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>58</sup> OJ L 344, 27.12.2005, p. 15.

Accordingly, Regulation (EC) No 2111/2005 is amended as follows:

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

"2. The common criteria for imposing an operating ban on an air carrier, which shall be based on the relevant safety standards, are set out in the Annex and are hereafter referred to as "common criteria".

The Commission is empowered to adopt delegated acts in accordance with Article 14a amending the Annex in order to modify the common criteria to take account of scientific and technical developments.";

(2) Article 8 is replaced by the following:

"Article 8  
Detailed rules

The Commission is empowered to adopt delegated acts in accordance with Article 14a *in order to supplement this Regulation by* laying down detailed rules in respect of the procedures referred to in this Chapter taking due account of the need for decisions to be taken swiftly on updating the Community list.

Where, in the case of measures referred to in the first paragraph, imperative grounds of urgency so require, the procedure provided for in Article 14b shall apply to delegated acts adopted pursuant to this Article.";

(3) the following Articles ■ are inserted:

"Article 14a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 3(2) and Article 8 shall be conferred on the Commission for *a* period of **five years** from ...[date of entry into force of this *amending Regulation*]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article 3(2) and Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 3(2) and Article 8 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of one month of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by one month at the initiative of the European Parliament or of the Council.

#### Article 14b

##### Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 14a(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(4) in Article 15, paragraph 4 is deleted.

11. Regulation (EC) No 336/2006 of the European Parliament and of the Council of 15 February 2006 on the implementation of the International Safety Management Code within the Community and repealing Council Regulation (EC) No 3051/95<sup>59</sup>

In order to update the provisions concerning the implementation of the International Safety Management Code, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annex II to Regulation (EC) No 336/2006. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>59</sup> OJ L 64, 4.3.2006, p. 1.

Accordingly, Regulation (EC) No 336/2006 is amended as follows:

(1) in Article 11, paragraph 2 is replaced by the following:

"2. *Within the scope of this Regulation as defined in Article 3, the* Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annex II in order to take account of developments at international level and in particular in the IMO, or to improve the effectiveness of this Regulation in the light of the experience gained in its implementation.";

(2) the following Article ■ is inserted:

"Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.



2. The power to adopt delegated acts referred to in Article 11(2) shall be conferred on the Commission for *a* period of **five years** from ... [*date of entry into force of this **amending Regulation***]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
  
3. The delegation of power referred to in Article 11(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 11(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(3) in Article 12, paragraph 3 is deleted.

12. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods<sup>60</sup>

In order to adapt Directive 2008/68/EC to technical and scientific progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>60</sup> OJ L 260, 30.9.2008, p. 13.

Accordingly, Directive 2008/68/EC is amended as follows:

(1) in Article 8, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the Annexes in order *to take account of amendments to the ADR, RID and ADN, in particular those relating* to scientific and technical progress , including the use of technologies for tracking and tracing ■ .";

(2) the following Article ■ is inserted:

"Article 8a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 8(1) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 8(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* **OJ L 123, 12.5.2016, p. 1.**";

(3) in Article 9, paragraph 3 is deleted.

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13. Directive 2009/15/EC of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations<sup>61</sup>

In order to adapt Directive 2009/15/EC to the evolution of relevant international instruments and to modify the maximum amounts payable to compensate the injured parties, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend that Directive so as to:

- incorporate subsequent amendments to certain international conventions, protocols, codes and resolutions related thereto, which have entered into force;
- alter certain amounts specified therein.

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<sup>61</sup> OJ L 131, 28.5.2009, p. 47.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive **2009/15/EC** is amended as follows:

(1) the following Article **■** is inserted:

"Article 5a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.



2. The power to adopt delegated acts referred to in Article 7(1) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 7(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 7(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (2) in Article 6, paragraph 3 is deleted;
- (3) in Article 7, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 5a amending this Directive, without broadening its scope, in order to:

- (a) incorporate, for the purposes of this Directive, subsequent amendments to the international conventions, protocols, codes and resolutions related thereto referred to in point (d) of Article 2, Article 3(1) and Article 5(2), which have entered into force;
- (b) alter the amounts specified in point (b)(ii) and (iii) of Article 5(2)."

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14. Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations<sup>62</sup>

In order to complete Regulation (EC) No 391/2009 and to adapt it to the evolution of international rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission:

- to amend the minimum criteria set out in Annex I to that Regulation taking into account, in particular, the relevant decisions of the IMO;
- to supplement that Regulation with criteria for the measurement of the effectiveness of the rules and procedures as well as the performance of the recognised organisations as regards the safety of, and the prevention of pollution from, their classed ships, having particular regard to the data produced by the Paris Memorandum of Understanding on Port State Control or by other similar schemes;

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<sup>62</sup> OJ L 131, 28.5.2009, p. 11.

- to supplement that Regulation with criteria for determining when such performance is to be considered an unacceptable threat to safety or the environment, which may take into account specific circumstances affecting smaller-sized or highly specialised organisations;
- to supplement that Regulation with detailed rules concerning fines and periodic penalty payments and the withdrawal of recognition of ship inspection and survey organisations.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 391/2009 is amended as follows:

- (1) in Article 12, paragraph 4 is deleted;
- (2) in Article 13, paragraph 1 is replaced by the following:
  - "1. The Commission is empowered to adopt delegated acts in accordance with Article 14a amending Annex I, without broadening its scope, in order to update the minimum criteria set out therein, taking into account, in particular, the relevant decisions of the IMO.";
- (3) in Article 14, paragraphs 1 and 2 are replaced by the following:
  - "1. The Commission is empowered to adopt delegated acts in accordance with Article 14a *in order to supplement this Regulation by establishing the following:*

- (a) criteria to measure the effectiveness of the rules and procedures as well as the performance of the recognised organisations as regards the safety of, and the prevention of pollution from, their classed ships, having particular regard to the data produced by the Paris Memorandum of Understanding on Port State Control or by other similar schemes;
  - (b) criteria to determine when such performance is to be considered an unacceptable threat to safety or the environment, which may take into account specific circumstances affecting smaller-sized or highly specialised organisations.
2. The Commission is empowered to adopt delegated acts in accordance with Article 14a *in order to supplement this Regulation by establishing* detailed rules on the imposition of fines and periodic penalty payments pursuant to Article 6, and, if necessary, regarding the withdrawal of recognition of ship inspection and survey organisations pursuant to Article 7.";

(4) the following Article ■ is inserted:

"Article 14a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 13(1) and Article 14(1) and (2) shall be conferred on the Commission for a ■ period of *five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*



3. The delegation of power referred to in Article 13(1) and Article 14(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 13(1) and Article 14(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1."

15. Regulation (EC) No 392/2009 of the European Parliament and of the Council of 23 April 2009 on the liability of carriers of passengers by sea in the event of accidents<sup>63</sup>

In order to adapt Regulation (EC) No 392/2009 to other Union and international rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission:

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<sup>63</sup> OJ L 131, 28.5.2009, p. 24.

- to amend Annex I to that Regulation so as to incorporate amendments to the provisions of the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974, as amended by the Protocol of 2002;
- to amend the limits set out in Annex I to that Regulation for ships of Class B under Article 4 of Directive 2009/45/EC of the European Parliament and of the Council<sup>64</sup>;
- to amend Annex II to that Regulation so as to incorporate amendments to the provisions of the IMO Guidelines.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>64</sup> Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships (OJ L 163, 25.6.2009, p. 1).

Accordingly, Regulation (EC) No 392/2009 is amended as follows:

(1) Article 9 is replaced by the following:

"Article 9

Amendment of the Annexes

1. The Commission is empowered to adopt delegated acts in accordance with Article 9a amending Annex I to this Regulation in order to incorporate the amendments to the limits set out in Article 3(1), Article 4bis(1), Article 7(1) and Article 8 of the Athens Convention to take account of decisions taken pursuant to Article 23 of that Convention.

The Commission is empowered to adopt, **by 31 December 2016**, on the basis of a suitable impact assessment, delegated acts in accordance with Article 9a amending the limits set out in Annex I to this Regulation for ships of Class B under Article 4 of Directive 2009/45/EC of the European Parliament and of the Council\*, taking into consideration ■ the consequences for fares and the ability of the market to obtain affordable insurance coverage at the level required against the policy background of strengthening passengers' rights, as well as the seasonal nature of some of the traffic.

2. The Commission is empowered to adopt delegated acts in accordance with Article 9a amending Annex II in order to incorporate amendments to the provisions of the IMO Guidelines.

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\* Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships (OJ L 163, 25.6.2009, p. 1).";

- (2) the following Article ■ is inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 9(1) and (2) shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 9(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 9(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

- (3) Article 10 is deleted.

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## X. HEALTH AND FOOD SAFETY

1. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products<sup>65</sup>

In order to achieve the objectives of Regulation (EC) No 141/2000, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement that Regulation with definitions of ‘similar medicinal product’ and ‘clinical superiority’. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States’ experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>65</sup> OJ L 18, 22.1.2000, p. 1.



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

(1) in Article 8, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 10b in order to supplement this Regulation by adopting the definitions of 'similar medicinal product' and 'clinical superiority'.";

(2) in Article 10a, paragraph 3 is deleted;

(3) the following Article ■ is inserted:

"Article 10b

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 8(4) shall be conferred on the Commission for *a period of five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of power referred to in Article 8(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1."

2. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC<sup>66</sup>

In order to achieve the objectives of Directive 2001/18/EC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Directive and to supplement that Directive with:

- derogatory criteria and information requirements for the notification for the placing on the market of certain types of genetically modified organisms (GMOs);
- minimum thresholds below which products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded do not have to be labelled as GMOs;
- lower thresholds than 0,9%, below which the labelling requirements set out in the Directive do not apply to traces of GMOs in products intended for direct processing;

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<sup>66</sup> OJ L 106, 17.4.2001, p.1.

- specific labelling requirements for GMOs that are not placed on the market within the meaning of this Directive.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2001/18/EC is amended as follows:

(1) Article 16 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 29a *in order to supplement this Directive by* establishing the criteria and information requirements referred to in paragraph 1, as well as any appropriate requirements for a summary of the dossier, after consultation of the relevant Scientific Committee. The criteria and information requirements shall be such as to ensure a high level of safety of human health and the environment and shall be based on the available scientific evidence concerning such safety and on experience gained from the release of comparable GMOs.";

(b) paragraph 3 is replaced by the following:

"3. Before adopting delegated acts pursuant to paragraph 2, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the experts referred to in Article 29a(4).";

(2) Article 21 is amended as follows:

(a) paragraph 2 is replaced by the following:

"2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, the Commission is empowered to adopt delegated acts in accordance with Article 29a ***in order to supplement this Directive by*** establishing minimum thresholds below which these products shall not have to be labelled in accordance with paragraph 1 of this Article. Threshold levels shall be established according to the product concerned.";

(b) in paragraph 3, the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 29a *in order to supplement this Directive by* establishing the thresholds referred to in the first subparagraph of this paragraph.";

(3) in Article 26, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 29a amending Annex IV by establishing specific labelling requirements referred to in paragraph 1, without duplicating or creating inconsistencies with labelling provisions laid down in existing Union legislation. In so doing, account should be taken, as appropriate, of labelling provisions established by Member States in accordance with Union legislation.";



- (4) Article 27 is replaced by the following:

"Article 27

Adaptation of the Annexes to technical progress

The Commission is empowered to adopt delegated acts in accordance with Article 29a amending Sections C and D of Annex II, Annexes III to VI, and Section C of Annex VII, in order to adapt them to technical progress.";

- (5) the following Article ■ is inserted:

"Article 29a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 shall be conferred on the Commission for a period of *five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegations of power referred to in Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(6) in Article 30, paragraph 3 is deleted.

3. 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<sup>67</sup>

In order to achieve the objectives of Directive 2001/83/EC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission:

- to amend that Directive in respect of one of the conditions that homeopathic medicinal products must satisfy in order to benefit from a special, simplified registration procedure if new scientific evidence so warrants;
- to amend that Directive in respect of the types of operations that are considered to constitute manufacture of active substances used as starting materials, to take account of scientific and technical progress;

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<sup>67</sup> OJ L 311, 28.11.2001, p. 67.

- to amend Annex I to that Directive to take account of technical and scientific progress;

■

- to supplement that Directive by specifying the principles and guidelines of good manufacturing practices for medicinal products.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making ■ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2001/83/EC is amended as follows:

- (1) in Article 14(1), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 121a amending the third indent of the first subparagraph if new scientific evidence so warrants.";

■

- (2) in Article 46a, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 121a to amend paragraph 1 to take account of scientific and technical progress.";

- (3) in Article 47, the first paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 121a *in order to supplement this Directive by* specifying the principles and guidelines of good manufacturing practices for medicinal products referred to in Article 46(f).";

- (4) Article 120 is replaced by the following:

*"Article 120*

The Commission is empowered to adopt delegated acts in accordance with Article 121a amending Annex I to take account of scientific and technical progress.";

- (5) in Article 121, paragraph 2a is deleted;

- (6) Article 121a is replaced by the following:

"Article 121a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 14(1), Article 22b, Article 23b, Article 46a, Article 47, Article 52b, Article 54a and Article 120 shall be conferred on the Commission for *a* period *of five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 14(1), Article 22b, Article 23b, Article 46a, Article 47, Article 52b, Article 54a and Article 120 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.



4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 14(1), Article 22b, Article 23b, Article 46a, Article 47, Article 52b, Article 54a and Article 120 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1."

**I**

4. Directive [2002/32/EC](#) of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed<sup>68</sup>

In order to achieve the objectives of Directive [2002/32/EC](#), the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I and II to that Directive to adapt them to technical progress and to supplement that Directive with acceptability criteria for detoxification processes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making [■](#) . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>68</sup> [OJ L 140, 30.5.2002, p. 10.](#)

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

(1) in Article 7(2), the first *and second subparagraphs are* replaced by the following:

“2. An immediate decision shall be taken as to whether Annexes I and II should be amended. The Commission is empowered to adopt delegated acts in accordance with Article **10a** amending those Annexes.

Where, in the case of those amendments, imperative grounds of urgency so require, the procedure provided for in Article **10b** shall apply to delegated acts adopted pursuant to this Article.

*The Member State may maintain the measures it has implemented as long as the Commission has not taken any decision.”;*

(2) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

“1. The Commission is empowered to adopt delegated acts in accordance with Article 10a amending Annexes I and II to adapt them to the scientific and technical developments.

Where, in the case of those amendments, imperative grounds of urgency so require, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article.”;

(b) in paragraph 2, the second indent is replaced by the following

“– is empowered to adopt delegated acts in accordance with Article 10a *in order to supplement this Directive by defining* acceptability criteria for detoxification processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes.”;

(3) the following Articles ■ are inserted:

"Article 10a

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 7(2) and Article 8(1) and (2) shall be conferred on the Commission for a ■ period of *five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 7(2) and Article 8(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 7(2) and Article 8(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months from the notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 10b

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 10a(6). In such case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(4) in Article 11, paragraphs 3 and 4 are deleted.

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5. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>69</sup>

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<sup>69</sup> OJ L 31, 1.2.2002, p.1.



In order to achieve the objectives of Regulation (EC) No 178/2002, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend that Regulation as regards the number and names of the Scientific Panels, and to supplement that Regulation with the procedure to be applied by the Authority to the requests for a scientific opinion, with the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, and with the arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 178/2002 is amended as follows:

- (1) in Article 28(4), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 57a amending the first subparagraph as regards the number and names of the Scientific Panels, in the light of technical and scientific development, at the Authority's request.";

- (2) Article 29(6) is replaced by the following:

"6. In order to apply this Article, the Commission after consulting the Authority shall adopt:

- (a) delegated acts in accordance with Article 57a *in order to supplement this Regulation by establishing* the procedure to be applied by the Authority to the requests for a scientific opinion;

- (b) implementing acts laying down the guidelines governing the scientific evaluation of substances, products or processes which are subject, under *Union* legislation, to a system of prior authorisation or entry on a positive list, in particular where *Union* legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2).";
- (3) in Article 36(3), the first subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 57a *in order to supplement this Regulation by* establishing the criteria for the inclusion of an institute on the list of competent organisations designated by the Member States, the arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.";

- (4) in Chapter V, the title of Section 1 is replaced by the following:

"SECTION 1  
EXERCISE OF THE DELEGATION, COMMITTEE AND MEDIATION  
PROCEDURES";

- (5) the following Article ■ is inserted after the title of Section 1:

"Article 57a  
Exercise of the delegation

1. The power to adopt delegated acts is conferred upon the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 28(4), Article 29(6) and Article 36(3) shall be conferred on the Commission for *a* period of *five years* from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 28(4), Article 29(6) and Article 36(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the *Interinstitutional Agreement of 13 April 2016* on Better Law-Making  
■\*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 28(4), Article 29(6) and Article 36(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(6) in Article 58, paragraph 3 is deleted.

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6. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC<sup>70</sup>

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<sup>70</sup> OJ L 268, 18.10.2003, p. 24.

In order to achieve the objectives of Regulation (EC) No 1830/2003, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement that Regulation by establishing a system for the development and assignment of unique identifiers to genetically modified organisms. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 1831/2003 is amended as follows:

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

"Article 8

Unique identifiers

The Commission is empowered to adopt delegated acts in accordance with Article 9a ***in order to supplement this Regulation by*** establishing and adapting a system for the development and assignment of unique identifiers to GMOs taking account of developments in international fora.";

- (2) the following Article ■ is inserted:

"Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.



2. The power to adopt delegated acts referred to in Article 8 shall be conferred on the Commission for *a* period of **five years** from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

- (3) in Article 10, paragraph 2 is deleted;
- (4) in Article 13, paragraph 2 is deleted.

7. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>71</sup>

In order to achieve the objectives of Regulation (EC) No 1831/2003, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I to IV to that Regulation in order to adapt them to technical progress and to supplement that Regulation with rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>71</sup> OJ L 268, 18.10.2003, p. 29.

Accordingly, Regulation (EC) No 1831/2003 is amended as follows:

(1) in Article 3, paragraph 5 is replaced by the following:

“5. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex IV in order to adapt the general conditions set out therein to technological progress or scientific development.”;

(2) in Article 6, paragraph 3 is replaced by the following:

“3. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex I in order to adapt feed additive categories and functional groups as a result of technological progress or scientific development.”;

(3) in Article 7(5), the third subparagraph is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 21a *in order to supplement this Regulation by establishing* rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food.”;

(4) in Article 16, paragraph 6 is replaced by the following:

“6. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex III to take technological progress and scientific development into account.”;

(5) in Article 21, the fourth paragraph is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex II.”;

(6) the following Article ■ is inserted:

“Article 21a  
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(6) and Article 21 shall be conferred on the Commission for a period of *five years* from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(6) and Article 21 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 3(5), Article 6(3), Article 7(5), Article 16(6) and Article 21 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.”;

- (7) in Article 22, paragraph 3 is deleted.

8. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods<sup>72</sup>

In order to achieve the objectives of Regulation (EC) No 2065/2003, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Regulation following a request to the Authority for scientific and/or technical assistance and to supplement that Regulation with quality criteria for validated analytical methods. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>72</sup> OJ L 309, 26.11.2003, p. *I*.



Accordingly, Regulation (EC) No 2065/2003 is amended as follows:

(1) in Article 17, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 18a *in order to supplement this Regulation by establishing* quality criteria for validated analytical methods referred to in point 4 of Annex II, including substances to be measured. Those delegated acts shall take into account available scientific evidence.";

(2) in Article 18, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes following a request to the Authority for scientific and/or technical assistance.";

(3) the following Article ■ is inserted:

"Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 17(3) and Article 18(1) shall be conferred on the Commission for *a* period of **five years** from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

3. The delegation of power referred to in Article 17(3) and Article 18(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the *Interinstitutional Agreement of 13 April 2016* on Better Law-Making **■** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17(3) and Article 18(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123 12.5.2016, p. 1.";

- (4) in Article 19, paragraph 3 is deleted.

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9. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>73</sup>

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<sup>73</sup> OJ L 139, 30.4.2004, p. 55.

In order to achieve the objectives of Regulation (EC) No 853/2004, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes II and III to that Regulation and to supplement that Regulation in respect of the use of substances other than potable water to remove surface contamination from products of animal origin, in respect of amendments of the special guarantees relating to the placing of certain food of animal origin on the market in Sweden or Finland and in respect of derogations from Annexes II and III to that Regulation (EC) No 853/2004. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

"2. 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. For that purpose the Commission is empowered to adopt delegated acts in accordance with Article 11a *supplementing this Regulation*. Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.";

(2) in Article 8(3), point (a) is replaced by the following:

"(a) The Commission is empowered to adopt delegated acts in accordance with Article 11a amending paragraphs 1 and 2 of this Article in order to update the requirements set out in those paragraphs , taking into account changes in Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004.";

(3) Article 9 is deleted;

(4) in Article 10, paragraphs 1 and 2 are replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes II and III. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of this Regulation, taking into account the relevant risk factors, and shall be justified on the basis of:

(a) the experience gained by food business operators and/or competent authorities, in particular on the implementation of HACCP-based systems pursuant to Article 5;

- (b) the experience gained by the Commission, in particular on the outcome of its audits;
- (c) technological developments and their practical consequences, and consumer expectations with regard to food composition;
- (d) scientific advice, particularly new risk assessments;
- (e) microbiological and temperature criteria for foodstuffs;
- (f) changes in patterns of consumption.

The amendments referred to in the first subparagraph shall concern:

- (a) the requirements on the identification marking of products of animal origin;
- (b) the objectives of HACCP-based procedures;



- (c) the requirements on the food chain information;
- (d) the specific hygiene requirements for the premises, including means of transport, where products of animal origin are produced, handled, processed, stored or distributed;
- (e) the specific hygiene requirements for the operations involving the production, handling, processing, storage, transport or distribution of products of animal origin;
- (f) the rules for the transport of meat while it is warm;
- (g) the health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;
- (h) the extension of Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;

- (i) the criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;
- (j) the additional health standards for live bivalve molluscs in cooperation with the relevant Union Reference Laboratory, including:
  - (i) limit values and analysis methods for other marine biotoxins;
  - (ii) virus testing procedures and virological standards; and
  - (iii) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;

2. The Commission is empowered to adopt delegated acts in accordance with Article 11a ***in order to supplement this Regulation by*** granting derogations from Annex II and III , taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:
- (a) to facilitate ***the fulfilment***, by small businesses, ***of the requirements laid down in the Annexes***;
  - (b) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;
  - (c) to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints;
  - (d) to ***facilitate the work of*** establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety.";

(5) Article 11 is amended as follows:

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

"Without prejudice to the general application of Article 9 and Article 10(1), the Commission may lay down the following measures by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2):";

(b) points 1, 5, 6, 7 and 8 are deleted;

(6) the following Article ■ is inserted:

"Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall be conferred on the Commission for *a* period of *five years* from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of powers referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before ***adopting*** a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making **█** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

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\* OJ L 123, 12.5.2016, p.1.";

(7) in Article 12, paragraph 3 is deleted.

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10. Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene<sup>74</sup>

In order to achieve the objectives of Regulation (EC) No 183/2005, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I, II and III to that Regulation in order to adapt them to technical progress and to supplement that Regulation by defining the specific microbiological criteria and targets, by requiring approval of feed business establishments and by granting derogations from Annexes I, II and III to that Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>74</sup> OJ L 35, 8.2.2005, p. 1.

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

- (1) in Article 5(3), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 30a ***in order to supplement this Regulation by*** defining the criteria and targets referred to in points (a) and (b) of the first subparagraph.";

- (2) in Article 10, point (3) is replaced by the following:

"(3) approval is required by a Delegated Regulation that the Commission is empowered to adopt in accordance with Article 30a ***in order to supplement this Regulation.***";

- (3) in Article 27, the second paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 30a to amend Annexes I, II and III.";



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

"Article 28

Derogations from Annexes I, II and III

The Commission is empowered to adopt delegated acts in accordance with Article 30a *in order to supplement this Regulation by* granting derogations from Annexes I, II and III for particular reasons, provided that such derogations do not affect the achievement of the objectives of this Regulation.";

- (5) the following Article ■ is inserted:

"Article 30a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(3), *point (3) of Article 10*, Article 27 and Article 28 shall be conferred on the Commission for a period of *five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 5(3), *point (3) of Article 10*, Article 27 and Article 28 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 5(3), *point (3) of Article 10*, Article 27 and Article 28 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p.1.";

- (6) in Article 31, paragraph 3 is deleted.

**I**

11. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>75</sup>

In order to achieve the objectives of Regulation (EC) No 1394/2007, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Regulation to adapt them to technical and scientific progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **II**. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>75</sup> OJ L 324, 10.12.2007, p. 121.

Accordingly, Regulation (EC) No 1394/2007 is amended as follows:

- (1) Article 24 is replaced by the following:

"Article 24

Amendments to the Annexes

The Commission is empowered to adopt delegated acts in accordance with Article 25a amending the Annexes to adapt them to technical and scientific progress, after consulting the Agency.";

- (2) the following Article ■ is inserted:

"Article 25a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 24 shall be conferred on the Commission for *a period of five years* from ... [*date of entry into force of this amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 24 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 24 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

(3) in Article 26, paragraph 3 is deleted.

**I**

12. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides<sup>76</sup>

In order to set a framework for Union action to achieve the sustainable use of pesticides, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend Annexes I to IV to Directive 2009/128/EC in order to take account of scientific and technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **■** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>76</sup> OJ L 309, 24.11.2009, p.71.



Accordingly, Directive 2009/128/EC is amended as follows:

(1) in Article 5, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex I in order to take account of scientific and technical progress.";

(2) in Article 8, paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex II in order to take account of scientific and technical progress.";

(3) in Article 14(4), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex III in order to take account of scientific and technical progress.";

- (4) in Article 15(1), the second subparagraph is replaced by the following:

"The Commission shall be empowered to adopt delegated acts in accordance with Article 20a amending Annex IV in order to take account of scientific and technical progress.";

- (5) the following Article ■ is inserted:

"Article 20a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(3), Article 8(7), Article 14(4) and Article 15(1) shall be conferred on the Commission for a period of *five years* from ... [*date of* entry into force of this *amending Regulation*]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
  
3. The delegation of power referred to in Article 5(3), Article 8(7), Article 14(4) and Article 15(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement *of 13 April 2016* on Better Law-Making **I** \*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 5(3), Article 8(7), Article 14(4) and Article 15(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or *of* the Council.

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\* OJ L 123, 12.5.2016, p. 1.";

**I**

(6) in Article *21, paragraph 2* is deleted.

## XI. TAXATION AND CUSTOMS UNION

Decision No 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on a paperless environment for customs and trade<sup>77</sup>

Under Article 15 of Decision No 70/2008/EC the Commission is empowered to extend certain time limits in accordance with Council Decision 1999/468/EC<sup>78</sup>. That empowerment has never been exercised and is no longer needed. Therefore, *there is no need to give any empowerment to the Commission*. Instead, the empowerment in Decision No 70/2008/EC should be revoked and Articles 15 and 16 of that Decision should be deleted.

Accordingly, in Decision No 70/2008/EC, Articles 15 and 16 are deleted.

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<sup>77</sup> OJ L 23, 26.1.2008, p. 21.

<sup>78</sup> Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

Joint Statement by the Parliament, the Council and the Commission

In point 27 of the Interinstitutional Agreement on Better Law-Making the three institutions acknowledged the need for the alignment of all existing legislation to the legal framework introduced by the Lisbon Treaty, and in particular the need to give high priority to the prompt alignment of all basic acts which still refer to the regulatory procedure with scrutiny. Following the proposal of the Commission to that end, this Regulation responds to that need by providing for the alignment of the regulatory procedure with scrutiny in a significant number of acts included in that proposal. The three institutions will continue to work on the alignment of the remaining acts of that proposal.

Commission Statement

The Commission notes the choice of the legislators to provide for a limited duration for all the empowerments in which the regulatory procedure with scrutiny is aligned through this Regulation, coupled with a reporting obligation and tacit renewal of the empowerment. In particular in view of the high number of reports which would become due at regular intervals of time and the fact that easily available information about the use of the empowerments is available through the Register of Delegated Acts, the Commission underlines that it has discretion about the way in which it will comply with the reporting obligation. Where appropriate, the Commission may therefore group reports due under several basic acts in one single document.