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ANNEX 1

**ANNEX**

*to 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**

## ANNEX

### **I. CLIMATE ACTION**

- 1. Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006<sup>1</sup>**

In order to ensure swift technical adaptation of Directive 2009/31/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of the necessary amendments to adapt 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 on Better Law-Making of 13 April 2016. 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 2009/31/EC is amended as follows:

- (1) Article 29 is replaced by the following:

*"Article 29*  
**Amendments of Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 29a amending the Annexes."

- (2) the following Article 29a 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 29 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 29 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.

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<sup>1</sup> OJ L 140, 5.6.2009, p. 114.

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 on Better Law-Making of 13 April 2016\*.

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 29 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 30 is deleted.

**2. Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020<sup>2</sup>**

In order to ensure the accurate accounting of transactions under Decision No 406/2009/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Decision with requirements applicable to Member States' registries and the Central Administrator as regards the handling of transactions. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Decision No 406/2009/EC, implementing powers should be conferred on the Commission in order to determine the annual emission allocations. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Experience has shown that an empowerment relating to the modalities of certain transfers is not needed.

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<sup>2</sup> OJ L 140, 5.6.2009, p. 136.

Accordingly, Decision No 406/2009/EC is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 2, the fourth and fifth subparagraphs are replaced by the following:

"When the relevant reviewed and verified emission data are available, the Commission shall determine the annual emission allocations for the period from 2013 to 2020 in terms of tonnes of carbon dioxide equivalent by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 13(2).";

(b) paragraph 6 is deleted;

(2) in Article 11, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 12a concerning the application of paragraphs 1 and 2 of this Article.";

(3) the following Article 12a 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(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 11(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 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 on Better Law-Making of 13 April 2016\*.

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(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.";

(4) in Article 13, paragraph 2 is replaced by the following:

"2. 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 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).".

### **3. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer<sup>3</sup>**

In order to ensure compliance with the Union's obligations as party to the Montreal Protocol on Substances that Deplete the Ozone Layer and to ensure the proper functioning of intra-Union and external trade in substances that deplete the ozone layer and products and equipment containing or relying on those substances, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to:

- amend Regulation (EC) No 1005/2009 to include certain substances in Part A and Part B of Annex II;
- amend that Regulation to make the necessary technical adaptations to Annex III and to the maximum amounts of controlled substances;
- amend Annex V to that Regulation in order to meet the commitments under the Montreal Protocol;
- amend Annex VI to that Regulation;
- amend the list of items on licensing of imports and exports;
- amend Annex VII to that Regulation to take new technological developments into account;
- amend the reporting requirements;
- supplement that Regulation with a list of products and equipment for which the recovery of controlled substances or destruction of products and equipment without prior recovery of controlled substances is to be considered technically and economically feasible;
- supplement that Regulation with a mechanism for the allocation of quotas to producers and importers;
- supplement that Regulation with rules on the form and content of labels of containers for certain controlled substances;
- supplement that Regulation as regards the monitoring of illegal trade;
- supplement that Regulation as regards the release for free circulation in the Union of certain products and equipment imported from States not party to the Protocol;
- supplement that Regulation with minimum qualification requirements;

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<sup>3</sup> OJ L 286, 31.10.2009, p. 1.

- supplement that Regulation with a list of technologies or practices to be used by undertakings to prevent and minimise leakage and emissions of controlled substances.

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 on Better Law-Making of 13 April 2016. 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 1005/2009 is amended as follows:

(1) in Article 7(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the form and content of the label to be used.";

(2) Article 8 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the form and content of the label to be used.";

(b) paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending the following, in the light of new information or technical developments or decisions taken by the Parties:

(a) Annex III;

(b) the maximum amount of controlled substances that may be used as process agents or emitted from process agent uses as referred to in the second and third subparagraphs of paragraph 4.";

(3) Article 10 is amended as follows:

(a) in paragraph 3, the second and third subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the form and content of the label to be used.

Controlled substances referred to in the first subparagraph shall only be placed on the market and further distributed under the conditions set out in Annex V.

The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Annex V in order to meet the commitments under the Protocol.";

(b) in paragraph 6, the third subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning a mechanism for the allocation of quotas to producers and importers.";

(4) in Article 13, paragraph 2 is replaced by the following:

"2.The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Annex VI regarding modifications and time-frames for the phasing out of the critical uses by defining cut-off dates for new applications and end dates for existing applications in case technically and economically feasible alternatives or technologies that are acceptable from the standpoint of environment and health are not available within the timeframe set out in that Annex or where necessary to ensure compliance with international obligations.";

(5) in Article 18, paragraph 9 is replaced by the following:

"9.The Commission is empowered to adopt delegated acts in accordance with Article 24a amending the list of items mentioned in paragraph 3 of this Article and in Annex IV in order to meet the commitments under the Protocol or to facilitate their application.";

(6) Article 19 is replaced by the following:

*"Article 19*  
**Measures for monitoring of illegal trade**

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning additional measures for the monitoring of controlled substances or new substances and of products and equipment containing or relying on controlled substances placed under temporary storage, customs warehousing or free zone procedure or in transit through the customs territory of the Union and subsequently re-exported, on the basis of an evaluation of the potential risks of illegal trade linked to such movements, taking into account the environmental benefits and socio-economic impacts of such measures.";

(7) in Article 20, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the rules, in line with decisions taken by the Parties, applicable to the release for free circulation in the Union of products and equipment imported from any State not party to the Protocol which were produced using controlled substances but do not contain substances which can be positively

identified as controlled substances. The identification of such products and equipment shall comply with periodical technical advice given to the Parties.";

(8) Article 22 is amended as follows:

(a) paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Annex VII in order to take new technological developments into account.";

(b) in paragraph 4, the second and third subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning a list of products and equipment, in line with decisions taken by the Parties, for which the recovery of controlled substances or destruction of products and equipment without prior recovery of controlled substances shall be considered technically and economically feasible, specifying, if appropriate, the technologies to be applied.

Any draft delegated act establishing such a list shall be accompanied and supported by a full economic assessment of costs and benefits, taking into account the individual circumstances of Member States.";

(c) in paragraph 5, the second and third subparagraphs are replaced by the following:

"The Commission shall evaluate the measures taken by the Member States and is empowered to adopt delegated acts in accordance with Article 24a concerning those minimum qualification requirements, in the light of that evaluation and of technical and other relevant information.";

(9) Article 23 is amended as follows:

(a) paragraph 4 is amended as follows:

(i) in the first subparagraph, the second sentence is replaced by the following:

"In the light of an evaluation of those measures taken by the Member States and of technical and other relevant information, the Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the harmonisation of those minimum qualification requirements.";

(ii) the second subparagraph is deleted.

(b) paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 24a establishing a list of technologies or practices to be used by



undertakings to prevent and minimise any leakage and emissions of controlled substances.";

(10) in Article 24, paragraphs 2 and 3 are replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Part A of Annex II to include substances that are included in Part B of that Annex that are found to be exported, imported, produced or put on the market in significant quantities and that are found by the Scientific Assessment Panel under the Protocol to have a significant ozone-depleting potential, and, if appropriate, to determine possible exemptions from paragraph 1.

3. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Part B of Annex II to include any substances that are not controlled substances but that are found by the Scientific Assessment Panel under the Protocol or another recognised authority of equivalent stature to have a significant ozone-depleting potential, in the light of relevant scientific information.";

(11) after the title of Chapter VII, the following Article 24a 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 7(2), Article 8(3) and (5), Article 10(3) and (6), Article 13(2), Article 18(9), Article 19, Article 20(2), Article 22(3), (4) and (5), Article 23(4) and (7), Article 24(2) and (3), Article 26(3) and Article 27(10) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 7(2), Article 8(3) and (5), Article 10(3) and (6), Article 13(2), Article 18(9), Article 19, Article 20(2), Article 22(3), (4) and (5), Article 23(4) and (7), Article 24(2) and (3), Article 26(3) and Article 27(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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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), Article 8(3) and(5), Article10(3) and (6), Article 13(2), Article 18(9), Article 19, Article 20(2), Article 22(3), (4) and (5), Article 23(4) and (7), Article 24(2) and (3), Article 26(3) and Article 27(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.";

(12) in Article 25, paragraph 3 is deleted;

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending the reporting requirements laid down in paragraph 1 of this Article in order to meet the commitments under the Protocol or to facilitate their application.";

(14) in Article 27, paragraph 10 is replaced by the following:

"10. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning amendments to the reporting requirements laid down in paragraphs 1 to 7 of this Article in order to meet the commitments under the Protocol or to facilitate their application.".

## II. COMMUNICATION NETWORKS, CONTENT AND TECHNOLOGY

### 4. Directive 2002/58/EC of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)<sup>4</sup>

In order to ensure an equivalent level of protection of fundamental rights and freedoms, with respect to the processing of personal data in the electronic communication sector and to ensure the free movement of such data and of electronic communication equipment and services in the Union, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Directive 2002/58/EC in respect of circumstances, format and procedures applicable to the information and notification requirements. 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 on Better Law-Making of 13 April 2016. 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 2002/58/EC is amended as follows:

(1) in Article 4, paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 14b, concerning the circumstances, format and procedures applicable to the information and notification requirements referred to in paragraphs 2, 3 and 4 of this Article, following consultation with the European Network and Information Security Agency (ENISA), the Working Party on the Protection of Individuals with regard to the Processing of Personal Data established by Article 29 of Directive 95/46/EC and the European Data Protection Supervisor.";

(2) Article 14a is deleted;

(3) the following Article 14b is inserted:

#### *"Article 14b*

#### **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.

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<sup>4</sup> OJ L 201, 31.7.2002, p. 37.

2. The power to adopt delegated acts referred to in Article 4(5) shall be conferred on the Commission for an indeterminate period of time from [from the date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 4(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 on Better Law-Making of 13 April 2016\*.
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(5) 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."

## **5. 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>5</sup>**

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 of the Treaty 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 function 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all

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<sup>5</sup> OJ L 113, 30.4.2002, p. 1.

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) is replaced by the following:

"(a) adopt delegated acts in accordance with Article 5a 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 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 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, to remedy the situation.";

(3) the following Articles 5a and 5b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.

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.

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*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.

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.

**6. 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 Decision)<sup>6</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.

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

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<sup>6</sup> OJ L 172, 2.7.2008, p. 15.

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

"3. The Commission may adopt, by means of implementing act, 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.

### **III. HUMANITARIAN AID AND CIVIL PROTECTION**

#### **7. Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid<sup>7</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 to adopt 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 empower the Commission to adopt delegated acts in accordance with Article 290 of the Treaty.

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>7</sup> OJ L 163, 2.7.1996, p. 1.



#### IV. EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

##### 8. Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>8</sup>

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and new findings, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend, in a technical way, the Annex to Directive 89/391/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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 89/391/EEC is amended as follows:

(1) the following Article 16a is inserted:

*"Article 16a*  
**Amendments to the Annex**

The Commission is empowered to adopt delegated acts in accordance with Article 17b amending, in a technical way, the Annex in order to take account of technical harmonisation and standardisation and technical progress, changes in international regulations or specifications and new findings.";

(2) Article 17 is deleted;

(3) the following Article 17b is inserted:

*"Article 17b*  
**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 16a shall be conferred on the Commission for an indeterminate period of time from [date of the entry into force of this Omnibus].

3. The delegation of power referred to in Article 16a 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

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<sup>8</sup> OJ L 183, 29.6.1989, p. 1.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 16a 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."

**9. 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>9</sup>**

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 of the Treaty should be delegated to the Commission to amend, in a technical way, 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 Inter-Institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 89/654/EEC is amended as follows:

(1) Article 9 is replaced by the following:

*"Article 9*  
**Amendments to the Annexes**

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<sup>9</sup> OJ L 393, 30.12.1989, p.1.

The Commission is empowered to adopt delegated acts in accordance with Article 9a amending the Annexes, in a technical way, 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.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 9a and 9b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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 the Council.

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

**10. 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>10</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 of the Treaty should be delegated to the Commission to amend, in a technical way, 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending the Annexes, in a technical way, 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.

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<sup>10</sup> OJ L 393, 30.12.1989, p. 18.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 9a and 9b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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.
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 the Council.

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

**11. 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>11</sup>**

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 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 90/269/EEC, in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 8b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 8a and 8b are inserted:

*"Article 8a*  
**Exercise of the delegation**

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<sup>11</sup> OJ L 156, 21.6.1990, p. 9.

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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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.
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 the Council.

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

**12. 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>12</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 of the Treaty should be delegated to the Commission to amend the Annex to Directive 90/270/EEC, in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending the Annex, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 10a and 10b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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

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<sup>12</sup> OJ L 156, 21.6.1990, p. 14.



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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

### **13. Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels<sup>13</sup>**

In order to take account of technical progress, 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 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 92/29/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending the Annexes, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 8b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 8a and 8b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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

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<sup>13</sup> OJ L 113, 30.4.1992, p. 19.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**14. 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>14</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 of the Treaty should be delegated to the Commission to amend Annex IV to Directive 92/57/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending Annex IV in a technical way 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 or knowledge in the field of temporary or mobile construction sites.

Where, in the case of imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 13a and 13b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>14</sup>

OJ L 245, 26.8.1992, p. 6.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**15. 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>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 safety and health signs at work, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 92/58/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending the Annexes, in a technical way, 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 health signs or devices at work.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 9b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 9a and 9b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>15</sup> OJ L 245, 26.8.1992, p. 23.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**16. Council Directive 92/91/EEC of 3 November 1992 concerning the minimum requirements for improving the safety and health protection of workers in the mineral- extracting industries through drilling (eleventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>16</sup>**

In order to take account of technical harmonisation and standardisation, of technical progress, changes in international regulations or specifications and knowledge with regard to the mineral-extracting industries through drilling, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to Directive 92/91/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 92/91/EEC 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 amending the Annex, in a technical way, in order to take account of technical harmonisation and standardisation concerning the mineral-extracting industries through drilling, as well as technical progress, changes in international regulations or specifications and knowledge with regard to the mineral-extracting industries through drilling.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 11a and 11b 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.

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<sup>16</sup> OJ L 348, 28.11.1992, p. 9.



2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**17. Council Directive 92/104/EEC of 3 December 1992 on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (twelfth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>17</sup>**

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and new findings concerning the surface and underground mineral-extracting industries, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to Directive 92/104/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 92/104/EEC 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 amending the Annex , in a technical way, in order to take account of technical harmonisation and standardisation concerning the surface and underground mineral-extracting industries, as well as technical progress, changes in international regulations or specifications and new findings concerning the surface or underground mineral-extracting industries.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 11a and 11b 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.

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<sup>17</sup> OJ L 404, 31.12.1992, p. 10.

2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**18. Council Directive 93/103/EC of 23 November 1993 concerning the minimum safety and health requirements for work on board fishing vessels (thirteenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)<sup>18</sup>**

In order to take account of technical harmonisation and standardisation, technical progress, changes in international regulations or specifications and new findings in the field of safety and health on board fishing vessels, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 93/103/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 93/103/EC is amended as follows:

(1) Article 12 is replaced by the following:

*"Article 12*

**Amendments to the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 12a amending the Annexes, in a technical way, in order to take account of technical harmonisation and standardisation concerning certain aspects of safety and health on board fishing vessels, as well as technical progress, changes in international regulations or specifications and new findings in the field of safety and health on board fishing vessels.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 12a and 12b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>18</sup> OJ L 307, 13.12.1993, p. 1.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

## **19. Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work<sup>19</sup>**

In order to achieve adequate protection of young people at work and to take account of technical progress, changes in international standards or specifications and new findings, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to Directive 94/33/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 94/33/EC is amended as follows:

(1) Article 15 is replaced by the following:

### *"Article 15* **Amendments of the Annex**

The Commission is empowered to adopt delegated acts in accordance with Article 15a amending the Annex, in a technical way, 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 15a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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.

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<sup>19</sup> OJ L 216, 20.8.1994, p. 12.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 the Council.

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

**20. 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>20</sup>**

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 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 98/24/EC, in a technical way, 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 concerning the establishment or revision of indicative occupational

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20 OJ L 131, 5.5.1998, p. 11.

exposure limit values, 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 the case of exceptional possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this paragraph."

(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 amending the Annexes, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";

(3) the following Articles 12a and 12b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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 the Council.

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

**21. Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>21</sup>**

In order to take account of technical harmonisation and standardisation in the field of explosion protection, technical progress, changes in international regulations or specifications and new findings on the prevention of and protection against explosions, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 1999/92/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 1999/92/EC is amended as follows:

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<sup>21</sup> OJ L 23, 28.1.2000, p. 57.

(1) Article 10 is replaced by the following:

*"Article 10*  
**Amendments to the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the Annexes, in a technical way, in order to take account of technical harmonisation and standardisation in the field of explosion protection, technical progress, changes in international regulations or specifications and new findings with regard to the prevention of and protection against explosions.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 10a and 10b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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 the Council.

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

**22. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>22</sup>**

In order to take account of technical progress, changes in international regulations or specifications and new findings with regard to exposure to biological agents, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 2000/54/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 2000/54/EC is amended as follows:

(1) Article 19 is replaced by the following:

*"Article 19*  
**Amendments to the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 19a amending the Annexes, in a technical way, in order to adapt them to technical progress, changes in international regulations or specifications and new findings in the field of exposure to biological agents.

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<sup>22</sup> OJ L 262, 17.10.2000, p. 21.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 19b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 19a and 19b are inserted:

*"Article 19a*

**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 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 19 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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.

*Article 19b*

**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.
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 19a(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 the Council.

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

**23. 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>**

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 of the Treaty should be delegated to the Commission to amend the Annex to Directive 2002/44/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 2002/44/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 amending the Annex, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 11a and 11b are inserted:

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

*"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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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.
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 the Council.

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

(3) Article 12 is deleted.

**24. 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>**

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 of the Treaty should be delegated to the Commission to amend, in a technical way, 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 12a and 12b 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.

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<sup>24</sup> OJ L 042, 15.2.2003, p. 38.

2. The power to adopt delegated acts referred to in Article 12 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

(3) Article 13 is deleted.



**25. 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>**

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 of the Treaty Union should be delegated to the Commission to amend Annex II to Directive 2004/37/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 2004/37/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 amending Annex II, in a technical way, 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 the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 17b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 17a and 17b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**26. 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>**

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 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 2006/25/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 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 amending the Annexes, in a technical way, 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.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this Article."

(2) the following Articles 10a and 10b 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.

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<sup>26</sup>

OJ L 114, 27.4.2006, p. 38.

2. The power to adopt delegated acts referred to in Article 10 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

(3) Article 11 is deleted.

**27. Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>27</sup>**

In order to take account of technical harmonisation and standardisation, technical progress and changes in international regulations or specifications or knowledge in the field of work equipment, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to Directive 2009/104/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 2009/104/EC is amended as follows:

(1) Article 11 is replaced by the following:

*" Article 11*

**Amendment of the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes I and II, in a technical way, in order to take account of technical harmonisation and standardisation of work equipment, as well as technical progress and changes in international regulations or specifications or knowledge in the field of work equipment.

Where, in the case of possible imminent risks to workers' health and safety, imperative grounds of urgency so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

(2) the following Articles 11a and 11b 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>27</sup> OJ L 260, 3.10.2009, p. 5.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 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.

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 the Council.

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

**28. 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>28</sup>**

In order to take account of technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex I to Directive 2009/148/EC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 2009/148/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, in a technical way, to adapt it to technical progress.

Where, in the case of possible imminent risks to workers' health and safety arising from exposure to asbestos at work, imperative grounds of urgency so require, the procedure provided for in Article 18b shall apply to delegated acts adopted pursuant to this paragraph.

A new assessment must be available at least once every 3 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 18a and 18b are inserted:

*"Article 18a*

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

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 an indeterminate period of time from [date of the entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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.
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 the Council.

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



## V. ENERGY

### **29. Directive 2009/73/EC of the European Parliament and the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC<sup>29</sup>**

In order to ensure an internal market in natural gas, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Directive 2009/73/EC with the necessary guidelines setting out the details of a number of procedures concerning gas market rules. 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 on Better Law-Making of 13 April 2016. 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 2009/73 EC is amended as follows:

(1) in Article 6, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines for regional cooperation in a spirit of solidarity.";

(2) in Article 11, paragraph 10 is replaced by the following:

"10. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines setting out the details of the procedure to be followed for the application of this Article.";

(3) in Article 15, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines to ensure full and effective compliance of the transmission system owner and of the storage system operator with paragraph 2 of this Article.";

(4) in Article 36, paragraph 10 is replaced by the following:

"10. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines for the application of the conditions laid down in paragraph 1 of this Article and setting out the procedure to be followed for the application of paragraphs 3, 6, 8 and 9 of this Article.";

(5) in Article 42, paragraph 5 is replaced by the following:

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<sup>29</sup> OJ L 211, 14.8.2009, p. 94.

"5. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines on the extent of the duties of the regulatory authorities to cooperate with each other and with the Agency.";

(6) in Article 43, paragraph 9 is replaced by the following:

"9. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines setting out the details of the procedure to be followed by the regulatory authorities, the Agency and the Commission as regards the compliance of decisions taken by regulatory authorities with the Guidelines referred to in this Article.";

(7) in Article 44, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 50a establishing Guidelines which specify the methods and arrangements for record keeping as well as the form and content of the data that shall be kept.";

(8) the following Article 50a is inserted:

*"Article 50a*  
**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(4), Article 11(10), Article 15(3), Article 36(10), Article 42(5), Article 43(9) and Article 44(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 6(4), Article 11(10), Article 15(3), Article 36(10), Article 42(5), Article 43(9) and Article 44(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 on Better Law-Making of 13 April 2016\*.

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 in Article 6(4), Article 11(10), Article 15(3), Article 36(10), Article 42(5), Article 43(9) and Article 44(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.";

(9) in Article 51, paragraph 3 is deleted.

**30. Regulation (EC) No 715/2009 of the European Parliament and of the Council of 13 July 2009 on conditions for access to the natural gas transmission networks and repealing Regulation (EC) No 1775/2005<sup>30</sup>**

In order to ensure conditions for access to the natural gas transmission networks, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Regulation (EC) No 715/2009 with necessary guidelines setting out procedural details, measures covering highly complex technical arrangements and measures specifying details of certain provisions of 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 on Better Law-Making of 13 April 2016. 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 715/2009 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 27a establishing Guidelines setting out the details of the procedure to be followed for the application of paragraphs 1 and 2 of this Article.";

(2) in Article 6(11), the second subparagraph is replaced by the following:

"Where the Commission proposes to adopt a network code on its own initiative, the Commission shall consult the Agency, the ENTSO for Gas and all relevant stakeholders in regard to the draft network code during a period of no less than two months. The Commission is empowered to adopt delegated acts in accordance with Article 27a adopting such network codes.";

(3) in Article 7, paragraph 3 is replaced by the following:

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<sup>30</sup> OJ L 211, 14.8.2009, p. 36.

"3. The Commission is empowered to adopt delegated acts in accordance with Article 27a to establish, amendments to any network code adopted under Article 6 taking account of the Agency's proposals.";

(4) in Article 12, paragraph 3 is replaced by the following:

"3. For the purposes of achieving the goals set out in paragraphs 1 and 2 of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 27a determining the geographical area covered by each regional cooperation structure, taking into account existing regional cooperation structures. For that purpose, the Commission shall consult the Agency and the ENTSO for Gas.

Each Member State shall be allowed to promote cooperation in more than one geographical area.";

(5) in Article 23(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 27a establishing Guidelines on the issues listed in paragraph 1 of this Article and amending the Guidelines referred to in points (a), (b) and (c) thereof.";

(6) the following Article 27a 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 3(5), Article 6(11), Article 7(3), Article 12(3) and Article 23(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(5), Article 6(11), Article 7(3), Article 12(3) and Article 23(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 on Better Law-Making of 13 April 2016\*.

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(11), Article 7(3), Article 12(3) and Article 23(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.";

(7) Article 28 is deleted.

### **31. 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>31</sup>**

In order to make the necessary technical adaptations to Regulation (EC) No 1222/2009 the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 12a is inserted:

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<sup>31</sup> OJ L 342, 22.12.2009, p. 46.

*"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 an indeterminate period of time [from the entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

## VI. ENVIRONMENT

### 32. Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment<sup>32</sup>

In order to adapt Directive 91/271/EEC to technical and scientific progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex I 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 on Better Law-Making of 13 April 2016. 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 91/271/EEC is amended as follows:

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

"2. Collecting systems referred to in paragraph 1 shall satisfy the requirements of section A of Annex I.

The Commission is empowered to adopt delegated acts in accordance with Article 17a amending those requirements.";

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

"3. Discharges from urban waste water treatment plants referred to in paragraphs 1 and 2 shall satisfy the relevant requirements of section B of Annex I.

The Commission is empowered to adopt delegated acts in accordance with Article 17a amending those requirements.";

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

"3. Discharges from urban waste water treatment plants referred to in paragraph 2 shall satisfy the relevant requirements of section B of Annex I.

The Commission is empowered to adopt delegated acts in accordance with Article 17a amending those requirements.";

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

"2. Regulations and specific authorisations shall satisfy the requirements set out in section C of Annex I.

The Commission is empowered to adopt delegated acts in accordance with Article 17a amending those requirements.";

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<sup>32</sup> OJ L 135, 30.5.1991, p. 40.

(5) in Article 12, paragraph 3 is replaced by the following:

"3. Prior regulations and specific authorisations of discharges from urban waste water treatment plants made pursuant to paragraph 2 within agglomerations of 2 000 to 10 000 p.e. in the case of discharges to fresh waters and estuaries, and within agglomerations of 10 000 p.e. or more in respect of all discharges, shall contain conditions to satisfy the relevant requirements of section B of Annex I.

The Commission is empowered to adopt delegated acts in accordance with Article 17a amending those requirements.";

(6) the following Article 17a is inserted:

*"Article 17a*

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 4(3), Article 5(3), Article 11(2) and Article 12(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(2), Article 4(3), Article 5(3), Article 11(2) and Article 12(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 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 on Better Law-Making of 13 April 2016\*.

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 4(3), Article 5(3), Article 11(2) and Article 12(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.";

(7) in Article 18, paragraph 3 is deleted.



### **33. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources<sup>33</sup>**

In order to adapt Directive 91/676/EEC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 91/676/EEC is amended as follows:

(1) Article 8 is replaced by the following:

#### *"Article 8*

The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the Annexes to adapt them to scientific and technical progress.";

(2) the following Article 8a is inserted:

#### *"Article 8a*

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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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<sup>33</sup>

OJ L 375, 31.12.1991, p. 1.

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) in Article 9, paragraph 3 is deleted.

#### **34. 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>34</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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**

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<sup>34</sup> OJ L 365, 31.12.1994, p. 24.

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 7a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

### **35. Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)<sup>35</sup>**

In order to establish additional technical rules necessary for the disposal of PCB and PCT pursuant to Directive 96/59/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by:

- fixing the reference methods of measurement to determine the PCB content;
- determining, for certain purposes, other less hazardous substitutes for PCBs;
- fixing, for certain purposes, technical standards for the other methods of disposing of PCBs.

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 on Better Law-Making of 13 April 2016, 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 96/59/EC is amended as follows:

(1) in Article 10, paragraph 2, is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 10b:

- (a) to fix the reference methods of measurement to determine the PCB content of contaminated materials;
- (b) if necessary, to determine, solely for the purposes of points (b) and (c) of Article 9(1), other less hazardous substitutes for PCBs;
- (c) to fix technical standards for the other methods of disposing of PCBs referred to in the second sentence of Article 8(2).

For the purposes of point (a) of the first subparagraph measurements effected before the determination of the reference methods shall remain valid.";

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

(3) the following Article 10b is inserted:

#### *"Article 10b*

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

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<sup>35</sup>

OJ L 243, 24.9.1996, p. 31.

2. The power to adopt delegated acts referred to in Article 10(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 10(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 on Better Law-Making of 13 April 2016\*.

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(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".

### **36. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption<sup>36</sup>**

In order to adapt Directive 98/83/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes II and 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 on Better Law-Making of 13 April 2016. 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.

The empowerment laid down in Annex I, part C, Note 10 to set monitoring frequencies and monitoring methods for radioactive substance has become obsolete due to the adoption of Council Directive 2013/51/EURATOM<sup>37</sup>.

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<sup>36</sup> OJ L 330, 5.12.1998, p. 32.

<sup>37</sup> Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.2013, p. 12.)

As far as the empowerment laid down in Annex III, part A, second paragraph is concerned, the possibility to amend Annex III by delegated acts is already foreseen under Article 11(2) of Directive 98/83/EC.

Accordingly, Directive 98/83/EC is amended as follows:

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes II and III, where necessary, to adapt them to scientific and technical progress.";

(2) the following Article 11a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of April 2016\*.
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;

(4) in Annex I, Part C is amended as follows:

- (a) the part of the table entitled "Radioactivity" is deleted;
- (b) notes 8, 9 and 10 are deleted;

(5) in Annex III, Part A, the second paragraph is deleted.

### **37. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles<sup>38</sup>**

In order to ensure that Directive 2000/53/EC remains up to date and to establish additional technical measures with regard to end-of life vehicles, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the Annexes to that Directive;
- to supplement that Directive with minimum requirements for the certificate of destruction;
- to supplement that Directive with rules necessary to control compliance of Member States with the targets and standards for component and material coding.

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 on Better Law-Making of 13 April 2016. 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 2000/53/EC is amended as follows:

(1) in Article 4(2), point (b) is replaced by the following:

"(b) The Commission is empowered to adopt delegated acts, in accordance with Article 9a amending Annex II on a regular basis to adapt it to technical and scientific progress, in order to:

- (i) as necessary, establish maximum concentration values up to which the existence of the substances referred to in point (a) in specific materials and components of vehicles is to be tolerated;
- (ii) exempt certain materials and components of vehicles from point (a) if the use of those substances is unavoidable;
- (iii) delete materials and components of vehicles from Annex II if the use of these substances is avoidable;
- (iv) under points (i) and (ii) designate those materials and components of vehicles that can be stripped before further treatment and require them to ; be labelled or made identifiable by other appropriate means. ";

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

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<sup>38</sup>

OJ L 269, 21.10.2000, p. 34.

"5. Member States shall take the necessary measures to ensure that their competent authorities mutually recognise and accept the certificates of destruction issued in other Member States in accordance with paragraph 3.

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning minimum requirements for the certificate of destruction.";

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

"6. The Commission is empowered to adopt delegated acts in accordance with Article 9a amending Annex I to adapt it to technical and scientific progress.";

(4) in Article 7(2), the third subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the detailed rules necessary to control compliance of Member States with the targets set out in the first subparagraph. When preparing such rules, the Commission shall take into account all relevant factors, *inter alia*, the availability of data and the issue of exports and imports of end-of-life vehicles.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the standards referred to in paragraph 1. When preparing such standards, the Commission shall take account of the work going on in this area in the relevant international forums and contribute to this work as appropriate.";

(6) the following Article 9a is inserted:

#### *"Article 9a*

#### **Exercise of the delegation**

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

2. The power to adopt delegated acts referred to in Article 4(2)(b), Article 5(5), Article 6(6), Article 7(2) and Article 8(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2)(b), Article 5(5), Article 6(6), Article 7(2) 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 on Better Law-Making of 13 April 2016\*.

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(2)(b), Article 5(5), Article 6(6), Article 7(2) and Article 8(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.";

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

### **38. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy<sup>39</sup>**

In order to adapt Directive 2000/60/EC to scientific and technical progress and to establish additional technical rules necessary for Union action in the field of water policy, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of the following:

- to amend Annexes I and III and section 1.3.6 of Annex V to that Directive;
- to supplement that Directive, with technical specifications and standardised methods for analysis and monitoring of water status;
- to supplement that Directive by setting out the results of the intercalibration exercise and establishing the values of the Member State monitoring system classifications.

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 on Better Law-Making of 13 April 2016. 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>39</sup> OJ L 327, 22.12.2000, p. 1.

Accordingly, Directive 2000/60/EC is amended as follows:

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 20a laying down technical specifications and standardised methods for analysis and monitoring of water status.";

(2) in Article 20(1), the first subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annexes I and III and section 1.3.6 of Annex V to adapt them to scientific and technical progress taking account of the periods for review and updating of the river basin management plans as referred to in Article 13.";

(3) the following Article 20a 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 8(3), in the first subparagraph of Article 20(1) and in Annex V, paragraph 1.4.1, point (ix), shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 8(3), in the first subparagraph of Article 20(1) and in Annex V, paragraph 1.4.1, point (ix), may be revoked at any time by the European Parliament and the Council. A decision to revoke shall put an end to the delegation of the power specified by 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 the 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 on Better Law-Making of 13 April 2016\*.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and the Council.

6. A delegated act adopted pursuant to Article 8(3), the first subparagraph of Article 20(1) and Annex V, paragraph 1.4.1, point (ix), 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 21, paragraph 3 is deleted;

(5) in Annex V, paragraph 1.4.1, point (ix) is replaced by the following:

"(ix) The Commission is empowered to adopt delegated acts in accordance with Article 20a setting out the results of the intercalibration exercise and establishing the values of the Member State monitoring system classifications in accordance with points (i) to (viii). It shall be published within six months of the completion of the intercalibration exercise."

### **39. 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>40</sup>**

In order to adapt Directive 2002/49/EC to technical and scientific progress, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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.";

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OJ L 189, 18.7.2002, p. 12.

(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 12a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 first 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:".

**40. 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>41</sup>**

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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 11a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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*

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<sup>41</sup> OJ L 143, 30.4.2004, p. 87.

*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 on Better Law-Making of 13 April 2016\*.

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.

**41. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air<sup>42</sup>**

In order to take account of scientific and technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Directive 2004/107/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 on Better Law-Making of 13 April 2016. 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 2004/107/EC is amended as follows:

(1) in Article 4, paragraph 15 is replaced by the following:

"15. The Commission is empowered to adopt delegated acts in accordance with Article 5a amending this Article, Section II of Annex II, III, IV and V respectively and Section V of Annex V to adapt them to scientific and technical progress.

However, the amendments may not result in any direct or indirect changes to target values.";

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<sup>42</sup> OJ L 23, 26.1.2005, p. 3.

(2) the following Article 5a is 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 4(15) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 4(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 on Better Law-Making of 13 April 2016\*.
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 Article 4(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.";

(3) in Article 6, paragraph 3 is deleted;

(4) in Annex V, Section V is replaced by the following:

"Reference air quality modelling techniques cannot be specified at present.".

**42. Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC<sup>43</sup>**

In order to adapt Directive 2006/7/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend Annex I to that Directive as regards the methods of analysis for the parameters set out in that Annex;
- to amend Annex V to that Directive;
- to supplement that Directive by specifying the EN/ISO standard on the equivalence of microbiological 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 on Better Law-Making of 13 April 2016. 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 2006/7/EC is amended as follows:

(1) in Article 15, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 15a:

- (a) specifying the EN/ISO standard on the equivalence of microbiological methods for the purposes of Article 3(9);
- (b) amending Annex I, where necessary in the light of scientific and technical progress, as regards the methods of analysis for the parameters set out in that Annex;
- (c) amending Annex V where necessary in the light of scientific and technical progress.";

(2) the following Article 15a 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(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 15(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

<sup>43</sup>

OJ L 64, 4.3.2006, p. 37.



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 on Better Law-Making of 13 April 2016\*.

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(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 16, paragraph 3 is deleted.

#### **43. Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries and amending Directive 2004/35/EC<sup>44</sup>**

In order to further develop the technical provisions of Directive 2006/21/EC and to adapt it to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the Annexes to that Directive to adapt them to scientific and technical progress;
- to supplement that Directive with technical requirements for the purposes of Article 13(6);
- to supplement that Directive to complete the technical requirements for waste characterisation contained in Annex II to supplement that Directive with an interpretation of the definition in point 3 of Article 3,
- to supplement that Directive with criteria for the classification of waste facilities in accordance with Annex III,
- to supplement that Directive with harmonised standards for sampling and analysis 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

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<sup>44</sup> OJ L 102, 11.4.2006, p. 15.

conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 2006/21/EEC is amended as follows:

(1) in Article 22, paragraphs 2 and 3 are replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 22a necessary for the following:

- (a) the elaboration of the technical requirements for the purposes of Article 13(6), including technical requirements relating to the definition of weak acid dissociable cyanide and its measurement method;
- (b) the completion of the technical requirements for waste characterisation contained in Annex II;
- (c) the interpretation of the definition contained in point 3 of Article 3;
- (d) the definition of the criteria for the classification of waste facilities in accordance with Annex III;
- (e) the determination of any harmonised standards for sampling and analysis methods needed for the technical implementation of this Directive.

When exercising the delegation of power provided for in the first subparagraph, the Commission shall give priority to the activities referred to in points (b), (c) and (d).

3. The Commission is empowered to adopt delegated acts in accordance with Article 22a amending the Annexes to adapt them to scientific and technical progress. Those amendments shall be made with a view to achieving a high level of environmental protection.";

(2) the following Article 22a is inserted:

*"Article 22a*

**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 22(2) and (3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 22(2) and (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 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 on Better Law-Making of 13 April 2016\*.

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 22(2) and (3) 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 23, paragraph 3 is deleted.

#### **44. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration<sup>45</sup>**

In order to adapt Directive 2006/118/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes II, III and IV to that Directive and to add new pollutants or indicators. 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 on Better Law-Making of 13 April 2016. 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 2006/118/EC is amended as follows:

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<sup>45</sup> OJ L 372, 27.12.2006, p. 19.

(1) Article 8 is replaced by the following:

*"Article 8*

**Technical adaptations**

1. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Parts A and C of Annex II, and Annexes III and IV to adapt them to scientific and technical progress, taking into consideration the period for reviewing and updating river basin management plans, as referred to in Article 13(7) of Directive 2000/60/EC.
2. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Part B of Annex II in order to add new pollutants or indicators.";

(2) the following Article 8a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament and the Council. A decision to revoke shall put an end to the delegation of the power specified by 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 the 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 on Better Law-Making of 13 April 2016\*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and 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

\* OJ L 123, 12.5.2016, p. 1.”;

(3) Article 9 is deleted.

**45. 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>46</sup>**

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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 to initiate 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;

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<sup>46</sup>

OJ L 33, 4.2.2006, p. 1.

(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 18a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**46. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE)<sup>47</sup>**

In order to update and further develop the technical rules applicable to the Infrastructure for Spatial Information in the Union, as set out in Directive 2007/2/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the description of the existing data themes in Annexes I, II and III to that Directive;
- to supplement that Directive with technical arrangements for the interoperability and, where practicable, harmonisation of data sets and services;
- to supplement that Directive with technical specifications for certain services and minimum performance criteria for spatial data services;
- to supplement that Directive with certain obligations;
- to supplement that Directive with harmonised conditions for access to spatial data sets and services.

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 on Better Law-Making of 13 April 2016. 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 2007/2/EC is amended as follows:

(1) in Article 4, paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending the description of the existing data themes set out in Annexes I, II and III, in order to take into account the evolving needs for spatial data in support of Union policies that affect the environment.";

(2) in Article 7, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 21a laying down technical arrangements for the interoperability and, where practicable, harmonisation of spatial data sets and services. Relevant user requirements, existing initiatives and international standards for the harmonisation of spatial data sets, as well as feasibility and cost-benefit considerations shall be taken into account in the development of those arrangements.

Where organisations established under international law have adopted relevant standards to ensure interoperability or harmonisation of spatial data sets and services, those standards shall be integrated, and the existing technical means shall be referred to, if appropriate, in the delegated acts mentioned in the first subparagraph.";

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<sup>47</sup>

OJ L 108, 25.4.2007, p. 1.

(3) Article 16 is replaced by the following:

*"Article 16*

The Commission is empowered to adopt delegated acts in accordance with Article 21a concerning rules, laying down, in particular, the following to supplement this Chapter:

- (a) technical specifications for the services referred to in Articles 11 and 12 and minimum performance criteria for those services, taking account of existing reporting requirements and recommendations adopted within the framework of environmental legislation of the Union, existing e-commerce services and technological progress;
- (b) the obligations referred to in Article 12.";

(4) in Article 17, paragraph 8 is replaced by the following:

"8. Member States shall provide the institutions and bodies of the Union with access to spatial data sets and services in accordance with harmonised conditions.

The Commission is empowered to adopt delegated acts in accordance with Article 21a laying down rules governing those conditions. Those rules shall fully respect the principles set out in paragraphs 1, 2 and 3 of this Article.";

(5) the following Article 21a is inserted:

*"Article 21a*

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(7), Article 7(1), Article 16 and Article 17(8) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 4(7), Article 7(1), Article 16 and Article 17(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 on Better Law-Making of 13 April 2016\*.



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(7), Article 7(1), Article 16 and Article 17(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.";

(6) in Article 22, paragraph 3 is deleted.

#### **47. Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks<sup>48</sup>**

In order to take account of scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to Directive 2007/60/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 on Better Law-Making of 13 April 2016. 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 2007/60/EC is amended as follows:

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending the Annex to adapt it to scientific and technical progress, taking into account the periods for reviewing and updating set out in Article 14.";

(2) the following Article 11a is inserted:

##### *"Article 11a*

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 an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>48</sup>

OJ L 288, 6.11.2007, p. 27.

3. The delegation of power referred to in Article 11(2) may be revoked at any time by the European Parliament and the Council. A decision to revoke shall put an end to the delegation of the power specified by 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 the 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 on Better Law-Making of 13 April 2016\*.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and 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.

#### **48. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe<sup>49</sup>**

In order to take account of technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I to VI, VIII, IX, X and XV to Directive 2008/50/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 on Better Law-Making of 13 April 2016. 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 2008/50/EC is amended as follows:

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<sup>49</sup> OJ L 152, 11.6.2008, p. 1.

(1) Article 28 is amended as follows:

(a) the title is replaced by the following:

**"Amendments and implementing measures";**

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

"The Commission is empowered to adopt delegated acts in accordance with Article 28a amending Annexes I to VI, VIII, IX, X and XV to adapt them to technical progress.";

(2) the following Article 28a is inserted:

*"Article 28a*  
**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 28(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 28(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 on Better Law-Making of 13 April 2016\*.

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(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.";

(3) in Article 29, paragraph 3 is deleted.

**49. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)<sup>50</sup>**

In order to adapt Directive 2008/56/EC to scientific and technical progress, to ensure consistency and to allow for comparison between marine regions or sub-regions, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes III, IV and V to that Directive and to supplement that Directive with criteria and methodological standards and specifications and standardised methods for monitoring and assessment to be used by the Member States. 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 on Better Law-Making of 13 April 2016. 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 2008/56/EC is amended as follows:

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 24a laying down, by 15 July 2010, criteria and methodological standards to be used by the Member States, on the basis of Annexes I and III, in such a way as to ensure consistency and to allow for comparison between marine regions or sub-regions of the extent to which good environmental status is being achieved.

Before proposing such criteria and standards the Commission shall consult all interested parties, including Regional Sea Conventions.";

(2) in Article 11, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 24a laying down specifications and standardised methods for monitoring and assessment, which take into account existing commitments and ensure comparability between monitoring and assessment results.";

(3) in Article 24, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Annexes III, IV and V to adapt them to scientific and technical progress, taking into account the periods for the review and updating of marine strategies laid down in Article 17(2).";

(4) the following Article 24a is inserted:

*"Article 24a*  
**Exercise of the delegation**

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<sup>50</sup> OJ L 164, 25.6.2008, p. 19.

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(3), Article 11(4) and Article 24(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 9(3), Article 11(4) and Article 24(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 on Better Law-Making of 13 April 2016\*.
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(3), Article 11(4) and Article 24(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.";

(5) in Article 25, paragraph 3 is deleted.

**50. 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>51</sup>**

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

- to amend Annex VI to that Regulation to harmonise the classification and labelling of substances;
- to amend that Regulation by adding an Annex relating to emergency health response;
- 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

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<sup>51</sup> OJ L 353, 31.12.2008, p. 1.

conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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. By 20 January 2012 the Commission shall carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review, and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission is empowered to adopt a delegated Regulation, in accordance with Article 53a, amending this Regulation by adding an Annex.";

(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), Article 12, Article 14, Article 18(3)(b), 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 53a and 53b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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.
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.

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

(5) in Article 54, paragraphs 3 and 4 are deleted.

**51. 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>52</sup>**

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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 8a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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.

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<sup>52</sup> OJ L 285, 31.10.2009, p. 36.



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 on Better Law-Making of 13 April 2016\*.

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.

## **52. Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds<sup>53</sup>**

In order to adapt Directive 2009/147/EC to technical and scientific progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and V 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 on Better Law-Making of 13 April 2016. 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 2009/147/EC is amended as follows:

(1) Article 15 is replaced by the following:

### *"Article 15*

The Commission is empowered to adopt delegated acts in accordance with Article 15a amending Annexes I and V to adapt them to technical and scientific progress.";

(2) the following Article 15a is inserted:

### *"Article 15a*

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<sup>53</sup> OJ L 20, 26.1.2010, p. 7.

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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.";

(3) Article 16 is deleted.

**53. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC<sup>54</sup>**

In order to update Regulation (EC) No 1221/2009 and to establish evaluation procedures, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Regulation and to supplement it with procedures for carrying out the peer evaluation of the EMAS Competent Bodies. 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the

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<sup>54</sup> OJ L 342, 22.12.2009, p. 1.

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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1221/2009 implementing powers should be conferred on the Commission concerning the harmonisation of certain procedures and in relation to sectoral reference documents. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1221/2009 is amended as follows:

(1) in Article 16, paragraph 4 is replaced by the following:

"4. Guidance documents referring to harmonisation procedures approved by the Forum of Competent Bodies shall be adopted by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 49(2).

Those documents shall be made publicly available.";

(2) in Article 17, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 48a concerning the procedures for carrying out the peer evaluation of the EMAS Competent Bodies, including appropriate appeals procedures against decisions taken as a result of the peer evaluation.";

(3) in Article 30, paragraph 6 is replaced by the following:

"6. The Commission shall adopt guidance documents referring to harmonisation procedures approved by the Forum of the Accreditation and Licensing Bodies by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 49(2).

Those documents shall be made publicly available. ";

(4) in Article 46, paragraph 6 is replaced by the following:

"6. The Commission shall adopt the sectoral reference documents referred to in paragraph 1 and the guide referred to in paragraph 4 by means of implementing acts in accordance with the procedure referred to in Article 49(2).";

(5) Article 48 is replaced by the following:

*"Article 48*  
**Amendment of Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 48a amending the Annexes where appropriate, in the light of experience gained in the operation of EMAS, in response to identified needs for guidance on EMAS

requirements and in the light of any changes in international standards or new standards which are of relevance to the effectiveness of this Regulation.";

(6) the following Article 48a is inserted:

*"Article 48a*  
**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 48 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 17(3) and Article 48 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 on Better Law-Making of 13 April 2016\*.
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 48 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 49, paragraph 3 is deleted.

**54. Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel<sup>55</sup>**

In order to update Regulation (EC) No 66/2010 and to establish additional technical rules necessary for the EU Ecolabel, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the Annexes to that Regulation;
- to supplement that Regulation with measures granting certain derogations;
- to supplement that Regulation with measures establishing specific EU Ecolabel criteria.

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 on Better Law-Making of 13 April 2016. 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.

As regards the development of EU Ecolabel criteria for food and feed, in 2011 the Commission published a study on the feasibility of developing Ecolabel criteria for food and feed products. Based on the final report of that feasibility study and the opinion of the European Union Ecolabelling Board, the Commission does not intend to develop Ecolabel criteria for food and feed products at this time. Therefore, it is not necessary to delegate power to the Commission to decide for which food and feed groups the development of Ecolabel criteria is feasible.

Accordingly, Regulation (EC) No 66/2010 is amended as follows:

(1) Article 6 is amended as follows:

(a) in paragraph 5, the second subparagraph is deleted;

(b) paragraph 7 is replaced by the following:

"7. For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission is empowered to adopt delegated acts in accordance with Article 15a granting derogations from paragraph 6 of this Article.

No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified in accordance

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<sup>55</sup>

OJ L 27, 30.1.2010, p. 1.

with the procedure set out in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight).";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 15a laying down, no later than nine months after consulting the EUEB, measures to establish specific EU Ecolabel criteria for each product group. These measures shall be published in the *Official Journal of the European Union*.

In exercising the delegated power referred to in the first subparagraph, the Commission shall take into account the comments of the EUEB and shall clearly highlight, document and provide explanations for the reasoning behind any changes in its final proposal compared to the proposal for draft criteria following the consultation of the EUEB.";

(3) Article 15 is replaced by the following:

*"Article 15*  
**Amendment of Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 15a amending the Annexes.

As regards modifications of the maximum fees provided for in Annex III the Commission shall take into account the need for fees to cover the costs of running the scheme.";

(4) the following Article 15a 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 6(7), Article 8(2) and Article 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 6(7), Article 8(2) and 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 on Better Law-Making of 13 April 2016\*.

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(7), Article 8(2) and Article 15 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.”;

(5) Article 16 is deleted.

## VII. EUROSTAT

### **55. Council Regulation (EEC) No 3924/91 of 19 December 1991 on the establishment of a Community survey of industrial production<sup>56</sup>**

In order to adapt Regulation (EEC) No 3924/91 to technical progress the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by:

- updating the Prodcom list and the information actually collected for each heading;
- adopting detailed rules for applying Article 3(3);
- deciding that for certain headings in the Prodcom list monthly or quarterly surveys are to be conducted;
- defining the arrangements related to the content of survey questionnaires and the detailed rules in accordance with which Member States are to process the completed questionnaires or information from other 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 on Better Law-Making of 13 April 2016. 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 (EEC) No 3924/91 is amended as follows:

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

“6. The Commission is empowered to adopt delegated acts in accordance with Article 9a updating the Prodcom list and the information actually collected for each heading.”;

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

“5. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning detailed rules for applying paragraph 3 of this Article, including for the adjustment to technical progress.”;

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

“However, for certain headings in the Prodcom list, the Commission is empowered to adopt delegated acts in accordance with Article 9a providing that monthly or quarterly surveys are to be conducted.”;

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

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<sup>56</sup>

OJ L 374, 31.12.1991, p. 1.



“1. The required information shall be collected by the Member States using survey questionnaires the content of which shall comply with the arrangements defined by the Commission. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning those arrangements.”;

(5) Article 6 is replaced by the following:

*“Article 6*  
**Processing of results**

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the detailed rules in accordance with which Member States shall process the completed questionnaires referred to in Article 5(1) or the information from other sources referred to in Article 5(3).”;

(6) the following Article 9a 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 2(6), Article 3(5), Article 4, Article 5(1) and Article 6 shall be conferred on the Commission for an indeterminate period of time [from the entry into force of this Omnibus].

3. The delegation of power referred to in Article 2(6), Article 3(5), Article 4, Article 5(1) and 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 on Better Law-Making of 13 April 2016\*.

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 2(6), Article 3(5), Article 4, Article 5(1) and Article 6 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 10, paragraph 3 is deleted.

**56. Council Regulation (EEC) No 696/93 of 15 March 1993 on the statistical units for the observation and analysis of the production system in the Community<sup>57</sup>**

In order to adapt Regulation (EEC) No 696/93 to economic and technical developments the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the statistical units of the production system, the criteria used and the definitions specified in 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 on Better Law-Making of 13 April 2016. 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 (EEC) No 696/93 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 in particular the statistical units of the production system, the criteria used and the definitions specified in the Annex in order to adapt them to economic and technical developments.”;

(2) the following Article 6a 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 an indeterminate period of time [from the entry into force of this Omnibus].
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.

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<sup>57</sup> OJ L 76, 30.3.1993, p. 1.

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 on Better Law-Making of 13 April 2016\*.

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 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.

#### **57. Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics<sup>58</sup>**

In order to adapt Regulation (EC) No 1165/98 to economic and technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to:

- amend the Annexes to that Regulation to update the list of variables, the definitions and the appropriate forms of the transmitted variables;
- amend the list of activities;
- supplement that Regulation concerning the approval and application of the European sample schemes;
- supplement that Regulation with the criteria for the measurement of quality;
- supplement that Regulation with the conditions for assuring the necessary data quality;
- supplement that Regulation by determining the terms for applying a European sample scheme;
- supplement that Regulation with the use of other observation units;
- supplement that Regulation with the list of variables to be transmitted in working-day adjusted form;
- supplement that Regulation with the terms of the allocation of a European sample scheme.

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 on Better Law-Making of 13 April 2016. 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

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<sup>58</sup> OJ L 162, 5.6.1998, p. 1.

have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Several empowerments only needed for transitional measures have now become obsolete.

Accordingly, Regulation (EC) No 1165/98 is amended as follows:

(1) in Article 3, the following paragraph 3 is added:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes to update the list of variables, the definitions and the appropriate forms of the transmitted variables.";

(2) in Article 4(2), the second subparagraph is replaced by the following:

"The details of the schemes referred to in the first subparagraph shall be as specified in the Annexes. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning their approval and application.";

(3) in Article 10, the following paragraph 5 is added:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the criteria for the measurement of quality.";

(4) Article 17 is deleted;

(5) the following Article 18a 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 3(3), Article 4(2), Article 10, Annex A points (a), (b) 3, (c) 2, (c) 10, (d) 2, (f) 8 and 9, Annex B points (b) 4 and (d) 2, Annex C points (b) 2, (d) 2 and (g) 2 and Annex D points (b) 2 and (d) 2. shall be conferred on the Commission for an indeterminate period of time [from the entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(3), Article 4(2), Article 10, Annex A points (a), (b) 3, (c) 2, (c) 10, (d) 2, (f) 8 and 9, Annex B points (b) 4 and (d) 2, Annex C points (b) 2, (d) 2 and (g) 2 and Annex D points (b) 2 and (d) 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 on Better Law-Making of 13 April 2016\*.

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(3), Article 4(2), Article 10, Annex A points (a), (b) 3, (c) 2, (c) 10, (d) 2, (f) 8 and 9, Annex B points (b) 4 and (d) 2, Annex C points (b) 2, (d) 2 and (g) 2 and Annex D points (b) 2 and (d) 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. ”.

(6) Annex A is amended as follows:

(i) point (a) is replaced by the following:

"(a) This Annex applies to all activities listed in Sections B to E of NACE Rev. 2, or, as the case may be, to all products listed in Sections B to E of the CPA. The information is not required for 37, 38.1, 38.2 and 39 of NACE Rev. 2. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the list of activities.";

(ii) point (b) 3. is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the use of other observation units.";

(iii) point (c) 2. is replaced by the following:

"2. The information on output prices for non-domestic markets (No 312) and import prices (No 340) may be compiled using unit values for products originating from foreign trade or other sources only if there is no significant deterioration in quality compared to specific price information. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the conditions for assuring the necessary data quality.";

(iv) point (c) 4. is replaced by the following:

"4. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation.";

(v) point (c) 10. is replaced by the following:

"10. The information on output prices and import prices (Nos 310, 311, 312 and 340) is not required for the following groups or classes of NACE Rev. 2 respectively CPA: 07.21, 24.46, 25.4, 30.1, 30.3, 30.4 and 38.3. In addition, the information on import prices (No 340) is not required for divisions 09, 18, 33 and 36 of CPA. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the list of activities.";

(vi) point (d) 2. is replaced by the following:

"2. In addition, the production variable (No 110) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the amendment of the list of variables to be transmitted in working-day adjusted form.";

(vii) point (f) 8. is replaced by the following:

"8. For the import price variable (No 340), the Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the determination of the terms for applying a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2).";

(viii) point (f) 9. is replaced by the following:

"9. The variables on the non-domestic markets (Nos 122 and 312) are to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as NACE Rev. 2 Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of NACE Rev. 2. The information on NACE Rev. 2 D and E is not required for variable 122. In addition, the import price variable (No 340) is to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as CPA Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of CPA. For the distinction into the euro-zone and non-euro-zone, the Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the determination of the terms for applying European sample schemes as defined in point (d) of the first subparagraph of Article 4(2). The European sample scheme may limit the scope of the import price variable to the import of products from non-euro-zone countries. The distinction into the euro-zone and non-euro-zone for the variables 122, 312 and 340 does not need to be transmitted by those Member States that have not adopted the euro as their currency.";

(7) Annex B is amended as follows:

(i) point (b) 4. is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the use of other observation units.";

(ii) point (c) 3. is replaced by the following:

"3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. ";

(iii) in point (c) 6. , the fourth subparagraph is deleted.

(iv) point (d) 2. is replaced by the following:

"2. In addition, the production variable (Nos 110, 115, 116) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form.

Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the amendment of the list of variables to be transmitted in working-day adjusted form.";

(9) Annex C is amended as follows:

(i) point (b) 2. is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the use of other observation units.";

(ii) point (c) 3. is replaced by the following:

"3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation.;

(iii) in point (c) 4. , the last paragraph is deleted;

(iv) point (d) 2. is replaced by the following:

"2. The turnover variable (No 120) and the volume of sales variable (No 123) are also to be transmitted in a working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the amendment of the list of variables to be transmitted in working-day adjusted form.";

(v) point (g) 2. is replaced by the following:

"2. The variables shall be transmitted for turnover (No 120) and the deflator of sales/volume of sales (No 330/123) within one month for the level of detail specified in paragraph 3 under heading (f) of this Annex. Member States may choose to participate for the turnover and deflator of sales/ volume of sales variables No 120 and 330/123 with contributions according to the allocation of a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2). The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the terms of the allocation of a European sample scheme.";

(10) Annex D is amended as follows:

(i) point (b) 2. is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the use of other observation units.";

(ii) point (c) 2 is replaced by the following:

“2. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation.”;

(iii) in point (c) 4. , the third subparagraph is deleted.

(iv) point (d) 2. is replaced by the following:

"2. The turnover variable (No 120) is also to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the amendment of the list of variables to be transmitted in working-day adjusted form may be amended by the Commission.”;

(v) in point (e) the fourth subparagraph is deleted.

(vi) point (f) 6. is deleted.

#### **58. Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs<sup>59</sup>**

In order to adapt Regulation (EC) No 530/1999 with a view to taking account of economic and technical changes, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation with the definition and breakdown of the information to be provided and the quality evaluation criteria. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 530/1999 concerning the technical format for the transmission of results implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 530/1999 is amended as follows:

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 10a concerning the definition and breakdown of the information to be provided under

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<sup>59</sup> OJ L 63, 12.3.1999, p. 6.



paragraphs 1 and 2 of this Article. These delegated acts shall be adopted for each reference period at least nine months before the beginning of the reference period.";

(2) Article 9 is replaced by the following:

*"Article 9*  
**Forwarding of results**

The results shall be forwarded to the Commission (Eurostat) within a period of 18 months from the end of the reference year. The Commission shall adopt the appropriate technical format for the transmission of these results by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2).";

(3) in Article 10, the following paragraph 3 is added:

"3.The Commission is empowered to adopt delegated acts in accordance with Article 10a concerning the quality evaluation criteria. Those delegated acts shall be adopted for each reference period at least nine months before the beginning of the reference period.";

(4) the following Article 10a 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 6(3) and Article 10(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 6(3) and Article 10(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 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 on Better Law-Making of 13 April 2016\*.

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 10(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.";

(5) Article 11 is deleted;

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

### **59. Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics<sup>60</sup>**

In order to update Regulation (EC) No 2150/2002 with a view to taking account of economic and technical developments in the collection and statistical processing of waste statistics, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend that Regulation in order to adjust it to economic and technical developments in the collection and statistical processing of data;
- to amend the processing and the transmission of results and the adaptation of the specifications listed in Annexes I, II and III to that Regulation;
- to supplement that Regulation by defining the minimum requirement for the coverage according to Annexes I and II, Section 7, point 1;
- to supplement that Regulation by establishing a table of equivalence between the statistical nomenclature of Annex III to that Regulation and the list of waste established by Commission Decision 2000/532/EC<sup>61</sup> and by defining the quality and accuracy conditions.

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 on Better Law-Making of 13 April 2016. 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.

Provisions relating to transitional measures have become obsolete.

In order to ensure uniform conditions for the implementation of Regulation (EC) No 2150/2002 concerning the production of results, the appropriate format for the transmission of results and the contents of the quality reports implementing powers should

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<sup>60</sup> OJ L 332, 9.12.2002, p. 1.

<sup>61</sup> Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).

be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 2150/2002 is amended as follows:

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

"5. The Commission is empowered to adopt delegated acts in accordance with Article 5b concerning the establishment of a table of equivalence between the statistical nomenclature of Annex III to this Regulation and the list of waste established by Commission Decision 2000/532/EC.\*

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\* Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3). ";

(2) Article 3 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 5b concerning the definition the quality and accuracy conditions.";

(b) in paragraph 4, the following subparagraph is added:

"For each item listed in Section 8 (activities and household) of Annex I, as well as for the characteristics listed in Section 3 and for each item amongst the types of operations listed in Section 8(2) of Annex II, Member States shall indicate the percentage to which the compiled statistics represent the universe of waste of the respective item. The Commission is empowered to adopt delegated acts in accordance with Article 5b supplementing this Regulation by defining the minimum requirement for the coverage.";

(3) Articles 4 and 5 are deleted;

(4) the following Articles 5a and 5b are inserted:

*"Article 5a*

**Adjustment to economic and technical developments**

The Commission is empowered to adopt delegated acts in accordance with Article 5b concerning the adjustment to economic and technical developments in the collection and statistical processing of data, as well as the processing and the transmission of results and the adaptation of the specifications listed in the Annexes.

*Article 5b*

**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 1(5), Article 3(1) and (4) and Article 5a, shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 1(5), Article 3(1) and (4) and Article 5a, 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 on Better Law-Making of 13 April 2016\*.
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 1(5), Article 3(1) and (4) and Article 5a 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.";

(5) Article 6 is replaced by the following:

*"Article 6*  
**Implementing measures**

The Commission shall adopt implementing acts necessary for the implementation of this Regulation concerning in particular:

- (a) the production of results in accordance with Article 3(2), (3) and (4), taking into account the economic structures and technical conditions in a Member State. Such implementing acts may allow an individual Member State not to report certain items in the breakdown, provided the impact on the quality of the statistics is proven to be limited. In all cases where exemptions are given, the total amount of waste for each item listed in Sections 2(1) and 8(1) of Annex I shall be compiled;
- (b) the appropriate format for the transmission of results by Member States within two years from the date of entry into force of this Regulation;
- (c) the contents of the quality reports as referred to in Section 7 of Annex I and Section 7 of Annex II.

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 7(2).";

(6) in Article 7, paragraph 3 is deleted;

(7) in Article 8, paragraphs 2 and 3 are deleted;

(8) in Annex I, point 1 of Section 7 is deleted;

(9) in Annex II, point 1 of Section 7 is deleted.

**60. Regulation (EC) No 437/2003 of the European Parliament and of the Council of 27 February 2003 on statistical returns in respect of the carriage of passengers, freight and mail by air<sup>62</sup>**

In order to update Regulation (EC) No 437/2003 with a view to taking account of economic and social developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the data collection characteristics and the specifications in the Annexes to that Regulation and to supplement that Regulation by establishing other standards of accuracy. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 437/2003 concerning the data files for the transmission, the description of the data codes and the medium to be used for data transmission, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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

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

"1. Each Member State shall collect statistical data relating to the following variables:

- (a) passengers;
- (b) freight and mail;
- (c) flight stages;
- (d) passenger seats available ;

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<sup>62</sup> OJ L 66, 11.3.2003, p. 1.

(e) aircraft movements.

The statistical variables in each area, the nomenclatures for their classification, their periodicity of observation and the definitions are set out in the Annexes.

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the data collection characteristics and the specifications in the Annexes.";

(2) Article 5 is replaced by the following:

*"Article 5*  
**Accuracy of statistics**

The collection of data shall be based on complete returns.

The Commission is empowered to adopt delegated acts in accordance with Article 10a concerning the establishment of other standards of accuracy.";

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

"2. The results shall be transmitted according to the data files shown in Annex I for which the description shall be specified by the Commission by means of implementing act.

The Commission shall also specify by means of implementing act the description of the data codes and the medium to be used for transmission.

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 11(2).";

(4) Article 10 is deleted;

(5) the following Article 10a 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 referred to in Article 3(1) and Article 5 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(1) and Article 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 on Better Law-Making of 13 April 2016\*.

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 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 11, paragraph 3 is deleted.

#### **61. Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index<sup>63</sup>**

In order to update Regulation (EC) No 450/2003 with a view to taking account of economic and social developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to:

- amend that Regulation by redefining the technical specification of the index and revising the weighting structure, by including certain economic activities;
- supplement that Regulation by identifying the economic activities in which the data is to be broken down and the economic activities in which the index is to be broken down;
- supplement that Regulation by establishing separate quality criteria and the methodology for chaining the index.

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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 450/2003 concerning the content of the quality report, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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<sup>63</sup> OJ L 69, 13.3.2003, p. 1.

Accordingly, Regulation (EC) No 450/2003 is amended as follows:

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

"4. The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning amendments to redefine the technical specification of the index and revise the weighting structure.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the amendments for the inclusion of economic activities defined by NACE Rev.2 sections O to S in the scope of this Regulation, taking into account the feasibility studies defined in Article 10.";

(3) Article 4 is replaced by the following:

*"Article 4*  
**Breakdown of variables**

1. Taking account of contributions to total employment and to labour costs at Union and national levels, the Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the identification of the economic activities defined by NACE Rev. 2 sections and by further disaggregations, not beyond the level of NACE Rev. 2 divisions (2-digit level) or groupings of divisions in which the data shall be broken down taking account of economic and social developments.

Labour cost indices shall be provided separately for the following labour cost categories:

- (a) total labour costs;
- (b) wages and salaries, defined by reference to item D.11 in Annex II to Regulation (EC) No 1726/1999;
- (c) employers' social contributions plus taxes paid by the employer less subsidies received by the employer, as defined by the sum of items D.12 and D.4 less D.5 in Annex II to Regulation (EC) No 1726/1999.

2. An index estimating total labour costs, excluding bonuses, where bonuses are defined by D.11112 in Annex II to Regulation (EC) No 1726/1999, shall be provided broken down by economic activities determined by the Commission, and shall be based on the NACE Rev. 2 classification.

The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the determination of these economic activities, taking into account the feasibility studies defined in Article 10.

3. The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the establishment of the methodology for chaining the index.";

(4) Article 8 is replaced by the following:



*"Article 8*  
**Quality**

1. The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the definition of separate quality criteria. The current data and back data transmitted shall satisfy these quality criteria.

2. The Member States shall provide annual quality reports to the Commission, beginning in 2003. The content of the reports shall be defined by the Commission by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2).";

(5) Article 10 is amended as follows:

(a) paragraph 5 is replaced by the following:

"5. The Commission shall adopt measures pursuant to the results of the feasibility studies by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2). Those measures shall respect the principle of cost-effectiveness, as defined in Article 2 of Regulation (EC) No 223/2009, including the minimisation of the burden on respondents.";

(b) paragraph 6 is deleted;

(6) Article 11 is deleted;

(7) the following Article 11a 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 2(4), Article 3(2) and Article 4 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this omnibus].

3. The delegation of power referred to in Article 2(4), Article 3(2) and Article 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 on Better Law-Making of 13 April 2016\*.

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 2(4), Article 3(2) and Article 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.";

(8) in Article 12, paragraph 3 is deleted;

(9) in the Annex, point 3 is deleted.

**62. Regulation (EC) No 1059/2003 of the European Parliament and of the Council of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS)<sup>64</sup>**

In order to update Regulation (EC) No 1059/2003 and with a view to ensuring the comparability of regional statistics and a consistent management of the NUTS classification, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to:

- amend Annex II to that Regulation and adapt it to the changes of the administrative units;
- amend the NUTS classification and the list of the time series and their length referred to in Annex III to that Regulation;
- supplement that Regulation with decisions concerning certain non-administrative units deviating from the thresholds.

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 on Better Law-Making of 13 April 2016. 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 1059/2003 is amended as follows:

(1) Article 3 is amended as follows:

(a) paragraph 4 is replaced by the following:

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<sup>64</sup> OJ L 154, 21.6.2003, p.1.

"4. The existing administrative units used for the NUTS classification are laid down in Annex II. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending Annex II to adapt it to the changes of those administrative units.";

(b) in paragraph 5, the third subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 6a concerning non-administrative units that may deviate from those thresholds because of particular geographical, socio-economic, historical, cultural or environmental circumstances, especially in the islands and the outermost regions.";

(2) in Article 4, paragraph 1 the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 6a amending Annex III.";

(3) in Article 5, paragraphs 4 and 5 are replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending the NUTS classification.

Amendments to the NUTS classification shall be adopted in the second half of the calendar year, not more frequently than every three years, on the basis of the criteria laid down in Article 3. Nevertheless, in the case of a substantial reorganisation of the relevant administrative structure of a Member State, the amendments to the NUTS classification may be adopted at intervals of less than three years.

The delegated acts referred to in the first subparagraph shall be applicable, with regard to the transmission of the data to the Commission, from 1 January of the second year after their adoption.

5. When an amendment is made to the NUTS classification, the Member State concerned shall transmit to the Commission the time series for the new regional breakdown, to replace data already transmitted. The Commission is empowered to adopt delegated acts in accordance with Article 6a concerning the list of the time series and their length, taking into account the feasibility of providing them. The time series are to be supplied within two years of the amendment of the NUTS classification.";

(4) the following Article 6a 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 3(4) and (5), Article 4(1) and Article 5(4) and (5) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(4) and (5), Article 4(1) and Article 5(4) and (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 on Better Law-Making of 13 April 2016\*.

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(4) and (5), Article 4(1) and Article 5(4) and (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 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.";

(5) Article 7 is deleted.

### **63. Regulation (EC) No 808/2004 of the European Parliament and of the Council of 21 April 2004 concerning Community statistics on the information society<sup>65</sup>**

In order to adapt Regulation (EC) No 808/2004 to economic and technical developments, in particular concerning the content of the modules, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission with respect to supplementing the modules of that Regulation concerning the selection and the specification, the adjustment and the modification of subjects and their characteristics, the coverage, the reference periods and breakdowns of characteristics, the periodicity and timing of data provision and the deadlines for transmission of results.

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 on Better Law-Making of 13 April 2016\*. 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 143, 30.4.2004, p.49.

Accordingly, Regulation (EC) No 808/2004 is amended as follows:

(1) Article 8 is replaced by the following:

*"Article 8*  
**Delegated powers**

1. The Commission is empowered to adopt delegated acts in accordance with Article 8a supplementing the modules of this Regulation concerning the selection and specification, the adjustment and modification of subjects and their characteristics, the coverage, reference periods and breakdowns of characteristics, the periodicity and timing of data provision and the deadlines for transmission of results.

Those delegated acts shall take account of economic and technical changes and take into account Member States' resources and the burden on respondents, technical and methodological feasibility and reliability of results.

2. Delegated acts shall be adopted at least nine months before the start of a data collection period.";

(2) the following Article 8a 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 an indeterminate period of time from [the entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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) Article 9 is deleted;

(4) in Annex I, point 3 is replaced by the following:

*“3. Duration and periodicity of data provision*

Statistics shall be provided annually for up to 15 reference years from 20 May 2004. Not all characteristics shall necessarily be provided each year; the periodicity of provision for each characteristic shall be specified and agreed upon as part of the delegated acts adopted pursuant to Article 8(1).”

(5) in Annex II, point 3 is replaced by the following:

*“3. Duration and periodicity of data provision*

Statistics shall be provided annually for up to 15 reference years from 20 May 2004. Not all characteristics shall necessarily be provided each year; the periodicity of provision for each characteristic shall be specified and agreed upon as part of the delegated acts adopted pursuant to Article 8(1).”.

#### **64. Regulation (EC) No 1161/2005 of the European Parliament and of the Council of 6 July 2005 on the compilation of quarterly non-financial accounts by institutional sector<sup>66</sup>**

In order to ensure the quality of the quarterly non-financial accounts for the Union and the euro area compiled under Regulation (EC) No 1161/2005, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to:

- amend that Regulation to adapt the time-period of transmission for certain items;
- amend that Regulation to adapt the proportion of the Union total;
- supplement that Regulation with a timetable for the transmission of certain items specified in the Annex, with decisions to require a breakdown of the transactions listed in the Annex by counterpart sector and with common quality standards.

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 on Better Law-Making of 13 April 2016. 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>66</sup> OJ L 191, 22.7.2005, p. 22.

Accordingly, Regulation (EC) No 1161/2005 is amended as follows:

(1) Article 2 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 7a concerning the timetable for the transmission of items P.1, P.2, D.42, D.43, D.44, D.45, and B.4G, and any decision to require a breakdown of the transactions listed in the Annex by counterpart sector. Any such decision shall only be adopted after the Commission has reported to the European Parliament and the Council on the implementation of this Regulation pursuant to Article 9.";

(b) paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 7a to amend paragraph 3 to adjust, by a maximum of five days, the time of transmission specified in that paragraph.";

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 7a amending paragraph 1 of this Article as regards the proportion of the Union total." ;

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

"1. The Commission is empowered to adopt delegated acts in accordance with Article 7a concerning the adoption of common quality standards.  
Member States shall take all measures necessary to ensure that the quality of transmitted data improves over time to meet these common quality standards.";

(4) the following Article 7a 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 2(2) and (4), Article 3(3) and Article 6(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 2(2) and (4), Article 3(3) and Article 6(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 on Better Law-Making of 13 April 2016\*.

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 2(2) and (4), Article 3(3) and Article 6(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.";

(5) in Article 8, paragraph 3 is deleted.

#### **65. Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises<sup>67</sup>**

In order to update Regulation (EC) No 1552/2005 with a view to taking account of economic and technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation:

- by extending the definition of statistical unit;
- by determining the sampling and precision requirements, the sample sizes needed to meet those requirements and the detailed specifications of the NACE Rev. 2 and size categories into which the results can be broken;
- by determining the specific data to be collected with respect to training and non-training enterprises and to the different forms of vocational training;
- by specifying the quality requirements for the data to be collected and transmitted for European statistics on vocational training in enterprises, and any measures necessary for assessing or improving quality of data;
- by determining the first reference year and the measures necessary concerning the collection, transmission and processing of the data.

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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1552/2005 concerning the structure of the quality reports, implementing powers should be

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<sup>67</sup> OJ L 255, 30.9.2005, p. 1.



conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1552/2005 is amended as follows:

(1) in Article 5, paragraph 2 is replaced by the following:

"2. Having regard to the specific national size distribution of enterprises and the evolution of policy needs, Member States may extend the definition of the statistical unit in their country.

In addition, the Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the extension of that definition, if such extension would substantially enhance the representativeness and the quality of the result of the survey in the Member States concerned.";

(2) in Article 7, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 13a determining the sampling and precision requirements, the sample sizes needed to meet those requirements, and the detailed specifications of the NACE Rev. 2 and size categories into which the results can be broken down.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the specific data to be collected with respect to training and non-training enterprises and to the different forms of vocational training.";

(4) Article 9 is amended as follows:

(a) paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the quality requirements for the data to be collected and transmitted for European statistics on vocational training in enterprises, and any measures necessary for assessing or improving the quality of the data.";

(b) the following paragraph 5 is added:

"5. The Commission shall determine the structure of the quality reports referred to in paragraph 2 by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 14(2).";

(5) in Article 10, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the determination of the first reference year for which the data are to be collected.";

(6) in Article 13, the first paragraph is replaced by the following:

" The Commission is empowered to adopt delegated acts in accordance with Article 13a to supplement this Regulation to take account of economic and technical developments concerning the collection, transmission and processing of the data.";

(7) the following Article 13a is 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 5(2), Article 7(3), Article 8(2), Article 9(4), Article 10(2) and Article 13 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 5(2), Article 7(3), Article 8(2), Article 9(4), Article 10(2) 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 on Better Law-Making of 13 April 2016\*.

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(2), Article 7(3), Article 8(2), Article 9(4), Article 10(2) and Article 13 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.";

(8) in Article 14, paragraph 3 is deleted.

**66. 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>68</sup>**

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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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) in Article 6, 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.";

(2) the following Article 6a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.

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<sup>68</sup>

OJ L 393, 30.12.2006, p.1.

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 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.

**67. Regulation (EC) No 458/2007 of the European Parliament and of the Council of 25 April 2007 on the European system of integrated social protection statistics (ESSPROS)<sup>69</sup>**

In order to adapt Regulation (EC) No 458/2007 to technological and economic developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Regulation by updating the rules on dissemination and to supplement it by establishing the first year for which full data should be collected and by adopting measures relating to the detailed classification of data covered and the definitions to be used. 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 on Better Law-Making of 13 April 2016. 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 458/2007 is amended as follows:

(1) Article 5, paragraph 2 is deleted.

(2) in Article 7, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 7a establishing the first year for which full data shall be collected, and adopting measures relating to the detailed classification of data covered and the definitions to be used.

The Commission is empowered to adopt delegated acts in accordance with Article 7a amending this Regulation to update the rules for dissemination.";

(3) the following Article 7a is inserted:

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<sup>69</sup> OJ L 113, 30.4.2007, p. 3.

*"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(3) and Annex I, point 1.1.2.4. shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this omnibus].
3. The delegation of power referred to in Article 7(3) and Annex I, point 1.1.2.4. 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 on Better Law-Making of 13 April 2016\*.
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(3) and Annex I, point 1.1.2.4. 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.";

(4) in Article 8, paragraph 3 is deleted;

(5) in Annex I, point '1.1.2.4. Other receipts' is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 7a to provide data covered (with reference to detailed classification)."

**68. Regulation (EC) No 716/2007 of the European Parliament and of the Council of 20 June 2007 on Community statistics on the structure and activity of foreign affiliates<sup>70</sup>**

In order to adapt Regulation (EC) No 716/2007 to economic and technical developments the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the definitions in Annexes I and II and the level of detail in Annex III and to supplement that Regulation with measures concerning inward and outward statistics on foreign affiliates.

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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 716/2007, implementing powers should be conferred on the Commission in order to define the contents and periodicity of the quality reports. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 716/2007 is amended as follows:

(1) in Article 2, the following paragraphs are added:

“The Commission is empowered to adopt delegated acts in accordance with Article 9a amending the definitions in Annexes I and II and the level of detail in Annex III.

Particular consideration shall be given to the principle that the benefits of such measures must outweigh their costs, and to the principle that any additional financial burden on Member States or enterprises should remain within a reasonable limit.”;

(2) in Article 5, paragraph 4 is replaced by the following:

“4. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the necessary measures for inward and outward statistics on foreign affiliates, on the basis of the conclusions of the pilot studies.

Particular consideration shall be given to the principle that the benefits of such measures must outweigh their costs, and to the principle that any additional financial burden on Member States or enterprises should remain within a reasonable limit.”;

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

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<sup>70</sup>

OJ L 171, 29.6.2007, p.17

“3. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning common quality standards.”;

(4) Article 9 is amended as follows:

(a) paragraph 1 is amended as follows:

- (i) between point (a) and point (b), the word "and" is deleted;
- (ii) the following point (c) is added:

"(c) defining the contents and periodicity of the quality reports.";

(b) paragraph 2 is deleted;

(5) the following Article 9a 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 2, Article 5(4) and Article 6(3) shall be conferred on the Commission for an indeterminate period of time [from the entry into force of this Omnibus].

3. The delegation of power referred to in Article 2, Article 5(4) and Article 6(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 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 on Better Law-Making of 13 April 2016\*.

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 2, Article 5(4) and Article 6(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 10, paragraph 3 is deleted.

**69. Regulation (EC) No 862/2007 of the European Parliament and of the Council of 11 July 2007 on Community statistics on migration and international protection and repealing Council Regulation (EEC) No 311/76 on the compilation of statistics on foreign workers<sup>71</sup>**

In order to adapt Regulation (EC) No 862/2007 to technological and economic developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Regulation to update certain definitions and to supplement it by determining the groupings of data and additional disaggregations and laying down rules on accuracy and quality standards. 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 on Better Law-Making of 13 April 2016. 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 862/2007 is amended as follows:

(1) the following Article 9a is inserted:

*"Article 9a*  
**Delegated acts**

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the definitions set out in Article 2(1).

The Commission is empowered to adopt delegated acts in accordance with Article 10a:

- (a) defining the categories of groups of country of birth, groups of country of previous and next usual residence and groups of citizenship as provided for in Article 3(1);
- (b) defining the categories of the reasons for the permit as provided for in Article 6(1)(a);
- (c) defining the additional disaggregations and the levels of disaggregations to be applied to the variables as provided for in Article 8;
- (d) laying down the rules on accuracy and quality standards.";

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

(3) the following Article 10a is inserted:

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<sup>71</sup> OJ L 199, 31.7.2007, p. 23.



*"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 9a shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.";

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

**70. Regulation (EC) No 1445/2007 of the European Parliament and of the Council of 11 December 2007 establishing common rules for the provision of basic information on Purchasing Power Parities and for their calculation and dissemination<sup>72</sup>**

In order to update Regulation (EC) No 1445/2007 with a view to taking account of economic and technical changes for the calculation and dissemination of Purchasing Power Parities, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Regulation to adapt the definitions and to amend the basic headings in Annex II and to supplement that Regulation with quality criteria. 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

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<sup>72</sup> OJ L 336, 20.12.2007, p. 1.

Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1445/2007 implementing powers should be conferred on the Commission to adopt the structure of the quality reports. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1445/2007 is amended as follows:

(1) in Article 3, the following paragraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the definitions and amending the list of basic headings in Annex II to take account of economic and technical changes, insofar as this does not involve a disproportionate increase in costs for the Member States.";

(2) Article 7 is amended as follows:

(a) paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 10a concerning common criteria on which the quality control is based.";

(b) the following paragraph 5 is added:

"5. The Commission shall adopt the structure of the quality reports, as specified in point 5.3 of Annex I, by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 11 (2).";

(3) the following Article 10a 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 3 and Article 7(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3 and Article 7(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 on Better Law-Making of 13 April 2016\*.

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 and Article 7(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.";

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

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

#### **71. Regulation (EC) No 177/2008 of the European Parliament and of the Council of 20 February 2008 establishing a common framework for business registers for statistical purposes and repealing Council Regulation (EEC) No 2186/93<sup>73</sup>**

In order to adapt Regulation (EC) No 177/2008 to economic and technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the list of register characteristics, their definition and their continuity rules in the Annex to that Regulation and to supplement that Regulation with common quality standards and rules for updating registers and by determining the extent to which certain enterprises and enterprise groups are to be included in the registers, specifying units consistent with those for agricultural statistics. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 177/2008, implementing powers should be conferred on the Commission concerning the

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<sup>73</sup> OJ L 61, 5.3.2008, p. 6.

content and periodicity of the quality reports. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 177/2008 is amended as follows:

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

“6. The Commission is empowered to adopt delegated acts in accordance with Article 15a determining the extent to which enterprises with less than half a person employed and all resident enterprise groups of no statistical importance to the Member States are to be included in the registers, and the definition of units consistent with those for agricultural statistics.”;

(2) in Article 5, paragraph 2 is replaced by the following:

“2. The Commission is empowered to adopt delegated acts in accordance with Article 15a amending the Annex to update the list of register characteristics and their definition and their continuity rules taking into account the principle that the benefits of the updating must outweigh its cost and the principle that the additional resources involved either for Member States or for enterprises remain reasonable.”;

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

“3. The Commission is empowered to adopt delegated acts in accordance with Article 15a concerning common quality standards.

The Commission shall adopt decisions concerning the content and periodicity of the quality reports by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 16(2).

The Commission shall take into account the cost of compiling the data.”;

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

“3. The Commission is empowered to adopt delegated acts in accordance with Article 15a concerning the rules for updating registers.”;

(5) in Article 15, paragraph 1 is deleted;

(6) the following Article 15a 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 3(6), Article 5(2), Article 6(3) and Article 8(3) shall be conferred on the Commission for an indeterminate period of time [from the entry into force of the Omnibus].

3. The delegation of power referred to in Article 3(6), Article 5(2), Article 6(3) and Article 8(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 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 on Better Law-Making of 13 April 2016\*.

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(6), Article 5(2), Article 6(3) and Article 8(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 16, paragraph 3 is deleted.

## **72. Regulation (EC) No 295/2008 of the European Parliament and of the Council of 11 March 2008 concerning structural business statistics<sup>74</sup>**

In order to adapt Regulation (EC) No 295/2008 to economic and technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation:

- as regards the scope, the list of characteristics, the reference period, the activities to be covered and the quality requirements of the flexible module;
- with the measures necessary on the basis of the evaluation of the pilot studies;
- with the component national results produced by Member States ;
- as regards the reference period for certain modules;
- with the review of the rules for the CETO flag and grouping the Member States;
- by updating the lists of characteristics, and preliminary results;
- as regards the frequency of the compilation of the statistics;
- as regards the first reference year for the compilation of the results;
- supplement that Regulation with the division 66 of NACE Rev. 2, the transmission of preliminary results or estimates;

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<sup>74</sup> OJ L 97, 9.4.2008, p. 13.

- as regards the breakdown of results, in particular the classifications to be used and the combinations of the size;
- by updating the periods of time for the transmission of data;
- by adapting the breakdown of activities to amendments or revisions of the NACE and the breakdown of products to amendments or revisions of the CPA, the change of the lower limit for the reference population;
- with criteria for the evaluation of quality.

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 on Better Law-Making of 13 April 2016. 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 295/2008 is amended as follows:

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

“The use of the flexible module referred to in point (j) of paragraph 2 shall be planned in close cooperation with Member States. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning its scope, list of characteristics, reference period, activities to be covered and quality requirements. The delegated act shall be adopted at least 12 months before the beginning of the reference period.

The Commission shall also specify the need for the information and the impact of the data collection in respect of the burden on businesses and the costs to the Member States.”;

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

“4. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the measures necessary on the basis of the evaluation of the pilot studies.”;

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

“2. In order that Union aggregates may be compiled, Member States shall produce component national results according to the levels of NACE Rev. 2 laid down in the Annexes to this Regulation or in delegated acts. The Commission is empowered to adopt such delegated acts in accordance with Article 11b.”;

(4) Article 8 is amended as follows:

(a) paragraph 2 is replaced by the following:

“2. The results shall be transmitted in an appropriate technical format, within a period of time starting from the end of the reference period. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the reference period for the modules provided for in Article 3(2)(a) to (h) and (j) and this period shall be no longer than 18 months. For the module provided for in Article 3(2)(i), the period of time shall be no longer than 30 months or 18 months as laid down in Annex IX, Section 9. In addition, a small number of estimated preliminary results shall be transmitted within a period of time starting from the end of the reference period which shall be laid down in accordance with that procedure for the modules provided for in Article 3(2)(a) to (g) and shall be no longer than 10 months. For the module provided for in Article 3(2)(i), the period of time for preliminary results shall be no longer than 18 months.”;

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

“The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the review of the rules for the CETO flag and grouping the Member States, by 29 April 2013 and every five years thereafter.”;

(5) in Article 11, paragraph 2 is deleted;

(6) the following Articles 11a and 11b are inserted:

*“Article 11a*  
**Delegated acts**

The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning:

- (a) the update of the lists of characteristics, and preliminary results in so far as such updating, after a quantitative assessment, does not imply an increase in the number of units surveyed nor a burden on the units which is disproportionate to the anticipated results (Articles 4 and 8 and Annex I, Section 6, Annex II, Section 6, Annex III, Section 6, Annex IV, Section 6);
- (b) the frequency of the compilation of the statistics (Article 3);
- (c) the first reference year for the compilation of the results (Article 8 and Annex I, Section 5);
- (d) the breakdown of results, in particular the classifications to be used and the combinations of the size classes (Article 7 and Annex VIII, Section 4, paragraphs 2 and 3, Annex IX, Section 8, paragraphs 2 and 3, and Annex IX, Section 10);
- (e) the update of the periods of time for the transmission of data (Article 8 and Annex I, Section 8, paragraph 1, and Annex VI, Section 7);
- (f) the adaptation of the breakdown of activities to amendments or revisions of the NACE and the breakdown of products to amendments or revisions of the CPA;
- (g) the change of the lower limit for the reference population (Annex VIII, Section 3);
- (h) and the criteria for the evaluation of quality (Article 6 and Annex I, Section 6, Annex II, Section 6, Annex III, Section 6 and Annex IV, Section 6).”

*Article 11b*  
**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(4), Article 4(4), Article 7(2), Article 8(2) and (3), Article 11a, Annex I, Sections 5, 6, 8(1) and (2), Section 6, of Annexes II, III and IV, Annex VI, Section 7, Annex VIII , Sections 3, 4(2) and (3), Annex IX Sections 8(2) and (3) and 10(2), shall be conferred on the Commission for an indeterminate period of time [from the entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(4), Article 4(4), Article 7(2), Article 8(2) and (3), Article 11a, Annex I, Sections 5, 6, 8(1) and (2), Section 6, of Annexes II, III and IV, Annex VI, Section 7, Annex VIII , Sections 3, 4(2) and (3), Annex IX Sections 8(2) and (3) and 10(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 on Better Law-Making of 13 April 2016\*.

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(4), Article 4(4), Article 7(2), Article 8(2) and (3), Article 11a, Annex I, Sections 5, 6, 8(1) and (2), Section 6, of Annexes II, III and IV, Annex VI, Section 7, Annex VIII , Sections 3, 4(2) and (3), Annex IX Sections 8(2) and (3) and 10(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.”;

(7) in Article 12 paragraph 3 is deleted;

(8) Annex I is amended as follows:

(a) sections 5 and 6 are replaced by the following:

#### “SECTION 5

##### **First reference year**

The first reference year for which statistics are compiled is the calendar year 2008. Data will be compiled according to the breakdown in Section 9. However, the Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the first reference year for which statistics on the activity classes covered by the NACE Rev. 2 groups 64.2, 64.3 and 64.9 and division 66 are to be compiled.



## SECTION 6

### **Report on the quality of statistics**

For each of the key characteristics Member States will indicate the degree of precision by reference to a confidence level of 95 %, which the Commission will include in the report provided for in Article 13, taking account of the application in each Member States of that Article. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the key characteristics.”

(b) section 8 is amended as follows:

(i) paragraph 1 is replaced by the following:

“1. The results are to be transmitted within 18 months of the end of the calendar year of the reference period, except for the NACE Rev. 2 activity classes 64.11 and 64.19. For the NACE Rev. 2 activity classes 64.11 and 64.19 the transmission delay is 10 months. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the transmission delay of the results on the activity classes covered by the NACE Rev. 2 groups 64.2, 64.3 and 64.9 and division 66.”;

(ii) in paragraph 2, the last paragraph is replaced by the following:

“These preliminary results or estimates are to be broken down to NACE Rev. 2, 3-digit level (group). The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the division 66 of NACE Rev. 2, the transmission of preliminary results or estimates.”;

(9) in Annex II, section 6 is replaced by the following:

## “SECTION 6

### **“Report on the quality of statistics**

For each key characteristic Member States will indicate the degree of precision by reference to a confidence level of 95 % which the Commission will include in the report provided for in Article 13, taking account of the application in each Member State of that Article. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the key characteristics.”;

(10) in Annex III, section 6 is replaced by the following:

## “SECTION 6

### **Report on the quality of statistics**

For each key characteristic Member States will indicate the degree of precision by reference to a confidence level of 95 % which the Commission will include in the report provided for in Article 13, taking account of the application in each Member State of that Article. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the key characteristics.”;

(11) in Annex IV, section 6 is replaced by the following:

## “SECTION 6

### **Report on the quality of statistics**

For each key characteristic Member States will indicate the degree of precision by reference to a confidence level of 95 % which the Commission will include in the report provided for in Article 13, taking account of the application in each Member State of that Article. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the key characteristics.”;

- (12) in Annex VI, section 7 is replaced by the following:

“SECTION 7

**Transmission of results**

The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the transmission delay of the results that will not be longer than 10 months starting from the end of the reference year.”;

- (13) Annex VIII is amended as follows:

- (a) in Section 3, the fifth sentence is replaced by the following:

"On the basis of this study, the Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the changing of the lower limit.”;

- (b) in section 4, in paragraphs 2 and 3, in table ‘Breakdown of turnover by product type’, the sentence in the column ‘Comment’ is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning the determination of product breakdown.”;

- (14) Annex IX is amended as follows:

- (a) in section 8, paragraphs 2 and 3 are replaced by the following:

“2. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning some results that shall also be broken down into size classes to the level of detail listed in Section 10, except for NACE Rev. 2 Sections L, M and N, where the breakdown is required only to the group level.

3. The Commission is empowered to adopt delegated acts in accordance with Article 11b concerning some results that shall also be broken down according to legal form to the level of the detail listed in Section 10, except for NACE Rev. 2 Sections L, M and N, where the breakdown is required only to the group level.”;

- (b) in section 10, at the end of paragraph 2, the subsection "Special aggregates" is replaced by the following:

“**Special aggregates**

To enable Union statistics on business demography to be compiled for the Information and Communication Technology sector, the Commission is empowered to adopt delegated acts in accordance with Article 11b concerning a number of special aggregates of the NACE Rev. 2 to be transmitted.”.

**73. 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>75</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 451/2008 is amended as follows:

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 6a amending the Annex:

- (a) to take account of technological or economic developments;
- (b) to align it with other economic and social classifications.";

(2) the following Article 6a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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<sup>75</sup>

OJ L 145, 4.6.2008, p. 65.

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 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.

**74. Regulation (EC) No 452/2008 of the European Parliament and of the Council of 23 April 2008 concerning the production and development of statistics on education and lifelong learning<sup>76</sup>**

In order to adapt Regulation (EC) No 452/2008 to policy or technical developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by selecting and specifying the subjects of the statistics, their characteristics, the breakdown of characteristics, the observation period and deadlines for transmission of results, the quality requirements including the required precision. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 452/2008, implementing powers should be conferred on the Commission concerning the quality reporting framework. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 452/2008 is amended as follows:

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

"1. The Commission is empowered to adopt delegated acts in accordance with Article 6a concerning:

- (a) the selection and specification of subjects covered by the domains and their characteristics in response to policy or technical needs;
- (b) the breakdown of characteristics;
- (c) the observation period and deadlines for transmission of results;
- (d) the quality requirements, including the required precision;

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<sup>76</sup> OJ L 145, 4.6.2008, p. 227.

Where those delegated acts require a significant enlargement of existing data collections or new data collections or surveys, delegated acts shall be based on a cost-benefit analysis as part of a comprehensive analysis of the effects and implications, taking into account the benefit of the measures, the costs for the Member States and the burden on respondents.

The Commission shall adopt measures concerning the quality reporting framework by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 7(2).";

(2) the following Article 6a 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(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 6(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 on Better Law-Making of 13 April 2016\*.
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(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 7, paragraph 3 is deleted.

**75. Regulation (EC) No 453/2008 of the European Parliament and of the Council of 23 April 2008 on quarterly statistics on Community job vacancies<sup>77</sup>**

In order to update Regulation (EC) No 453/2008 with a view to providing regular quarterly statistics on job vacancies, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by defining the concepts of ‘active steps to find a suitable candidate’ and ‘specific period of time’, by determining certain reference dates, by setting out the framework for feasibility studies and by adopting any appropriate acts based on the results of those studies. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 453/2008 concerning the format for transmission of data and metadata, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 453/2008 is amended as follows:

(1) Article 2 is amended as follows:

(a) point 1 is replaced by the following:

"1. ‘job vacancy’ shall mean a paid post that is newly created, unoccupied, or about to become vacant:

(a) for which the employer is taking active steps and is prepared to take further steps to find a suitable candidate from outside the enterprise concerned; and

(b) which the employer intends to fill either immediately or within a specific period of time.

The statistics provided shall distinguish, on an optional basis, between vacancies for fixed-term and permanent jobs.";

(b) the following second paragraph is added:

"For the purposes of point 1 of the first paragraph, the Commission is empowered to adopt delegated acts in accordance with Article 8a defining the concepts ‘active steps to find a suitable candidate’ and ‘specific period of time.'";

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

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<sup>77</sup> OJ L 145, 4.6.2008, p. 234.

"1. Member States shall compile the quarterly data with reference to specific reference dates. The Commission is empowered to adopt delegated acts in accordance with Article 8a determining those specific reference dates.";

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

"1. The Commission is empowered to adopt delegated acts in accordance with Article 8a determining the date of the first reference quarter as well as the transmission deadlines. Any revision of quarterly data for previous quarters shall be transmitted at the same time.

Member States shall transmit the data and metadata to the Commission (Eurostat) according to a format determined by the Commission by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 9(3).";

(4) in Article 7, paragraphs 1, 2 and 3 are replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 8a concerning the appropriate framework for the establishment of a series of feasibility studies.

Those studies shall be undertaken by those Member States that have difficulties in providing data for:

(a) units with fewer than 10 employees; and/or

(b) the following activities:

(i) public administration and defence; compulsory social security;

(ii) education;

(iii) human health and social work activities;

(iv) arts, entertainments and recreation;

(v) activities of membership organisations, repair of computers and personal and household goods and other personal service activities.

2. Member States undertaking feasibility studies shall each submit a report on the results of those studies within 12 months of the entry into force of the delegated acts referred to in paragraph 1.

3. The Commission is empowered to adopt delegated acts in accordance with Article 8a supplementing this Regulation by adopting the necessary measures as soon as possible after the results of the feasibility studies become available, in dialogue with the Member States, and within a reasonable time frame.";

(5) the following Article 8a 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 2, Article 3(1), Article 5(1) and Article 7(1) and (3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 2, Article 3(1), Article 5(1) and Article 7(1) and (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 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 on Better Law-Making of 13 April 2016\*.

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 2, Article 3(1), Article 5(1) and Article 7(1) and (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 9, paragraph 2 is deleted.

## **76. Regulation (EC) No 763/2008 of the European Parliament and of the Council of 9 July 2008 on population and housing censuses<sup>78</sup>**

In order to update Regulation (EC) No 763/2008, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by establishing subsequent reference years and adopting the programme of the statistical data and the metadata. 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 on Better Law-Making of 13 April 2016. 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 763/2008 is amended as follows:

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<sup>78</sup> OJ L 218, 13.8.2008, p. 14.



(1) Article 5 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Each Member State shall determine a reference date. The reference date shall fall in a year specified on the basis of this Regulation (reference year). The first reference year shall be 2011.

The Commission is empowered to adopt delegated acts in accordance with Article 7a concerning the establishment of the subsequent reference years. Reference years shall fall during the beginning of every decade";

(b) paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 7a concerning establishing a programme of the statistical data and of the metadata to be transmitted to fulfil the requirements of this Regulation.";

(2) in Article 7, paragraph 2 is deleted;

(3) the following Article 7a 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 5(1) and (3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 5(1) and (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 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 on Better Law-Making of 13 April 2016\*.

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(1) and (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.";

(4) in Article 8, paragraph 3 is deleted.

## **77. Regulation (EC) No 1099/2008 of the European Parliament and of the Council of 22 October 2008 on energy statistics<sup>79</sup>**

In order to adapt Regulation (EC) No 1099/2008 to technical progress and new needs, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission

- to amend the list of data sources and the applicable clarifications or definitions in that Regulation;
- to amend the arrangements for the transmission of the national data in that Regulation;
- to supplement that Regulation with the annual nuclear statistics;
- to supplement that Regulation with the renewable energy statistics, as well as the final energy consumption statistics.

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 on Better Law-Making of 13 April 2016. 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 1099/2008 is amended as follows:

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the list of data sources.";

(2) in Article 4, paragraphs 2 and 3 are replaced by the following:

"2. Applicable clarifications or definitions of the technical terms used are provided in the individual Annexes and also in Annex A (Clarifications of terminology).

The Commission is empowered to adopt delegated acts in accordance with Article 10a further clarifying the terminology by adding relevant NACE references after a revision of the NACE classification has entered into force.

3. The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the data to be forwarded and the applicable clarifications or definitions.";

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<sup>79</sup> OJ L 304, 14.11.2008, p.1.

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the arrangements for the transmission of the national statistics.";

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

"The Commission is empowered to adopt delegated acts in accordance with Article 10a regarding the set of annual nuclear statistics.";

(5) Article 9 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 10a regarding the set of renewable energy statistics and the set of final energy consumption statistics.";

(b) paragraph 3 is deleted;

(6) in Article 10, paragraph 1 is deleted;

(7) the following Article 10a 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 3(3), Article 4(2) and (3), Article 5(3), Article 8, and Article 9(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(3), Article 4(2) and (3), Article 5(3), Article 8 and Article 9(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 on Better Law-Making of 13 April 2016\*.

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(3), Article 4(2) and (3), Article 5(3), Article 8 and Article 9(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.";

(8) in Article 11, paragraph 2 is deleted;

(9) in Annex A, the 'Note' in point 2 is deleted.

**78. Regulation (EC) No 1166/2008 of the European Parliament and of the Council of 19 November 2008 on farm structure surveys and the survey on agricultural production methods and repealing Council Regulation (EEC) No 571/88<sup>80</sup>**

In order to adapt Regulation (EC) No 1166/2008 to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the list of characteristics set out in Annex III to that Regulation and to supplement that Regulation with coefficients for the livestock units and the definition of the characteristics. 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 on Better Law-Making of 13 April 2016. 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 1166/2008 is amended as follows:

(1) Article 2 is amended as follows:

(a) point (b) is replaced by the following:

"(b) 'livestock unit' means a standard measurement unit that allows the aggregation of the various categories of livestock in order to enable them to be compared. Livestock units are defined on the basis of the feed requirements of the individual animal categories.";

(b) the following second paragraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 14b concerning the coefficients for the individual animal categories referred to in point (b) of the first paragraph.";

(2) Article 7 is amended as follows:

(a) paragraph 2 is replaced by the following:

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<sup>80</sup>

OJ L 321, 1.12.2008, p. 14.

"2. The Commission is empowered to adopt delegated acts in accordance with Article 14b amending the list of characteristics set out in Annex III for the farm structure surveys for 2013 and 2016."

(b) paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 14b concerning the definitions of the characteristics.";

(3) in Article 11, paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 14b concerning the definitions of the characteristics."

(4) the following Article 14b is inserted:

*"Article 14b*  
**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 2, Article 7(2) and (4) and Article 11(7) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 2, Article 7(2) and (4) and Article 11(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 on Better Law-Making of 13 April 2016\*.

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 2, Article 7(2) and (4) and Article 11(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.";

(5) Article 15 is deleted.

**79. Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work<sup>81</sup>**

In order to enhance the application of Regulation (EC) No 1338/2008, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation by laying down the variables, definitions and classifications of the subjects, referred to in Annexes I to V and their breakdown as well as the reference periods, intervals and time limits for the provision of data and the provision of metadata. 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 on Better Law-Making of 13 April 2016. 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 1338/2008 is amended as follows:

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

"2. Whenever the adoption of a delegated act is envisaged in accordance with Article 9a, a cost-benefit analysis, taking into account the benefits of the availability of the data in relation to the cost of the data collection and the burden on Member States, shall be carried out.";

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

"2. Member States shall transmit the data and metadata required by this Regulation in electronic form, in accordance with an interchange standard agreed between the Commission (Eurostat) and the Member States.

The data shall be provided in accordance with the time limits set out, at the intervals provided for, and in respect of the reference periods which are indicated in the Annexes or in delegated acts. The Commission is empowered to adopt such delegated acts in accordance with Article 9a.";

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

"1. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning:

- (a) the characteristics, namely variables, definitions and classifications of the subjects, referred to in Annexes I to V;
- (b) the breakdown of those characteristics;
- (c) the reference periods, intervals and time limits for data provision;
- (d) the provision of metadata.

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<sup>81</sup> OJ L 354, 31.12.2008, p. 70.

Those acts shall take account of, in particular, the provisions of Article 5, Article 6(2) and (3) and Article 7(1), as well as the availability, suitability and the legal context of existing Union data sources after examination of all sources related to the respective domains and subjects.";

(4) the following Article 9a 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 6(2), Article 7(2) and Article 9(1) and in points (c), (d) and (e) of Annexes I, II, III, IV and V shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this omnibus].
3. The delegation of power referred to in Article 6 (2), Article 7(2) and Article 9(1) and in points (c), (d) and (e) of Annexes I, II, III, IV and V 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 on Better Law-Making of 13 April 2016\*.
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), Article 7(2) and Article 9(1) and in points (c), (d) and (e) of Annexes I, II, III, IV and V 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.";

(5) in Article 10, paragraph 2 is deleted;

(6) Annex I is amended as follows:

(a) point (c) is replaced by the following:

*"(c) Reference periods, intervals and time limits for data provision*

Statistics shall be provided every five years from the EHIS; a different frequency may be needed for other data collections, such as those on morbidity or accidents and injuries, as well as for some specific survey modules. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the first reference year, the interval and the time limit for provision of the data.";

(b) in point (d), the second paragraph is replaced by the following:

"Not all subjects are necessarily to be covered at the time of each data provision. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics.";

(c) point (e) is replaced by the following:

*"(e) Metadata*

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the provision of metadata, including metadata concerning characteristics of surveys and other sources used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.";

(7) Annex II is amended as follows:

(a) point (c) is replaced by the following:

*"(c) Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the first reference year, the interval and the time limit for provision of the data.";

(b) in point (d) the fourth paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics.";

(c) point (e) is replaced by the following:

*"(e) Metadata*

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the provision of metadata, including metadata concerning characteristics of sources and compilations used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.";

(8) Annex III is amended as follows:



(a) point (c) is replaced by the following:

*"(c) Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the first reference year. The data shall be submitted no later than 24 months after the end of the reference year. Provisional or estimated data can be provided earlier. In the case of public-health incidents, additional special data collections may be established, either for all deaths or for specific causes of death.";

(b) in fourth paragraph of point (d) is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics.";

(c) point (e) is replaced by the following:

*"(e) Metadata*

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.";

(9) Annex IV is amended as follows:

(a) point (c) is replaced by the following:

*"(c)Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the first reference year. The data shall be submitted no later than 18 months after the end of the reference year.";

(b) in point (d) the fourth paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics.";

(c) point (e) is replaced by the following:

*" (e) Metadata*

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the provision of metadata, including metadata concerning population covered, the declaration rates for accidents at work and, when relevant, sampling characteristics, as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.";

(10) Annex V is amended as follows:

(a) point (c) is replaced by the following:

*"(c) Reference periods, intervals and time limits for data provision*

For occupational diseases, statistics shall be provided annually and submitted no later than 15 months after the end of the reference year. The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the reference periods, the intervals and the time limits for provision of the other data collections.";

(b) in point (d) the fourth paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics.";

(c) point (e) is replaced by the following:

*"(e) Metadata*

The Commission is empowered to adopt delegated acts in accordance with Article 9a concerning the measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.".

#### **80. Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides<sup>82</sup>**

In order to update Regulation (EC) No 1185/2009, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the requirements relating to the provision of the quality reports referred to in Section 6 of Annexes I and II respectively and the list of substances to be covered and their classification in categories of products and chemical classes as set out in Annex III and to supplement that Regulation with a definition of the 'area treated' as referred to in Section 2 of Annex II. 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 on Better Law-Making of 13 April 2016. 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 1185/2009 is amended as follows:

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<sup>82</sup> OJ L 324, 10.10.2009, p 1.

(1) Article 5 is amended as follows:

(a) in paragraph 1, the second subparagraph is deleted;

(b) the following paragraph 1a is inserted:

"1a. The Commission is empowered to adopt delegated acts in accordance with Article 5a amending the requirements relating to the provision of the quality reports referred to in Section 6 of Annexes I and II respectively."

(c) paragraphs 2 and 3 are replaced by the following:

2. The Commission is empowered to adopt delegated acts in accordance with Article 5a supplementing Section 2 of Annex II in respect of the definition of 'area treated'.

3. The Commission is empowered to adopt delegated acts in accordance with Article 5a amending the list of substances to be covered and their classification into categories of products and chemical classes as set out in Annex III on a regular basis and at least every five years.";

(2) the following Article 5a is 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 5(1a), (2) and (3) shall be conferred on the Commission for an indeterminate period of time from [date of the entry into force of this Omnibus].

3. The delegation of power referred to in Article 5(1a), (2) and (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 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 on Better Law-Making of 13 April 2016\*.

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(1a), (2) and (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.";

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

## VIII. FINANCIAL STABILITY, FINANCIAL SERVICES AND CAPITAL MARKETS UNION

### 81. Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards<sup>83</sup>

In order to decide on the applicability within the Union of international accounting standards developed by the International Accounting Standards Board, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Regulation (EC) No 1606/2002. 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 on Better Law-Making of 13 April 2016. 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 1606/2002 is amended as follows:

(1) Article 3 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 5a concerning the applicability within the Union of international accounting standards.

Where, in the case of possible imminent risks to the stability of financial markets, imperative grounds of urgency so require, the procedure provided for in Article 5b shall apply to delegated acts adopted pursuant to this paragraph.";

(b) paragraph 3 is deleted;

(2) the following Articles 5a and 5b 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) shall be conferred on the Commission for an indeterminate period of time [from the entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(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

<sup>83</sup>

OJ L 243, 11.9.2002, p. 1.

by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016\*.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

A delegated act adopted pursuant to Article 3(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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*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.";

(3) Articles 6 and 7 are deleted.

**82. Council Directive 2009/110/EC of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC** <sup>84</sup>

In order to adapt Directive 2009/110/EC to take account of inflation or technological and market developments, and to ensure a convergent application of certain exemptions set out in that Directive, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend 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 on Better Law-Making of 13 April 2016. 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

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<sup>84</sup> OJ L 267, 10.10.2009, p. 7.

have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2009/110/EC is amended as follows:

(1) Article 14 is replaced by the following:

*"Article 14*  
**Delegated acts**

The Commission is empowered to adopt delegated acts in accordance with Article 14a:

- a) amending this Directive in order to take account of inflation or technological and market developments;
- b) amending Article 1(4) and (5) to ensure the convergent application of the exemptions referred to in those provisions.";

(2) the following Article 14a is 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 an indeterminate period of time [from the entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

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\* OJ L 123, 12.5.2016, p. 1.”;

(3) Article 15 is deleted.



## **IX. INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES**

### **83. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers<sup>85</sup>**

In order to take into account new developments in aerosol dispenser technology and ensure a high level of safety, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Directive 75/324/EEC 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 on Better Law-Making of 13 April 2016. 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 75/324/EEC is amended as follows:

- (1) Article 5 is replaced by the following:

#### *"Article 5*

The Commission is empowered to adopt delegated acts in accordance with Article 10a amending the Annex to adapt it to technical progress.";

- (2) Articles 6 and 7 are deleted;

- (3) in Article 10(3), the first subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 10a amending this Directive to ensure necessary technical adaptations concerning the hazard analysis, the technical characteristics of aerosol dispensers, the physical and chemical properties of the contents, the labelling and flammability requirements and test methods and procedures for aerosol dispensers.

- (4) the following Article 10a is 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 5 and Article 10(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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<sup>85</sup> OJ L 147, 9.6.1975, p. 40.

3. The delegation of power referred to in Article 5 and Article 10(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 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 on Better Law-Making of 13 April 2016\*.

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 and Article 10(3) 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."

**84. 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>86</sup>**

In order to adapt Directive 76/211/EC to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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."

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<sup>86</sup> OJ L 46, 21.2.1976, p. 1.

(2) the following Article 6a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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."

**85. Directive 80/181/EEC of the Council of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC<sup>87</sup>**

In order to adapt Directive 80/181/EEC to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to that Directive and to supplement that Directive with supplementary indications. It is of particular importance that the Commission carry out appropriate

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<sup>87</sup> OJ L 39, 15.2.1980, p. 40.

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 on Better Law-Making of 13 April 2016. 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 80/181/EEC is amended as follows:

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

*“Article 6a*

The Commission is empowered to adopt delegated acts in accordance with Article 6c establishing supplementary indications.

The Commission is empowered to adopt delegated acts in accordance with Article 6c amending Chapter I of the Annex to adapt it to technical progress.

(2) the following Article 6c is inserted:

*"Article 6c*

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 6a shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 6a 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 on Better Law-Making of 13 April 2016\*.

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 6a 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."

**86. Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service<sup>88</sup>**

In order to ensure swift technical adaptation of the quality-of-service standards, in particular on routing times and on the regularity and reliability of cross-border services, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to Directive 97/67/EC to adapt them to technical progress and to supplement that Directive with standardised conditions for performance monitoring. 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 on Better Law-Making of 13 April 2016. 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 97/67EC is amended as follows:

(1) in Article 16, the third and fourth paragraphs are replaced by the following:

"Those standards shall be set by:

- (a) the Member States in the case of national services;
- (b) the European Parliament and the Council in the case of intra-Union cross-border services (see Annex II).

The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex II to adapt the standards for intra-Union cross-border services to technical progress or market developments.

Independent performance monitoring shall be carried out at least once a year by external bodies having no links with the universal service providers under standardised conditions and shall be the subject of reports published at least once a year.

The Commission is empowered to adopt delegated acts in accordance with Article 21a specifying such standardised conditions.";

(2) the title of Chapter 8 is replaced by the following:

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<sup>88</sup> OJ L 15, 21.1.1998, p. 14.

"Delegated and implementing acts";

(3) after the title of Chapter 8, the following Article 20a 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 16 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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 21, the second paragraph is deleted.

**87. 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>89</sup>**

In order to adapt Directive 2000/14/EC to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 2000/14/EC is amended as follows:

(1) the following Article 17a is 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 18a shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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

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<sup>89</sup>

OJ L 162, 3.7.2000, p. 1.

European Parliament or of the Council.

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\* OJ L 123, 12. 5. 2016, p.1.";

(2) in Article 18, paragraph 2 is deleted;

(3) 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 17a 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.";

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

**88. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers<sup>90</sup>**

In order to adopt the necessary technical adaptations to Regulation (EC) No 2003/2003, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I to IV to that Regulation for the purpose of adapting and modernising the measuring, sampling and analysis methods and specifying the control measures and to amend Annex I to that Regulation to include new types of fertilisers. 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 on Better Law-Making of 13 April 2016. 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 2003/2003 is amended as follows:

(1) in Article 29, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 31a amending Annexes I to IV for the purpose of adapting and modernising the measuring, sampling and analysis methods and shall, wherever possible, use European standards.

The Commission is also empowered to adopt delegated acts in accordance with Article 31a amending Annexes I to IV for the purpose of specifying the control

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<sup>90</sup> OJ L 304, 21.11.2003, p. 1.



measures provided for in paragraphs 1, 2 and 3 of this Article and in Articles 8, 26 and 27. Such acts shall in particular address the question of the frequency with which tests need to be repeated, as well as measures that are designed to ensure that the fertiliser put on the market is identical with the fertiliser tested.";

(2) Article 31 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 31a amending Annex I to include new types of fertilisers.";

(b) paragraph 4 is deleted;

(3) the following Article 31a is inserted:

*"Article 31a*  
**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 29(4) and Article 31(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 29(4) and Article 31(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 on Better Law-Making of 13 April 2016\*.

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 29(4) and Article 31(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."

**89. 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>91</sup>**

In order to adopt the necessary technical adaptation to Directive 2004/9/EC, the power to adopt acts in accordance with Article 290 of the Treaty 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.

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 on Better Law-Making of 13 April 2016. 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.";

(2) the following Article 6a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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.

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<sup>91</sup> OJ L 50, 20.2.2004, p. 28.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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."

**90. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances<sup>92</sup>**

In order to ensure the necessary technical adaptations to Directive 2004/10/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex I to that Directive in order to adapt it to technical progress with regard to the principles of good laboratory practice, and to amend that Directive in order to introduce necessary technical adaptations. 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 on Better Law-Making of 13 April 2016. 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>92</sup> OJ L 50, 20.2.2004, p. 44.

Accordingly, Directive 2004/10/EC is amended as follows:

(1) Article 3a is replaced by the following:

*"Article 3a*

The Commission is empowered to adopt delegated acts in accordance with Article 3b amending Annex I to adapt it to technical progress, with regard to principles of GLP.";

(2) the following Article 3b is inserted:

*"Article 3b*

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 3a and Article 5(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3a and Article 5(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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 3a and Article 5(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 4 is deleted;

(4) in Article 5(2), the third and fourth subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 3b amending this Directive to introduce necessary technical adaptations."

**91. Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC<sup>93</sup>**

In order to take into account new developments, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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 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.";

(2) 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).";

(3) the following Article 21a 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.

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<sup>93</sup> OJ L 157, 9.6.2006, p. 24.

2. The power to adopt delegated acts referred to in Article 8(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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 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 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)."

## **92. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market**

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In order to ensure swift technical adaptation of Directive 2006/123/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Directive with common criteria and certain time-limits. 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the

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<sup>94</sup> OJ L 376, 27.12.2006, p. 36

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 2006/123/EC is amended as follows:

(1) in Article 23, paragraph 4 is replaced by the following:

"4. For the implementation of paragraph 1, the Commission may, in accordance with the procedure referred to in Article 40(2), establish a list of services which exhibit the characteristics referred to in paragraph 1 of this Article.

The Commission is empowered to adopt delegated acts in accordance with Article 39a establishing common criteria for defining, for the purposes of the insurance or guarantees referred to in paragraph 1 of this Article, what is appropriate to the nature and extent of the risk.";

(2) Article 36 is replaced by the following:

*"Article 36*  
**Delegated and implementing acts**

The Commission is empowered to adopt delegated acts in accordance with Article 39a in order to specify the time-limits provided for in Articles 28 and 35.

The Commission shall also adopt, by means of implementing acts, the practical arrangements for the exchange of information by electronic means between Member States, and in particular the interoperability provisions for information systems. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 40(2).";

(3) the following Article 39a is inserted:

*"Article 39a*  
**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 23(4) and Article 36 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 23(4) and Article 36 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 on Better Law-Making of 13 April 2016\*.

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 23(4) and Article 36 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 40, paragraph 3 is deleted.

**93. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>95</sup>**

The power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend Regulation (EC) No 1907/2006 in order to vary the percentage of dossiers selected for compliance checking and to amend or include further criteria for their selection;
- to amend the Annexes to that Regulation in certain cases;
- to supplement that Regulation with rules on test 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 on Better Law-Making of 13 April 2016. 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 1907/2006 is amended as follows:

(1) in Article 13, paragraphs 2 and 3 are replaced by the following:

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<sup>95</sup> OJ L 396, 30.12.2006, p. 1.



“2. The methods referred to in paragraph 1 shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, amend if appropriate Commission Regulation (EC) No 440/2008\*, and the Annexes to this Regulation, if relevant, so as to replace, reduce or refine animal testing. To that end the Commission is empowered to adopt delegated acts in accordance with Article 131a to amend that Commission Regulation and to amend the Annexes to this Regulation.

3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

The Commission is empowered to adopt delegated acts in accordance with Article 131a laying down test methods.

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

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\* Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142 31.5.2008, p. 1)”;

(2) in Article 41, paragraph 7 is replaced by the following:

“7. The Commission is empowered to adopt delegated acts in accordance with Article 131a, after consulting with the Agency, to vary the percentage of dossiers selected and to amend or include further criteria in paragraph 5.”;

(3) Article 58 is amended as follows:

(a) in paragraph 1, the introductory wording are replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 131a amending Annex XIV to include substances referred to in Article 57. Those acts shall specify for each substance:”;

(b) paragraph 8 is replaced by the following:

“8. The Commission shall adopt delegated acts in accordance with Article 131a amending Annex XIV to remove substances which, as a result of new information, no longer meet the criteria of Article 57.”;

(4) in Article 68, paragraphs 1 and 2 are replaced by the following:

“1. The Commission shall adopt delegated acts in accordance with Article 131a amending Annex XVII in order to introduce new restrictions or adapt current restrictions for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure

set out in Articles 69 to 73, when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of such substances, which needs to be addressed on a Union-wide basis. Any such act shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

2. The Commission is empowered to adopt delegated acts in accordance with Article 131a amending Annex XVII in relation to restrictions on consumer use in respect of a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers. Articles 69 to 73 shall not apply.”;

(5) Article 131 is replaced by the following:

*"Article 131*  
**Amendments to the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 131a amending the Annexes.”;

(6) the following Article 131a is inserted:

*"Article 131a*  
**Exercise of the Delegation**

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

2. The power to adopt delegated acts referred to in Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(9) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(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 on Better Law-Making of 13 April 2016\*.

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(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(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.

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

(7) in Article 133, paragraph 4 is deleted;

(8) Article 138 is amended as follows:

(a) paragraph 5 is deleted;

(b) in paragraph 9, the second sentence is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 131a amending those testing requirements on the basis of that review, while ensuring a high level of protection of health and the environment.”.

#### **94. 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>96</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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.

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;

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<sup>96</sup>

OJ L 106, 28.4.2009, p. 7.

(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 16a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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 17 is deleted.

**95. 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>97</sup>**

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 of the Treaty 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 on Better Law-Making of 13 April 2016<sup>\*</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.

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 13a and 13b are inserted:

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<sup>97</sup> OJ L 146, 10.6.2009, p. 1.

*"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 an indeterminate period of time from the [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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.";

(4) Article 14 is deleted.

**96. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys**<sup>98</sup>

In order to harmonise the safety levels of toys throughout the Union and to remove obstacles to trade in toys between Member States, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend:

- Annex I, points 11 and 13 of Part III of Annex II, and Annex V to Directive 2009/48/EC; to adapt them to technical and scientific developments;
- Appendix C to Annex II to that Directive so as to lay down specific limit values for chemicals used in toys for use by children under 36 months or in other toys intended to be placed in the mouth;
- Appendix A to Annex II to that Directive so as to lay down permitted uses in toys of substances or mixtures classified as carcinogenic, mutagenic or toxic for reproduction of category 1A, 1B or 2 under Regulation (EC) No 1272/2008.

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 on Better Law-Making of 13 April 2016. 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 2009/48/EC is amended as follows:

(1) Article 46 is replaced by the following:

*"Article 46*  
**Amendments to the Annexes**

1. The Commission is empowered to adopt delegated acts in accordance with Article 46a amending Annex I, points 11 and 13 of Part III of Annex II, and Annex V to adapt them to technical and scientific developments.
2. The Commission is empowered to adopt delegated acts in accordance with Article 46a amending Appendix C to Annex II in order to lay down specific limit values for chemicals used in toys for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food.
3. The Commission is empowered to adopt delegated acts in accordance with Article 46a amending Appendix A to Annex II in order to decide upon permitted uses in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of category 1A, 1B or 2 under Regulation

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<sup>98</sup>

OJ L 170, 30.6.2009, p. 1.

(EC) No 1272/2008 and that have been evaluated by the relevant Scientific Committee.";

(2) the following Article 46a is inserted:

*"Article 46a*  
**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 46 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 46 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 on Better Law-Making of 13 April 2016\*.
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 46 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 47 is deleted.

**97. 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>99</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 of the Treaty should be delegated to the Commission to supplement that Regulation with

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<sup>99</sup> OJ L 35, 4.2.2009, p. 32.



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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. 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 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 the light of technical progress concerning:

- (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 12a 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 an indeterminate period of time from the date of entry into force of this Regulation.

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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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.

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

(3) Article 13 is deleted.

**98. 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>100</sup>**

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 of the Treaty 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>101</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

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<sup>100</sup> OJ L 216, 20.8.2009, p. 76

<sup>101</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 L94, 28.3.2014, p.243).

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 on Better Law-Making of 13 April 2016. 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 2009/81/EC is amended as follows:

(1) 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 third subparagraph is inserted:

"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.";

(2) 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.";

(3) the following Articles 66a and 66 b 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 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 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.";

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

**99. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of eco-design requirements for energy-related products<sup>102</sup>**

In order to improve the environmental impact of energy-related products and achieve energy savings, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Directive 2009/125/EC with specific ecodesign requirements for selected environmental aspects which have a significant environmental impact. 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 on Better Law-Making of 13 April 2016. 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 2009/125/EC is amended as follows:

(1) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Where a product meets the criteria listed in paragraph 2, it shall be covered by a delegated act or by a self-regulation measure in accordance with paragraph 3(b).

The Commission is empowered to adopt such delegated acts in accordance with Article 18a.";

(b) paragraph 3 is replaced by the following

"3. In preparing a delegated act the Commission shall take into account:

(a) Union environmental priorities, such as those set out in Decision No 1600/2002/EC or in the Commission's European Climate Change Programme (ECCP);

(b) relevant Union legislation and self-regulation, such as voluntary agreements, which, following an assessment in accordance with Article 17, are expected to achieve the policy objectives more quickly or at lesser expense than mandatory requirements.";

(c) paragraph 10 is replaced by the following:

"10. Where appropriate a delegated act laying down ecodesign requirements shall include provisions on the balancing of various environmental aspects.";

(2) in Article 16(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt those measures by delegated acts in accordance with Article 18a.";

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<sup>102</sup>

OJ L 285, 31.10.2009, p. 10.

(3) the following Article 18a is inserted:

*"Article 18a*  
**Delegated acts**

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(1) and Article 16(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 15(1) and Article 16(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 on Better Law-Making of 13 April 2016\*.
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(1) and Article 16(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.";

(6) in Article 19, the third paragraph is deleted.

**100. Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefore<sup>103</sup>**

In order to adapt Regulation (EC) No 661/2009 to technical progress the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend certain limit values and Annex IV and to supplement that Regulation with technical requirements for motor vehicles, systems, components and separate technical units, 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. 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) 661/2009 is amended as follows:

(1) the title of Chapter IV is replaced by the following:

"Delegation of powers";

(2) Article 14 is replaced by the following:

*“Article 14*  
**Delegated powers**

The Commission is empowered to adopt delegated acts in accordance with Article 14a required in the light of technical progress in respect of:

- (a) detailed rules concerning the specific procedures, tests and technical requirements for the type-approval of motor vehicles, their trailers and components and separate technical units with regard to the provisions of Articles 5 to 12;
- (b) detailed rules concerning specific safety requirements for vehicles intended for the transport of dangerous goods by road within or between Member States, taking account of UNECE Regulation 105;
- (c) a more precise definition of the physical characteristics and performance requirements a tyre must fulfil to be defined as ‘special use tyre’, ‘off-road professional tyre’, ‘reinforced tyre’, ‘extra load tyre’, ‘snow tyre’, ‘T-type temporary-use spare tyre’ or ‘traction tyre’ in accordance with points 8 to 13 of the second paragraph of Article 3;
- (d) measures amending the limit values on rolling resistance and rolling noise laid down in Parts B and C of Annex II insofar as is necessary as a result of

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<sup>103</sup> OJ L 200, 31.7.2009, p. 1.

- changes in test procedures and without lowering the level of protection of the environment;
- (e) detailed rules on the procedure for the determination of the noise levels referred to in point 1 of Part C of Annex II;
  - (f) measures amending Annex IV to include the UNECE Regulations that are mandatory under Article 4(4) of Decision 97/836/EC;
  - (g) administrative provisions concerning the specific procedures, tests and technical requirements for the type-approval of motor vehicles, their trailers and components and separate technical units with regard to the provisions of Articles 5 to 12;
  - (h) measures exempting certain vehicles or classes of vehicles of categories M2, M3, N2 and N3 from the obligation to install advanced vehicle systems referred to in Article 10 where, following a cost/benefit analysis and taking into account all relevant safety aspects, the application of those systems proves not to be appropriate to the vehicle or class of vehicles concerned;
  - (i) other measures necessary for the application of this Regulation.";

(2) the following Article 14a is 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 an indeterminate period of time from the date of entry into force of this Regulation.
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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 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 15 is deleted.

**101. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products<sup>104</sup>**

In order to ensure that Regulation (EU) No 1223/2009 is adapted to technical and scientific progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the definition of nanomaterials in that Regulation;
- to amend that Regulation in respect of notification requirements;
- to amend that Regulation to extend the scope of Annex IV to hair colouring products;
- to amend the Annexes to that Regulation in relation to substances that are carcinogenic, mutagenic or toxic for reproduction;
- to amend the notification information in that Regulation and to amend Annexes II and III in relation to nanomaterials;
- to amend Annexes II to VI to that Regulation where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Union-wide basis;
- to amend Annexes III to VI and VIII to that Regulation for the purpose of adapting them to technical and scientific progress;
- to supplement that Regulation with a list of common criteria for claims.

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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of the relevant provisions of Regulation (EC) No 1223/2009 concerning derogations in relation to animal testing, implementing powers should be conferred on the Commission to adopt decisions authorising derogations from the prohibition on animal testing. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EU) No 1223/2009 is amended as follows:

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<sup>104</sup> OJ L 342, 22.12.2009, p. 59.

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

“3. In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission is empowered to adopt delegated acts in accordance with Article 31a amending paragraph 1(k) to adjust and adapt that point to technical and scientific progress and to definitions subsequently agreed at international level.”;

(2) in Article 13, paragraph 8 is replaced by the following:

“8. The Commission is empowered to adopt delegated acts in accordance with Article 31a amending paragraphs 1 to 7 of this Article by adding requirements, taking into account technical and scientific progress and specific needs related to market surveillance.”;

(3) in Article 14, paragraph 2 is replaced by the following:

“2. Subject to a decision of the Commission to extend the scope of Annex IV to hair colouring products, such products shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair which are listed there but not used in accordance with the conditions laid down in that Annex.

To adopt the decision referred to in the first subparagraph, the Commission is empowered to adopt delegated acts in accordance with Article 31a amending Annex IV.”;

(4) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

“1. The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

For the purposes of this paragraph the Commission is empowered to adopt delegated acts in accordance with Article 31a amending the Annexes to this Regulation.”;

(b) in paragraph 2, the fourth and fifth subparagraphs are replaced by the following:

“For the purposes of this paragraph, the Commission shall adopt delegated acts in accordance with Article 31a amending the Annexes to this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Where, in case of risk to human health arising from the use of substances in cosmetic products, imperative grounds of urgency so require, the procedure

provided for in Article 31b shall apply to delegated acts adopted pursuant to this Article .";

(5) Article 16 is amended as follows:

(a) paragraphs 6 and 7 are replaced by the following:

"6. The Commission is empowered to adopt delegated acts in accordance with Article 31a amending Annexes II and III, taking into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data.

7. The Commission is empowered to adopt delegated acts in accordance with Article 31a amending paragraph 3 by adding requirements, taking into account technical and scientific progress.";

(b) paragraph 8 is deleted;

(c) paragraph 9 is replaced by the following:

"9. Where, in case of risk to human health arising from the use of substances in cosmetic products, imperative grounds of urgency so require, the procedure provided for in Article 31b shall apply to delegated acts adopted pursuant to paragraphs 6 and 7.";

(6) in Article 18(2), the ninth subparagraph is replaced by the following:

"The measures referred to in the sixth subparagraph shall be adopted by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 32(2).";

(7) in Article 20(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 31a establishing a list of common criteria for claims which may be used in respect of cosmetic products, after consulting the SCCS or other relevant authorities and taking into account the provisions of Directive 2005/29/EC.";

(8) Article 31 is replaced by the following:

*"Article 31*  
**Amendment of the Annexes**

1. The Commission is empowered to adopt delegated acts in accordance with Article 31a, after consulting the SCCS, amending Annexes II to VI where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Union-wide basis.

Where, in case of a potential risk to human health arising from the use of substances in cosmetic products, imperative grounds of urgency so require, the procedure provided for in Article 31b shall apply to delegated acts adopted pursuant this paragraph.

2. The Commission is empowered to adopt delegated acts in accordance with Article 31a, after consulting the SCCS, amending Annexes III to VI and VIII for the purposes of adapting them to technical and scientific progress.

3. The Commission is empowered to adopt delegated acts in accordance with Article 31a, after consulting the SCCS, amending Annex I where it appears necessary, in order to ensure the safety of cosmetic products placed on the market.";

(9) the following Articles 31a and 31b are inserted:

*"Article 31a*

**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 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), Article 20(2) and Article 31(1), (2) and (3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16(8) and (9), Article 20(2) and Article 31(1), (2) and (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 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 on Better Law-Making of 13 April 2016\*.

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 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), Article 20(2) and Article 31(1), (2) and (3) 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 31b*

**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 31a(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) in Article 32, paragraphs 3 and 4 are deleted.

## X. JUSTICE AND CONSUMERS

### 102. 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>105</sup>

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 of the Treaty should be delegated to the Commission to amend Annex I to Directive 92/85/EEC in a technical way. 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and 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 92/85/EEC is amended as follows:

(1) in Article 13, paragraph 1 is replaced by the following:

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

Where, in the case of possible imminent risks to the health or safety of pregnant workers, workers who have recently given birth or breastfeeding workers, imperative grounds of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this paragraph.";

(2) the following Articles 13a and 13b 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(1) shall be conferred on the Commission for an indeterminate period of time from [date of the entry into force of this Omnibus].

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<sup>105</sup> OJ L 348, 28.11.1992, p. 1.

3. The delegation of power referred to in Article 13(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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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) 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.

#### *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.

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."

**103. 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/EC<sup>106</sup>**

In order to update Directive 2008/48/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Directive to add additional assumptions for the calculation of the annual percentage rate 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 on Better Law-Making of 13 April 2016. 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 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 the 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 the 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 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 24a 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 an indeterminate period of time from [the entry into force of this Omnibus].

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*

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<sup>106</sup> OJ L 133, 22.5.2008, p. 66.



*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 on Better Law-Making of 13 April 2016\*.

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 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 25 is deleted.

## **XI. MOBILITY AND TRANSPORT**

### **104. Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation<sup>107</sup>**

In order to adapt Regulation (EEC) No 3922/91 to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex 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 on Better Law-Making of 13 April 2016. 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 (EEC) No 3922/91 is amended as follows:

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

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

Where imperative grounds of urgency so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this paragraph.";

(2) the following Articles 11a and 11b 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(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 11(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.

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<sup>107</sup> OJ L 373, 31.12.1991, p. 4.

4. Before the adoption of a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016\*.

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(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 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 12b(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 the Council.

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

(3) in Article 12, paragraphs 3 and 4 are deleted.

#### **105. Council Directive 95/50/EC of 6 October 1995 on uniform procedures for checks on the transport of dangerous goods by road<sup>108</sup>**

In order to adapt Directive 95/50/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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>109</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 on Better Law-Making of 13 April 2016. 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

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<sup>108</sup> OJ L 249, 17.10.1995, p. 35.

<sup>109</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).

have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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 9aa 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**106. Council Directive 97/70/EC of 11 December 1997 setting up a harmonised safety regime for fishing vessels of 24 meters in length and over<sup>110</sup>**

In order to adapt Directive 97/70/EC to the evolution of international law, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Directive in order to apply subsequent amendments to the Torremolinos Protocol. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Directive 97/70/EC, implementing powers should be conferred on the Commission to adopt provisions for a harmonised interpretation of those provisions of the Annex to the Torremolinos Protocol which have been left to the discretion of the administrations of individual contracting parties, as far as necessary to ensure their consistent implementation in the Union. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Directive 97/70/EC is amended as follows:

(1) Article 8 is replaced by the following:

*"Article 8*  
**Delegated and implementing acts**

1. The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Articles 2, 3, 4, 6 and 7 and the Annexes in order to apply, for the purposes of this Directive, subsequent amendments to the Torremolinos Protocol.

2. The Commission may establish a harmonised interpretation of those provisions of the Annex to the Torremolinos Protocol which have been left to the discretion of the administrations of individual contracting parties, as far as necessary to ensure their consistent implementation in the Union, by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 9(2).

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<sup>110</sup> OJ L 34, 9.2.1998, p. 1.

3. The amendments to the international instrument referred to in Article 2(4) may be excluded from the scope of this Directive, pursuant to Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council\*.

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\* 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 (OJ L 324, 29.11.2002, p. 1).";

(2) the following Article 8a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**107. Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residue<sup>111</sup>**

In order to improve the regime established by Directive 2000/59/EC and to adapt that Directive to the evolution of other Union and international instruments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend that Directive in order to adapt the references to Union and IMO instruments to bring them into line with Union or IMO measures which have entered into force;
- 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 on Better Law-Making of 13 April 2016. 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 2000/59/EC is amended as follows:

(1) the following Article 13a is 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 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.

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<sup>111</sup> OJ L 332, 28.12.2000, p. 81.

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 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) Article 14 is deleted;

(3) Article 15 is replaced by the following:

*"Article 15*  
**Amendments**

1. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending the references to Union and IMO instruments in this Directive in order to bring them in line with Union or IMO measures which have entered into force, in so far as such amendments do not broaden the scope of this Directive.
2. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending the Annexes where necessary in order to improve the regime established by this Directive, in so far as such amendments do not broaden the scope of this Directive.
3. The amendments to the international instruments referred to in Article 2 may be excluded from the scope of this Directive pursuant to Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council\*.

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\* 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 (OJ L 324, 29.11.2002, p. 1)."



**108. Directive 2001/96/EC of the European Parliament and of the Council of 4 December 2001 establishing harmonised requirements and procedures for the safe loading and unloading of bulk carriers<sup>112</sup>**

In order to adapt Directive 2001/96/EC to the evolution of Union and international rules and to improve the applicable procedures, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Directive in respect of:

- certain definitions;
- the references to international conventions and codes and to IMO Resolutions and Circulars, the references to ISO standards and the references to Union instruments and the Annexes thereto;
- the procedures between bulk carriers and terminals;
- certain reporting obligations.

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 on Better Law-Making of 13 April 2016. 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 2001/96/EC is amended as follows:

- (1) Article 14 is deleted;
- (2) Article 15 is replaced by the following:

*"Article 15*  
**Amendments**

1. The Commission is empowered to adopt delegated acts in accordance with Article 15a amending the definitions set out in points (1) to (6) and (15) to (18) of Article 3, the references to international conventions and codes and to IMO Resolutions and Circulars, the references to ISO standards and the references to Union instruments in order to bring them into line with international and Union instruments which have been adopted, amended or brought into force after the adoption of this Directive, provided that the scope of this Directive is not thereby broadened.

2. The Commission is empowered to adopt delegated acts in accordance with Article 15a amending Article 8 concerning the procedures between bulk carriers and terminals, the reporting obligations referred to in Article 11(2), and the Annexes, provided that such acts do not broaden the scope of this Directive.

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<sup>112</sup> OJ L 13, 16.1.2002, p. 9.

3. The amendments to the international instruments referred to in Article 3 may be excluded from the scope of this Directive, pursuant to Article 5 of Regulation (EC) No 2099/2002.

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

(3) the following Article 15a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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 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.";

**109. 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>113</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 of the Treaty should be delegated to the Commission to amend:

- the references to Union and 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.

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 on Better Law-Making of 13 April 2016. 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. 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, in so far as such amendments do not broaden the scope of this Directive.
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, in so far as such amendments do not broaden its scope.";

(2) the following Article 27a is inserted:

*"Article 27a*  
**Exercise of the delegation**

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<sup>113</sup> OJ L 208, 5.8.2002, p. 10.

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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

**110. 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>114</sup>**

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 of the Treaty 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

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<sup>114</sup> OJ L 324, 29.11.2002, p. 1.

laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 Article 2(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 7a 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 an indeterminate period of time from [date of the entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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."

#### **111. 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>115</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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 International Maritime Organisation (IMO), and to improve the effectiveness of this Directive in the light of experience and technical progress.";

(2) the following Article 10a is inserted:

*"Article 10a*  
**Exercise of the delegation**

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<sup>115</sup> OJ L 123, 17.5.2003, p. 22.

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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**112. 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>116</sup>**

In order to adapt Directive 2003/59/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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,

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<sup>116</sup> OJ L 226, 10.9.2003, p. 4.

including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 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 11a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

**113. Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships<sup>117</sup>**

In order to further develop the control of harmful anti-fouling systems on ships, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the references to the AFS-Convention, the AFS-Certificate, the AFS-Declaration and the AFS-Statement of Compliance in Regulation (EC) No 782/2003;
- to amend the Annexes to that Regulation, including relevant IMO guidelines in relation to Article 11 of the AFS-Convention in order to take account of developments at international level and in particular in the International Maritime Organisation (IMO), or to improve the effectiveness of that Regulation in the light of experience;
- to supplement that Regulation with a harmonised survey and certification regime for certain ships.

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 on Better Law-Making of 13 April 2016. 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 782/2003 is amended as follows:

(1) Article 6 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (b) is replaced by the following:

" (b) Ships of 24 metres or more in length, but less than 400 gross tonnage, excluding fixed or floating platforms, FSUs and FPSOs, shall carry an AFS-Declaration to demonstrate compliance with Articles 4 and 5.";

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<sup>117</sup> OJ L 115, 9.5.2003, p. 1.

(ii) the following second subparagraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 8a concerning the establishment of a harmonised survey and certification regime for the ships referred to in point (b) of this paragraph, if necessary.";

(b) paragraph 3 is deleted;

(2) in Article 7, the second paragraph is deleted;

(3) Article 8 is replaced by the following:

*"Article 8*  
**Amendments**

The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the references to the AFS-Convention, the AFS-Certificate, the AFS-Declaration and the AFS-Statement of Compliance, and the Annexes to this Regulation, including relevant IMO guidelines in relation to Article 11 of the AFS-Convention in order to take account of developments at international level and in particular in the International Maritime Organisation (IMO), or to improve the effectiveness of this Regulation in the light of experience.";

(4) the following Article 8a 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(1) and Article 8 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 6(1) 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 on Better Law-Making of 13 April 2016\*.
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(1) 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 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.";

(5) Article 9 is deleted.

#### **114. Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community<sup>118</sup>**

In order to adapt and further develop certain technical specifications of electronic road toll systems, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend the Annex to Directive 2004/52/EC to adapt it to technical progress;
- to supplement that Directive with decisions relating to the definition of the European electronic toll service and technical decisions relating to the realisation of that service.

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 on Better Law-Making of 13 April 2016. 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 2004/52/EC is amended as follows:

(1) Article 4 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 4a amending the Annex in order to adapt it to technical progress.";

(b) paragraphs 4 and 5 are replaced by the following:

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<sup>118</sup> OJ L 166, 30.4.2004, p. 124.

"4. The Commission is empowered to adopt delegated acts in accordance with Article 4a concerning the definition of the European electronic toll service. Such acts shall only be adopted if all the conditions, evaluated on the basis of appropriate studies, are in place to enable interoperability to work from all points of view, including technical, legal and commercial conditions.

5. The Commission is empowered to adopt delegated acts in accordance with Article 4a concerning technical decisions relating to the realisation of the European electronic toll service.";

(2) the following Article 4a is inserted:

*"Article 4a*  
**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(2), (4) and (5) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2), (4) and (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 on Better Law-Making of 13 April 2016\*.

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(2), (4) and (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 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 5, paragraph 2 is deleted.

**115. Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the trans-European road network<sup>119</sup>**

In order to adapt Directive 2004/54/EC to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 2004/54/EC is amended as follows:

(1) Article 16 is replaced by the following:

*"Article 16*  
**Amendment of Annexes**

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

(2) the following Article 16a is inserted:

*"Article 16a*  
**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 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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.

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<sup>119</sup> OJ L 167, 30.4.2004, p. 39.

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 on Better Law-Making of 13 April 2016\*.

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 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 17, paragraph 3 is deleted.

#### **116. Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security<sup>120</sup>**

In order to adapt Regulation (EC) No 725/2004 to the evolution of international law, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Regulation in order to integrate the amendments to certain international instruments. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 725/2004 implementing powers should be conferred on the Commission in order to define harmonised procedures for the application of the mandatory provisions of the ISPS Code, without broadening the scope of that Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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

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<sup>120</sup> OJ L 129, 29.4.2004, p. 6.

(1) in Article 10, paragraphs 2 and 3 are replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 10a amending this Regulation in order to integrate the amendments to the international instruments referred to in Article 2 in respect of ships operating domestic services and the port facilities serving them to which this Regulation applies, in so far as they constitute a technical update of the provisions of the SOLAS Convention and the ISPS Code.

Where, in the case of the measures referred to in previous subparagraph , imperative grounds of urgency so require, the procedure provided for in Article 10b shall apply to delegated acts adopted pursuant to this paragraph. The procedure for checking conformity established in paragraph 5 of this Article shall not apply in these cases.

3. The Commission shall establish harmonised procedures for the application of the mandatory provisions of the ISPS Code, without broadening the scope of this Regulation. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 11(2).";

(2) the following Articles 10a and 10b 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(2) shall be conferred on the Commission for an indeterminate period of time from [date of the entry into force of this Omnibus].

3. The delegation of power referred to in Article 10(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 on Better Law-Making of 13 April 2016\*.

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(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.

*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 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 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) in Article 11, paragraphs 4 and 5 are deleted.

**117. 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>121</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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:

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<sup>121</sup> OJ L 138, 30.4.2004, p. 1.



"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 8a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**118. 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>122</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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. 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 International Maritime Organisation (IMO), and to improve the effectiveness of this Regulation in the light of experience and technical progress, insofar as such amendments do not broaden the scope of this Regulation.";

(3) the following Article 9a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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*

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<sup>122</sup>

OJ L 138, 30.4.2004, p. 19.

*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 on Better Law-Making of 13 April 2016\*.

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."

**119. Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community<sup>123</sup>**

In order to improve the detection of unfair pricing practices, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement Regulation (EC) No 868/2004 with a detailed methodology for determining the existence of unfair pricing practices. 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 on Better Law-Making of 13 April 2016. 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 868/2004 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 14a concerning a detailed methodology for determining the existence of unfair pricing practices. This methodology shall cover, *inter alia*, the manner in which normal competitive pricing, actual costs and reasonable profit margins are to be assessed in the specific context of the aviation sector.";

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<sup>123</sup> OJ L 162, 30.4.2004, p. 1.

(2) the following Article 14a is 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 5(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 5(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 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 on Better Law-Making of 13 April 2016\*.
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) 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 15, paragraph 4 is deleted.

**120. 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>124</sup>**

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 of the Treaty 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

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<sup>124</sup> OJ L 255, 30.9.2005, p. 152.

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 on Better Law-Making of 13 April 2016. 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 10a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

## **121. Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security<sup>125</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 2005/65/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 the 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 14a and 14b 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.

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<sup>125</sup> OJ L 310, 25.11.2005, p. 28.

2. The power to adopt delegated acts referred to in Article 14 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

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.

**122. 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>126</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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 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 paragraph 1, 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 14a and 14b are inserted:

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<sup>126</sup> OJ L 344, 27.12.2005, p. 15.



*"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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.
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.

**123. Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences<sup>127</sup>**

In order to reinforce the necessary measures guaranteeing the security of driving licences, to guarantee future interoperability and to adapt Directive 2006/126/EC to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I to VI to that Directive and to supplement that Directive with specifications to secure against forgery.

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 on Better Law-Making of 13 April 2016. 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 2006/126/EC is amended as follows:

(1) Article 1 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 8a concerning requirements for the microchip referred to in Annex I. Those requirements shall provide for EC type-approval, which shall only be granted when the ability to resist attempts to tamper with or alter data is demonstrated.

Without prejudice to data protection rules, Member States may introduce a storage medium (microchip) as part of the driving licence, as soon as those delegated acts are in force.";

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

"The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Annex I in order to guarantee future interoperability.";

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

"2. The material used for the driving licence, as set out in Annex I, shall be made secure against forgery.

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<sup>127</sup> OJ L 403, 30.12.2006, p. 18.

The Commission is empowered to adopt delegated acts in accordance with Article 8a in order to establish appropriate anti-forgery specifications.

Member States are free to introduce additional security features.";

(3) Article 8 is replaced by the following:

*"Article 8*  
**Amendment of Annexes I to VI**

The Commission is empowered to adopt delegated acts in accordance with Article 8a amending Annexes I to VI in order to adapt them to scientific and technical progress.";

(4) the following Article 8a 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 1(2) and (3), Article 3(2) and Article 8 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 1(2) and (3), 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 on Better Law-Making of 13 April 2016\*.
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 1(2) and (3), 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 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.";

(5) Article 9 is deleted.

**124. 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>128</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 336/2006 is amended as follows:

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

"2. 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 International Maritime Organisation (IMO), or to improve the effectiveness of this Regulation in the light of the experience gained in its implementation.";

(2) the following Article 11a 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.

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<sup>128</sup> OJ L 64, 4.3.2006, p. 1.

2. The power to adopt delegated acts referred to in Article 11(2) shall be conferred on the Commission for an indeterminate period of time from [the date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**125. Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community<sup>129</sup>.**

In order to adopt the necessary technical measures for the proper functioning of Directive 2007/59/EC and to adapt it to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Directive so as to adapt them to scientific and technical progress, as well as to supplement that Directive:

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<sup>129</sup> OJ L 315, 3.12.2007, p. 51.

- establishing the model for the licence, the certificate and the certified copy of the certificate, and by determining their physical characteristics, taking into account therein anti-forgery measures;
- by adopting the Community Codes for the different types in categories A and B;
- by adapting basic parameters of registers to progress;
- by adopting the common criteria for defining vocational competences and assessing staff;
- by adopting Union criteria on the choice of examiners and examinations;
- by adopting technical and operating specifications for smartcards.

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 on Better Law-Making of 13 April 2016. 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 2007/59/EC is amended as follows:

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

"4. The Commission is empowered to adopt delegated acts in accordance with Article 31a establishing, on the basis of a draft prepared by the Agency, a Community model for the licence, the certificate and the certified copy of the certificate, and to determine their physical characteristics, taking into account therein anti-forgery measures.

The Commission is empowered to adopt delegated acts in accordance with Article 31a establishing, on the basis of a recommendation prepared by the Agency, the Community Codes for the different types in categories A and B as referred to in paragraph 3 of this Article. ";

(2) in Article 22(4), the second subparagraph is replaced by the following:

"To this end, the Commission is empowered to adopt delegated acts in accordance with Article 31a establishing, on the basis of a draft prepared by the Agency, the basic parameters of the registers to be set up, such as data to be recorded, their format and the data exchange protocol, access rights, the duration of data retention and the procedures to be followed in cases of bankruptcy. ";

(3) Article 23(3) is amended as follows:

(a) point (b) is replaced by the following:

"(b) the criteria proposed by the Agency pursuant to Article 36 of Regulation (EU) 2016/796.";

(b) the following second subparagraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 31a in order to establish those criteria.";

(4) in Article 25, paragraph 5 is replaced by the following:

"5. The choice of examiners and examinations may be subject to Union criteria. The Commission is empowered to adopt delegated acts in accordance with Article 31a establishing such Union criteria on the basis of a draft prepared by the Agency.

Where, in the case of establishing the Union criteria for the choice of examiners and examinations, imperative grounds of urgency so require, the procedure provided for in Article 31b shall apply to delegated acts adopted pursuant to this Article.

In the absence of such Union criteria, the competent authorities shall establish national criteria.";

(5) in Article 31, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 31a, amending the Annexes in order to adapt them to scientific and technical progress.

Where, in the case of Annexes to be adapted to scientific and technical progress, imperative grounds of urgency so require, the procedure provided for in Article 31b shall apply to delegated acts adopted pursuant to this Article.";

(6) the following Articles 31a and 32b are inserted:

*"Article 31a*

**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(4), Article 22(4), Article 23(3), Article 25(5), Article 31(1) and Article 34 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(4), Article 22(4), Article 23(3), Article 25(5), Article 31(1) and Article 34 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 on Better Law-Making of 13 April 2016\*.

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(4), Article 22(4), Article 23(3), Article 25(5), Article 31(1) and Article 34 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 31b*

#### **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 31a(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) in Article 32, paragraphs 3 and 4 are deleted;

(8) in Article 34, the second paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 31a laying down the technical and operating specifications for such a smartcard."



**126. Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations<sup>130</sup>**

In order to adopt the necessary measures to adapt Regulation (EC) No 1371/2007 to technical progress and the experience gained in its implementation the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend Annexes II and III to that Regulation;
- to amend that Regulation by adjusting the financial amounts in accordance with inflation;
- to supplement that Regulation by taking appropriate action if the exemptions granted by Member States are deemed not to be in accordance with the provisions of Article 2;
- to supplement that Regulation by adopting technical specifications for interoperability of telematics applications for passengers;
- to supplement that Regulation by adopting the measures to ensure that railway undertakings are adequately insured or make equivalent arrangements for cover of their liabilities under 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 on Better Law-Making of 13 April 2016. 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 1371/2007 is amended as follows:

(1) Articles 33 and 34 are replaced by the following:

*"Article 33*  
**Amendment of Annexes II and III**

The Commission is empowered to adopt delegated acts in accordance with Article 34a amending Annexes II and III in the light of experience gained in the implementation of the Regulation.

*Article 34*  
**Delegated acts**

1. The Commission is empowered to adopt delegated acts in accordance with Article 34a concerning the measures referred to in Articles 2, 10 and 12.
2. The Commission is empowered to adopt delegated acts in accordance with Article 34a to amend this Regulation by adjusting the financial amounts referred to therein, other than in Annex I, in light of inflation.";

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<sup>130</sup> OJ L 315, 3.12.2007, p. 14.

(2) the following Article 34a is inserted:

*Article 34a*  
**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 33 and Article 34 shall be conferred on the Commission for an indeterminate period of time from [the date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 33 and Article 34 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 on Better Law-Making of 13 April 2016\*.
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 33 and Article 34 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 35 is deleted.

**127. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods<sup>131</sup>**

In order to adapt Directive 2008/68/EC to technical and scientific progress, the power to adopt acts in accordance with Article 290 of the Treaty 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

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<sup>131</sup> OJ L 260, 30.9.2008, p. 13.

laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 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 adapt them to scientific and technical progress, including the use of technologies for tracking and tracing, in the fields covered by this Directive, in particular to take account of amendments to the ADR, RID and ADN.";

(2) the following Article 8a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**128. Directive 2008/96/EC of the European Parliament and of the Council of 19 November 2008 on road infrastructure safety management<sup>132</sup>**

In order to adapt Directive 2008/96/EC to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Directive and to supplement that Directive by determining common criteria on reporting accident severity.

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 on Better Law-Making of 13 April 2016. 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 2008/96/EC is amended as follows:

(1) in Article 7, the following paragraph 1a is inserted:

"1a. The Commission is empowered to adopt delegated acts in accordance with Article 12a determining common criteria according to which accident severity, including number of fatalities and injured persons, is to be reported.";

(2) in Article 11, paragraph 2 is deleted;

(3) Article 12 is replaced by the following:

*"Article 12*  
**Amendment of Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 12a amending the Annexes in order to adapt them to technical progress.";

(4) the following Article 12a is inserted:

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<sup>132</sup> OJ L 319, 29.11.2008, p. 59.

*"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 7(1a) and Article 12 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 7(1a) 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 on Better Law-Making of 13 April 2016\*.
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(1a) and Article 12 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.";

(5) Article 13 is deleted;

(6) in Annex IV, point (5) is replaced by the following:

"(5) accident severity".

**129. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002<sup>133</sup>**

In order to improve the content and functioning of the common basic standards for safeguarding civil aviation against acts of unlawful interference that jeopardise the security of civil aviation, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend Regulation (EC) No 300/2008 by adopting an additional annex related to the specifications for the national quality control programme
- to supplement that Regulation with general measures relating to certain elements of the common basic standards;
- to supplement that Regulation with criteria to allow Member States to derogate from the common basic standards.

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 on Better Law-Making of 13 April 2016. 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 300/2008 is amended as follows:

(1) Article 4 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) the first subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 18a laying down certain elements of the common basic standards.";

(ii) the third subparagraph is replaced by the following:

"Where, in case of adopting general measures relating to certain common basic standards, imperative grounds of urgency so require, the procedure provided for in Article 18b shall apply to delegated acts adopted pursuant to this Article.";

(b) in paragraph 4, the first and second subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 18a setting criteria to allow Member States to derogate from the common

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<sup>133</sup>

OJ L 97, 9.4.2008, p. 72.

basic standards referred to in paragraph 1 and to adopt alternative security measures that provide an adequate level of protection on the basis of a local risk assessment. Such alternative measures shall be justified by reasons relating to the size of the aircraft, or by reasons relating to the nature, scale or frequency of operations or of other relevant activities.

Where, in the case of setting criteria to allow Member States to derogate from the common basic standards, imperative grounds of urgency so require, the procedure provided for in Article 18b shall apply to delegated acts adopted pursuant to this paragraph.";

(2) in Article 11(2), the first and second subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 18a amending this Regulation by adding an Annex related to the specifications for the national quality control programme.

Where , in the case of specifications for the national quality control programmes, imperative grounds of urgency so require, the procedure provided for in Article 18b shall apply to delegated acts adopted pursuant to this paragraph.";

(3) the following Articles 18a and 18b are 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 4(2) and (4) and Article 11(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2) and (4) and 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 on the *Official Journal of the European Union* or at a later date specified in 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 Inter-institutional Agreement on Better Law Making of 13 April 2016\*.

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(2) and (4) and 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.

*Article 18b*  
**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 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.";

(4) in Article 19, paragraphs 3 and 4 are deleted.

**130. 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>134</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 of the Treaty 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.

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 on Better Law-Making of 13 April 2016. 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>134</sup> OJ L 131, 28.5.2009, p. 47.



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

(1) the following Article 5a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 points (ii) and (iii) of Article 5(2)(b).".

**131. Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 establishing the fundamental principles governing the investigation of accidents in the maritime transport sector and amending Council Directive 1999/35/EC and Directive 2002/59/EC of the European Parliament and of the Council<sup>135</sup>**

In order to adapt Directive 2009/18/EC to the evolution of Union and international rules, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission:

- to amend that Directive in order to update definitions and references made to Union acts and to IMO instruments in order to bring them into line with Union or IMO measures which have entered into force;
- to amend the Annexes to that Directive in order to adapt them to technical progress and experience gained in their implementation;
- to supplement that Directive with the common methodology for investigating marine casualties and incidents.

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 on Better Law-Making of 13 April 2016. 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 2009/18/EC is amended as follows:

(1) in Article 5, paragraph 4 is replaced by the following:

"4. When carrying out safety investigations, the investigative body shall follow the common methodology for investigating marine casualties and incidents. Investigators may depart from that methodology in a specific case where this can be justified as necessary, in their professional judgement, and if needed to achieve the aims of the investigation.

The Commission is empowered to adopt delegated acts in accordance with Article 18a concerning the common methodology for investigating marine casualties and incidents taking into account any relevant lessons drawn from safety investigations.";

(2) the following Article 18a is inserted:

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<sup>135</sup> OJ L 131, 28.5.2009, p. 114.

*"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 5(4) and Article 20 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 5(4) and Article 20 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 on Better Law-Making of 13 April 2016\*.
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(4) and Article 20 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 19, paragraph 3 is deleted;

(4) Article 20 is replaced by the following:

*"Article 20*

**Amending powers**

1. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending definitions in this Directive and references made to Union acts and to IMO instruments in order to bring them into line with Union or IMO

measures which have entered into force, subject to observance of the limits of this Directive.

2. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes to this Directive in order to adapt them to technical progress and experience gained in their implementation.

3. Amendments to the IMO Code for the Investigation of Marine Casualties and Incidents may be excluded from the scope of this Directive pursuant to Article 5 of Regulation (EC) No 2099/2002."

### **132. Directive 2009/33/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of clean and energy-efficient road transport vehicles<sup>136</sup>**

In order to adapt Directive 2009/33/EC to inflation and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to that Directive so as to adapt the data for the calculation of the operational lifetime costs of road transport vehicles. 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 on Better Law-Making of 13 April 2016. 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 2009/33/EC is amended as follows:

(1) Article 7 is replaced by the following:

#### *"Article 7* **Amendment of the Annex**

The Commission is empowered to adopt delegated acts in accordance with Article 8a amending the Annex in order to adapt the data for the calculation of the operational lifetime costs of road transport vehicles to inflation and to technical progress.";

(2) the following Article 8a 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.

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<sup>136</sup>

OJ L 120, 15.5.2009, p. 5.

2. The power to adopt delegated acts referred to in Article 7 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.";

(3) Article 9 is deleted.

### **133. 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>137</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 of the Treaty 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

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<sup>137</sup> OJ L 131, 28.5.2009, p. 11.

- 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;
- 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 on Better Law-Making of 13 April 2016. 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 concerning:

(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 concerning 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 14a 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 an indeterminate period of time from [the date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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."

**134. 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>138</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 of the Treaty should be delegated to the Commission:

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<sup>138</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;
- 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>139</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 on Better Law-Making of 13 April 2016. 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 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 4*bis*(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, 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, for the period until 31 December 2016, 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)";

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<sup>139</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).



(2) the following Article 9a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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.

**135. Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC<sup>140</sup>**

In order to determine the degree of gravity of certain breaches of the applicable rules and to adapt Regulation (EC) No 1071/2009 to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II and III to that Regulation and to supplement that Regulation by drawing up a list of categories, types and degrees of seriousness of serious infringements of Union rules which, in addition to those set out in Annex IV, may lead to the loss of good repute. 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 on Better Law-Making of 13 April 2016. 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.

Several empowerments of the Commission under Regulation (EC) No 1071/2009 allowing for the adoption of postponement measures are no longer needed.

Accordingly, Regulation (EC) No 1071/2009 is amended as follows:

(1) in Article 6(2)(b), the first and second paragraphs are replaced by the following:

"the Commission is empowered to adopt delegated acts in accordance with Article 24a establishing a list of categories, types and degrees of seriousness of serious infringements of Union rules which, in addition to those set out in Annex IV, may lead to the loss of good repute. Member States shall take into account information on those infringements, including information received from other Member States, when setting the priorities for checks pursuant to Article 12(1).";

(2) in Article 8, paragraph 9 is replaced by the following:

"9. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending Annexes I, II and III in order to adapt them to technical progress.";

(3) in Article 11(4), the third subparagraph is deleted;

(4) in Article 12(2), the second subparagraph is deleted;

(5) in Article 16, paragraph 7 is deleted;

(6) the following Article 24a is inserted:

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<sup>140</sup> OJ L 300, 14.11.2009, p. 51.

*"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 6(2) and Article 8(9) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 6(2) and Article 8(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 on Better Law-Making of 13 April 2016\*.
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 Article 8(9) 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 25, paragraph 3 is deleted.

**136. Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market<sup>141</sup>**

In order to adapt Regulation (EC) No 1072/2009 to technical progress, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II and III to that Regulation and to amend that Regulation in relation to the period of validity of the Community licence.

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<sup>141</sup> OJ L 300, 14.11.2009, p. 72.

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 on Better Law-Making of 13 April 2016. 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 1072/2009 is amended as follows:

(1) Article 4 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 14a amending this Regulation to adapt the period of validity of the Community licence to technical progress, in particular the national electronic registers of road transport undertakings as provided for in Article 16 of Regulation (EC) No 1071/2009.";

(b) in paragraph 4, the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 14a amending Annexes I and II in order to adapt them to technical progress.";

(2) in Article 5, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 14a amending Annex III in order to adapt it to technical progress.";

(3) after the title of Chapter V, the following Article 14a is 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 4(2) and (4) and Article 5(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2) and (4) and Article 5(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 on Better Law-Making of 13 April 2016\*.

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(2) and (4) and Article 5(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.";

(4) Article 15 is deleted.

**137. Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus services, and amending Regulation (EC) No 561/2006<sup>142</sup>**

In order to adapt Regulation (EC) No 1073/2009 to technical progress and to establish the technical measures necessary for its proper functioning, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Regulation, as well as to supplement it by establishing:

- the procedures for the names of occasional service carriers and the connection points en route;
- the formats of certificates for own-account transport operations;
- the formats of authorisations for regular services;
- the formats of applications for such authorisations;
- the formats for journey forms for occasional services, the format of the book of journey forms and the way in which they are used;
- the format of the table to be used for the communication of statistics on the number of authorisations issued for cabotage operations in the form of regular services performed by a carrier not resident in the host Member State in the course of a regular international service.

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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all

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<sup>142</sup> OJ L 300, 14.11.2009, p. 88.

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 1073/2009 is amended as follows:

(1) in Article 4(2), the third subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 25a amending Annexes I and II in order to adapt them to technical progress.";

(2) Article 5 is amended as follows:

(a) in paragraph 3, the fifth subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the procedures for the names of such carriers and the connection points en route to be communicated to the competent authorities of the Member States concerned.";

(b) in paragraph 5, the third subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the format of certificates.";

(3) in Article 6, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the format of authorisations.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the format of applications.";

(5) in Article 12, paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the format of the journey form, the book of journey forms and the way in which they are used.";

(6) the following Article 25a 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 4(2), Article 5(3) and (5), Article 6(4), Article 7(2), Article 12(5) and Article 28(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2), Article 5(3) and (5), Article 6(4), Article 7(2), Article 12(5) and Article 28(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 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 on Better Law-Making of 13 April 2016\*.

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(2), Article 5(3) and (5), Article 6(4), Article 7(2), Article 12(5) and Article 28(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.";

(7) Article 26 is deleted;

(8) in Article 28, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 25a concerning the format of the table to be used for the communication of the statistics referred to in paragraph 2."

## **XII. HEALTH AND FOOD SAFETY**

### **138. Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption<sup>143</sup>**

In order to achieve the objectives of Directive 89/108/EEC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Directive with the purity criteria to be satisfied by cryogenic media, the sampling procedures for quick-frozen foodstuffs and the procedures for monitoring their temperature and for monitoring temperatures in the means of transport, warehousing and storage. 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 on Better Law-Making of 13 April 2016. 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 89/108/EEC is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 11a determining the purity criteria to be satisfied by those cryogenic media.";

(2) Article 11 is replaced by the following:

#### *"Article 11*

"The Commission is empowered to adopt delegated acts in accordance with Article 11a determining the sampling procedures for quick-frozen foodstuffs and the procedures for monitoring their temperature and for monitoring temperatures in the means of transport, warehousing and storage.";

(3) the following Article 11a is inserted:

#### *"Article 11a*

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 Articles 4 and 11 shall be conferred for an indeterminate period of time from [the date of the entry into force of this Omnibus].

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<sup>143</sup>

OJ L 40, 11.2.1989, p. 34



3. The delegation of powers referred to in Articles 4 and 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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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 4 and 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 the Council.

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

(4) in Article 12 is deleted.

**139. Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation<sup>144</sup>**

In order to achieve the objectives of Directive 1999/2/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Directive to the extent necessary to ensure the protection of public health and to supplement that Directive in respect of exceptions relating to the maximum radiation dose for foodstuffs, the supplementary requirements for facilities. 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 on Better Law-Making of 13 April 2016. 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 1999/2/EC is amended as follows:

(1) in Article 5, paragraph 2 is replaced by the following:

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<sup>144</sup> OJ L 66, 13.3.1999, p.16.

"2. The Commission is empowered to adopt delegated acts in accordance with Article 11a allowing exceptions to paragraph 1 taking into account the available scientific knowledge and the relevant international standards.";

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

"2. Approval shall be granted only if the facility:

- meets the requirements of the joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (reference FAO/WHO/CAC, Vol. XV, edition 1), and any supplementary requirement which may be adopted by the Commission,
- designates a person responsible for compliance with all the conditions necessary for the application of the process.

The Commission is empowered to adopt delegated acts in accordance with Article 11a concerning the supplementary requirement referred to in the first indent of the first subparagraph of this Article taking into account requirements in terms of efficacy and safety of treatment used, and related to good hygienic practices of food processing.";

(3) the following Articles 11a and 11b are inserted:

*"Article 11a*

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(2), Article 7(2) and Article 14(3) shall be conferred for an indeterminate period of time from [the entry into force of this OMNIBUS].
3. The delegation of powers referred to in Article 5(2), Article 7(2) and Article 14(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 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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.
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(2), Article 7(2) and Article 14(3) 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.

#### *Article 11b*

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 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.";

(4) in Article 12, paragraphs 3, 4 and 5 are deleted;

(5) in Article 14, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending this Directive to the extent necessary to ensure the protection of public health and shall be limited to prohibitions or restrictions as compared to the previous legal situation.

Where imperative grounds of urgency related to human health so require, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this paragraph."

#### **140. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products<sup>145</sup>**

In order to achieve the objectives of Regulation (EC) No 141/2000, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 141/2000 is amended as follows:

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<sup>145</sup> OJ L 18, 22.1.2000, p. 1.

(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 supplementing 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 10b 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 to the Commission for an indeterminate period from [date of entry into force of this omnibus].
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 on Better Law-Making of 13 April 2016\*.
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."

**141. 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>146</sup>**

In order to achieve the objectives of Directive 2001/18/EC, the power to adopt acts in accordance with Article 290 of the Treaty 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 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 ;
- 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 on Better Law-Making of 13 April 2016. 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, 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).";

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<sup>146</sup>

OJ L 106, 17.4.2001, p.1

(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, 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, 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 29a 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 an indeterminate period of time from [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

#### **142. 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>147</sup>**

In order to achieve the objectives of Directive 2001/83/EC, the power to adopt acts in accordance with Article 290 of the Treaty 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;
- to amend Annex I to that Directive to take account of technical and scientific progress;
- to supplement that Directive with appropriate arrangements for the examination of variations to the terms of marketing authorisations granted in accordance with that Directive;
- 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the

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<sup>147</sup> OJ L 311, 28.11.2001, p. 67.

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 23b, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 121a establishing the arrangements referred to in in paragraph 1.";

(3) 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.";

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

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

(5) 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.";

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

(7) 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 to the Commission for an indeterminate period from [date of entry into force of this omnibus].



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 on Better Law-Making of 13 April 2016\*.

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.";

(8) Articles 121b and 121c are deleted.

**143. Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>148</sup>**

In order to achieve the objectives of Regulation (EC) No 999/2001, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Regulation and to supplement that Regulation by:

- approving rapid tests,
- amending the age of bovine animals to be covered by annual monitoring programmes,
- laying down the criteria to demonstrate improvement of the epidemiological situation of the country and to list them in the Annex,
- deciding to allow feeding of young animals of ruminant species with proteins derived from fish,
- laying down detailed criteria for granting such exemption from prohibitions concerning animal feeding,

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<sup>148</sup> OJ L 147, 31.5.2001, p.1

- deciding to introduce a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious and technically unavoidable contamination,
- deciding on the age,
- laying down rules providing for exemptions from the requirement to remove and destroy specified risk material,
- approving production processes,
- deciding to extend certain provisions to other animal species,
- deciding to extend to other products of animal origin,
- adopting the method to confirm BSE in ovine and caprine animals.

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 on Better Law-Making of 13 April 2016. 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 999/2001 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 23b approving the rapid tests referred to in the second subparagraph. The Commission is empowered to adopt delegated acts in accordance with Article 23b amending Annex X, Chapter C, point 4 to update the list set out therein.";

(2) Article 6 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 23b approving the rapid tests for that purpose. The Commission is empowered to adopt delegated acts in accordance with Article 23b amending Annex X to list those tests.";

(b) in paragraph 1b, the first and the second subparagraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 23b amending paragraph 1a(a) and (c) to adapt the age laid down therein according to scientific progress and after consultation of the EFSA.

At the request of a Member State which can demonstrate the improvement of the epidemiological situation of the country, the annual monitoring programmes of that particular Member State may be revised. The Commission is empowered to adopt delegated acts in accordance with Article 23b:

(a) establishing certain criteria according to which the improvement of the epidemiological situation of the country, for the purpose of revising the monitoring programmes, should be assessed;

(b) amending point 7 of Part I of Chapter A of Annex III to list the criteria referred to in point (a).";

(3) Article 7 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 23b amending Annex IV to allow the feeding of young animals of ruminant species with proteins derived from fish, taking into account:

- (a) a scientific assessment of the dietary needs of young ruminants
- (b) the rules adopted for the implementation of this Article provided for in paragraph 5 of this Article
- (c) an assessment of the control aspects of this derogation.";

(b) in paragraph 4, the third subparagraph is replaced by the following:

"At the request of a Member State or third country a decision in accordance with the procedure referred to in Article 24(2) may be taken to grant individual exemptions from the restrictions in this paragraph. Any exemption shall take account of the provisions provided for in paragraph 3 of this Article. The Commission is empowered to adopt delegated acts in accordance with Article 23b laying down detailed criteria to be taken into account when granting such exemption.";

(c) paragraph 4a is replaced by the following:

"4a. The Commission is empowered to adopt delegated acts in accordance with Article 23b setting a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious and technically unavoidable contamination, based on a favourable risk assessment taking into account at least the amount and possible source of contamination and the final destination of the consignment.";

(4) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and with Regulation (EC) No 1069/2009. It shall not be imported into the Union. The list of specified risk material referred to in Annex V shall include at least the brain, spinal cord, eyes and tonsils of bovine animals aged over 12 months and the vertebral column of bovine animals above an age to be determined by the Commission. The Commission is empowered to adopt delegated acts in accordance with Article 23b to determine that age. The Commission is empowered to adopt delegated acts in accordance with Article 23b amending the list of specified risk material in Annex V taking into account the different risk categories

laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a) and (1b)(b).";

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

"The Commission is empowered to adopt delegated acts in accordance with Article 23b to approve an alternative test allowing to detect BSE prior to slaughter and to amend the list in Annex X. Paragraph 1 of this Article shall not apply to tissues from animals which have undergone the alternative test, provided that this test is applied under the conditions provided for in Annex V and the test results are negative.";

(c) paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 23b laying down rules providing for exemptions from paragraphs 1 to 4 of this Article, with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement of the ban of ruminant protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.";

(5) Article 9 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 23b approving production processes that shall be used to produce the products of animal origin listed in Annex VI.";

(b) paragraph 3 is replaced by the following:

"3. Paragraphs 1 and 2 shall not apply, in the light of the criteria set out in point 5 of Annex V, to ruminants which have undergone the alternative test referred to in Article 8(2) and listed in Annex X, where the results of the test were negative.";

(6) in Article 15, paragraph 3 is replaced by the following:

"3. The Commission is empowered to adopt delegated acts in accordance with Article 23b supplementing this Regulation to extend the provisions of paragraphs 1 and 2 to other animal species.";

(7) in Article 16(7), the first sentence is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 23b supplementing this Regulation to extend the provisions of paragraphs 1 to 6 to other products of animal origin.";

(8) in Article 20(2), the second sentence is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 23b laying down the method to confirm BSE in ovine and caprine animals.";

(9) Article 23 is replaced by the following:

*"Article 23*  
**Amendment of the Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 23b amending the Annexes. The amendments shall have the aim of adapting the provisions contained in those Annexes to the evolution of the epidemiological situation, of the available scientific knowledge, of the relevant international standards, of the available analytical methods for official controls or of the results of controls or studies on the implementation of those provisions and shall take into account the following criteria:

- (i) where relevant, the conclusions of the available EFSA opinion;
- (ii) the need to maintain a high level of protection of human and animal health in the Union.";

(10) Article 23a is deleted;

(11) the following Article 23b is inserted:

*"Article 23b*  
**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 6(1), and (1b), Article 7(3), (4), and (4a), Article 8(1), (2), and (5), Article 9(1), and (3), Article 15(3), Article 16(7), Article 20(2) and Article 23 shall be conferred for an indeterminate period of time from the date of the entry into force of this Omnibus].

3. The delegation of powers referred to in Article 5(3), Article 6(1), and (1b), Article 7(3), (4), and (4a), Article 8(1), (2), and (5), Article 9(1), and (3), Article 15(3), Article 16(7), Article 20(2) and Article 23 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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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 6(1), and (1b), Article 7(3), (4), and (4a), Article 8(1), (2), and (5), Article 9(1), and (3), Article 15(3), Article 16(7), Article 20(2) and Article 23 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.";

(12) in Article 24, paragraph 3 is deleted.

#### **144. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed<sup>149</sup>**

In order to achieve the objectives of Directive 2002/32/EC, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 2002/32/EC is amended as follows:

(1) in Article 7(2), the first subparagraph is 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 11a amending those Annexes.

Where, in the case of these amendments, imperative grounds of urgency so require, the procedure provided for in Article 11a shall apply to delegated acts adopted pursuant to this Article.”;

(2) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

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<sup>149</sup> OJ L 140, 30.5.2002, p. 10

“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 to define 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 10a and 10b 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 an indeterminate period of time from the [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

#### **145. Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements<sup>150</sup>**

In order to achieve the objectives of Directive 2002/46/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Directive in order to adapt those Annexes to technical progress and to supplement that Directive as regards the purity criteria for substances listed in Annex II thereto, and the minimum amounts of vitamins and minerals that are to be present in food supplements. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Directive 2002/46/EC, implementing powers should be conferred on the Commission concerning setting maximum amounts of vitamins and minerals. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Directive 2002/46/EC is amended as follows:

(1) Article 4 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 concerning the purity criteria for substances listed in Annex II, except where such criteria apply pursuant to paragraph 3.";;

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<sup>150</sup> OJ L 183, 12.7.2002, p.51



(b) paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 12a amending the lists in Annexes I and II in order to adapt them to technical progress.

Where in the case of the removal of a vitamin or a mineral from the lists referred to in paragraph 1 of this Article, imperative ground of urgency so require, the procedure provided for in Article 12b shall apply to delegated acts adopted pursuant to this Article.";

(2) in Article 5, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 12a setting the minimum amounts of vitamins and minerals referred to in paragraph 3 of this Article.

The Commission shall set the maximum amounts of vitamins and minerals referred to in paragraphs 1 and 2 of this Article by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 13(2).";

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

(4) the following Articles 12a and 12b are inserted:

*“Article 12a*

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(2) and (5) and Article 5(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4(2) and (5) and Article 5(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 Inter-Institutional Agreement on Better Law-Making of 13 April 2016\*.

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(2) and (5) and Article 5(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.

#### *Article 12b*

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 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) in Article 13, paragraphs 3 and 4 are deleted.

#### **146. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC<sup>151</sup>**

In order to achieve the objectives of Directive 2002/98/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I to IV to that Directive to adapt them to technical and scientific progress and to supplement that Directive with certain technical requirements. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of point (i) of the second paragraph of Article 29 of Directive 2002/98/EC, implementing powers should be conferred on the Commission in order to establish the procedure for notifying serious adverse reactions and events as well as the notification format. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Directive 2002/98/EC is amended as follows:

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<sup>151</sup> OJ L 33, 8.2.2003, p. 30.

(1) after the title of Chapter IX, the following Articles 27a and 27b are 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 the first and third paragraphs of Article 29 shall be conferred for an indeterminate period of time from [date of entry into force of this omnibus].
3. The delegation of power referred to in the first and third paragraphs of Article 29 may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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 on Better Law-Making of 13 April 2016\*.
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 the first and third paragraphs of Article 29 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.

*Article 27b*  
**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 28a(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 the Council.

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

(2) in Article 28, paragraphs 3 and 4 are deleted;

(3) Article 29 is amended as follows:

(a) the first paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 27a concerning amendments to the technical requirements set out in Annexes I to IV in order to adapt them to technical and scientific progress.

Where, in the case of the technical requirements set out in Annexes III and IV imperative grounds of urgency so require, the procedure provided for in Article 27b shall apply to delegated acts adopted pursuant to this Article.";

(b) in the second paragraph, point (i) is deleted;

(c) the third and fourth paragraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 27a supplementing this Directive in respect of the technical requirements referred to in the second paragraph.

Where, in the case of the technical requirements referred to in points (b), (c), (d), (e), (f) and (g) of the second paragraph, imperative grounds of urgency so require, the procedure provided for in Article 27b shall apply to delegated acts adopted pursuant to this Article.";

(d) the following fifth paragraph is added:

"The Commission shall establish the procedure for notifying serious adverse reactions and events as well as the notification format by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 28(2).".

**147. 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>152</sup>**

In order to achieve the objectives of Regulation (EC) No 178/2002, the power to adopt acts in accordance with Article 290 of the Treaty 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.

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<sup>152</sup> OJ L 31, 1.2.2002, p.1.

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 on Better Law-Making of 13 April 2016. 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 concerning 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 Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community 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 establishing the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, 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  
DELEGATIONS OF POWER, IMPLEMENTING AND MEDIATION  
PROCEDURES";**

(5) the following Article 57a 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 powers to adopt delegated acts referred to in Article 28(4), Article 29(6) and Article 36(3) shall be conferred upon the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.
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.

**148. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC<sup>153</sup>**

In order to achieve the objectives of Directive 2003/99/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex I to that Directive in order to update the lists of zoonoses or zoonotic agents set out in that Annex, to amend Annexes II, III and IV to that Directive and to supplement that Directive with coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that

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<sup>153</sup> OJ L 325, 12.12.2003, p. 31

those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 2003/99/EC is amended as follows:

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

"4. The Commission is empowered to adopt delegated acts in accordance with Article 11a to amend Annex I in order to update the lists of zoonoses or zoonotic agents, taking account in particular of the following criteria:

- (a) their occurrence in animal and human population, feed and food ;
- (b) the gravity of their effects for humans ;
- (c) their economic consequences for animal and human health care and for feed and food businesses ;
- (d) epidemiological trends in animal and human populations feed and food.

Where imperative grounds of urgency so require, in order to protect human health, the procedure provided for in Article 11b shall apply to delegated acts adopted pursuant to this Article.";

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

"1. If data collected through routine monitoring in accordance with Article 4 are not sufficient, the Commission is empowered to adopt delegated acts in accordance with Article 11a, laying down coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. Those delegated acts shall be adopted especially when specific needs are identified and when there is need to assess risks or to establish baseline values related to zoonoses or zoonotic agents at the level of Member States or at Union level.";

(3) in Article 11, the first and second paragraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 11a to amend Annexes II, III and IV, taking account in particular of the following criteria:

- (a) the occurrence of zoonoses, zoonotic agents and antimicrobial resistance in animal and human population, feed, food and the environment,
- (b) the availability of new monitoring and reporting tools,
- (c) the needs required for the assessment of trends at national, European or global level.";

(4) the following Articles 11a and 11b 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 4(4), Article 5(1) and Article 11 shall be conferred for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of powers referred to in Articles 4(4), Article 5(1) and 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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.
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 4(4), Article 5(1) and 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 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 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 11a(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 the Council.

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

(5) in Article 12, paragraphs 3 and 4 are deleted.



**149. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>154</sup>**

In order to achieve the objectives of Regulation (EC) No 1829/2003, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to that Regulation in order to adapt to technical progress and to supplement that Regulation by establishing appropriate lower thresholds for GMO presence in food and feed, below which the labelling requirements do not apply, subject to certain conditions and by establishing specific rules concerning the information to be given by mass caterers providing food to the final consumer.

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 on Better Law-Making of 13 April 2016\*. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1829/2003, implementing powers should be conferred on the Commission concerning measures for operators to satisfy the competent authorities, measures necessary for operators to comply with the labelling requirements and rules to facilitate the uniform application of certain provisions. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1829/2003 is amended as follows:

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

"2. The Commission may decide, by means of implementing acts, whether a type of food falls within the scope of this Section. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2).";

(2) in Article 12, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, establishing appropriate lower thresholds, in particular in respect of foods containing or consisting of GMOs, or taking account of advances in science and technology.";

(3) Article 14 is replaced by the following:

*"Article 14*  
**Delegated and implementing powers**

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<sup>154</sup> OJ L 268, 18.10.2003, p. 1

1. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, adopting specific rules concerning the information to be given by mass caterers providing food to the final consumer. In order to take account of the specific situation of mass caterers, such rules may provide for adaptation of the requirements set out in Article 13(1)(e).

2. The Commission may adopt, by means of implementing acts:

(a) measures necessary for operators to satisfy the competent authorities as referred to in Article 12(3);

(b) measures necessary for operators to comply with the labelling requirements set out in Article 13;

(c) detailed rules to facilitate the uniform application of Article 13.

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2).";

(4) in Article 15, paragraph 2 is replaced by the following:

"2. The Commission may decide, by means of implementing acts, whether a type of feed falls within the scope of this Section. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2).";

(5) in Article 24, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, establishing appropriate lower thresholds, in particular in respect of feed containing or consisting of GMOs, or taking account of advances in science and technology.";

(6) Article 26 is replaced by the following:

*"Article 26*  
**Implementing powers**

The Commission may adopt, by means of implementing acts:

(a) measures necessary for operators to satisfy the competent authorities as referred to in Article 24(3);

(b) measures necessary for operators to comply with the labelling requirements set out in Article 25;

(c) detailed rules to facilitate the uniform application of Article 25.

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2). "

(7) in Article 32, the sixth paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts, in accordance with Article 34a, amending the Annex in order to adapt it to technical progress.";

(8) the following Article 34a is inserted:

*"Article 34a*  
**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(4), Article 14(1a), Article 24(4) and Article 32, sixth paragraph, shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegations of power referred to in Article 12(4), Article 14(1a), Article 24(4) and Article 32, sixth paragraph, 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 on Better Law-Making of 13 April 2016\*.

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(4), Article 14(1a), Article 24(4) or Article 32, sixth paragraph, 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.";

(9) in Article 35, paragraph 3 is deleted;

(10) in Article 47, paragraph 3 is deleted.

**150. Regulation (EC) No 1830/2003 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>155</sup>**

In order to achieve the objectives of Regulation (EC) No 1830/2003, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 1830/2003 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, 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 9a 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 an indeterminate period of time from [date of entry into force of this Omnibus].
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.

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<sup>155</sup> OJ L 268, 18.10.2003, p. 24

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 on Better Law-Making of 13 April 2016\*.

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, the first subparagraph of paragraph 2 is deleted.

#### **151. 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>156</sup>**

In order to achieve the objectives of Regulation (EC) No 1831/2003, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II, III and 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 on Better Law-Making of 13 April 2016. 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) 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.”;

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<sup>156</sup> OJ L 268, 18.10.2003, p. 29

(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:

“5. The Commission is empowered to adopt delegated acts in accordance with Article 21a concerning the establishment of 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 21a 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 an indeterminate period of time from the [date of entry into force of this Omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**152. 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>157</sup>**

In order to achieve the objectives of Regulation (EC) No 2065/2003, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 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 concerning 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 18a is inserted:

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<sup>157</sup> OJ L 309, 26.11.2003, p. 1

*"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 an indeterminate period of time from [date of entry into force of this Omnibus].
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 Inter-Institutional Agreement on Better Law-Making of 13 April 2016\*.
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.

**153. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents<sup>158</sup>**

In order to achieve the objectives of Regulation (EC) No 2160/2003, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II and III to that Regulation and to supplement that Regulation as regards the Union targets for the reduction of the prevalence of zoonoses and zoonotic agents, specific control methods, specific rules on criteria relating to imports from third countries, the responsibilities and tasks of the Union

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<sup>158</sup> OJ L 325, 12.12.2003, p.1.



reference laboratories and certain responsibilities and tasks of the national reference laboratories. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) 2160/2003, implementing powers should be conferred on the Commission concerning approving methods for testing. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 2160/2003 is amended as follows:

(1) Article 4 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 13a concerning the Union targets for the reduction of the prevalence of zoonoses and zoonotic agents listed in Annex I, column 1, in the animal populations listed in Annex I, column 2, taking account, in particular, of:

(a) the experience gained under existing national measures; and

(b) information forwarded to the Commission or to the European Food Safety Authority under existing Union requirements, in particular in the framework of information provided for in Directive 2003/99/EC, in particular Article 5 thereof.";

(b) in paragraph 6, point (a) is replaced by the following:

"(a) The Commission is empowered to adopt delegated acts in accordance with Article 13a amending Annex I for the purposes listed in point (b), after taking account in particular of the criteria listed in point (c).";

(c) paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending Annex III to add criteria to determine which salmonella serotypes have public health significance.";

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

"6. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending Annex II to adapt the requirements and minimum

sampling rules laid down therein, after taking account in particular of the criteria listed in point (c) of Article 4(6).";

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

"1. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning:

(a) specific control methods that may or shall be applied for the reduction of prevalence of zoonoses and zoonotic agents at the stage of the primary production of animals and other stages in the food chain;

(b) rules that may be adopted concerning the conditions for the use of the methods referred to in point (a);

(c) detailed rules that may be adopted concerning necessary documents and procedures as well as minimum requirements for the methods referred to in point (a); and

(d) certain specific control methods that shall not be used as a part of control programmes.";

(4) in Article 9, paragraph 4 is replaced by the following:

"4. Without prejudice to Article 5(6), the Commission is empowered to adopt delegated acts in accordance with Article 13a establishing the rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article.";

(5) in Article 10(5), the second and third sentences are replaced by the following:

"The authorisation may be withdrawn in accordance with the same procedure. and, without prejudice to Article 5(6), the Commission is empowered to adopt delegated acts in accordance with Article 13a establishing specific rules concerning such criteria.";

(6) Article 11 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 13a laying down the responsibilities and tasks of the Union reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories.";

(b) paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 13a laying down certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their

activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a).";

(7) in Article 12(3), the third subparagraph is replaced by the following:

"3. The Commission may approve, by means of implementing acts, other methods for testing referred in paragraph 3. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 14(2).";

(8) in Article 13, the first paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 13a amending elements concerning the relevant health certificates.";

(9) the following Article 13a is 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 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4) and Article 13 shall be conferred for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of powers referred to in Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), 11(2) and (4) 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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4) 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 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.";

(9) in Article 14, paragraph 3 is deleted.

**154. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>159</sup>**

In order to achieve the objectives of Directive 2004/23/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Directive with traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality, and to supplement that Directive with certain technical requirements. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Directive 2004/23/EC implementing powers should be conferred on the Commission to establish procedures for ensuring traceability and for verifying the equivalent standards of quality and safety of imported tissues and cells. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Directive 2004/23/EC is amended as follows:

(1) in Article 8, paragraphs 5 and 6 are replaced by the following :

"5. The Commission is empowered to adopt delegated acts in accordance with Article 28a to establish traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety.

6. The Commission shall establish the procedures for ensuring traceability at Union level by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).";

(2) in Article 9, paragraph 4 is replaced by the following:

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<sup>159</sup> OJ L 102, 7.4.2004, p. 48.

"4. The Commission shall establish the procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).";

(3) in Article 28, the second and third paragraphs are replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 28a with respect to the technical requirements referred to in points (a) to (i) of the first paragraph.

Where, in the case of the technical requirements referred to in points (d) and (e) of the first paragraph, imperative grounds of urgency so require, the procedure provided for in Article 28b shall apply to delegated acts adopted pursuant to this Article.";

(4) the following Articles 28a and 28b are inserted:

*"Article 28a*  
**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 delegation of power referred to in Article 8(5) and in the second paragraph of Article 28 shall be conferred for an indeterminate period of time from the [date of entry into force of this omnibus].

3. The delegation of power referred to in Article 8(5) and in the second paragraph of Article 28 may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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 on Better Law-Making of 13 April 2016\*.

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(5) and in the second paragraph of Article 28 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.

*Article 28b*  
**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 28a(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 the Council.

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

(5) in Article 29, paragraphs 3 and 4 are deleted.

**155. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs<sup>160</sup>**

In order to achieve the objectives of Regulation (EC) No 852/2004, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Regulation and to supplement that Regulation in respect of specific hygiene measures, approval requirements of food business establishments, specific provisions for the application of the requirements of the Regulation to specific foodstuffs in order to address specific risks or emerging hazards in relation to public health and in respect of derogations from the Annexes 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 on Better Law-Making of 13 April 2016. 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 852/2004 is amended as follows:

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

"4. The Commission is empowered to adopt delegated acts in accordance with Article 13a adopting the specific hygiene measures referred to in paragraph 3, in particular concerning:

(a) the determination of microbiological criteria and associated sampling and analysis methods;

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<sup>160</sup> OJ L 139, 30.4.2004, p. 1

(b) the introduction of specific requirements on temperature control and maintenance of the cold chain; and

(c) the setting of specific microbiological targets.";

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

"(c) by a delegated act that the Commission is empowered to adopt in accordance with Article 13a."

(3) Article 12 is replaced by the following:

*"Article 12*

The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning specific provisions for the application of the requirements of this Regulation to specific foodstuffs in order to address specific risks or emerging hazards in relation to public health.";

(4) in Article 13, paragraphs 1 and 2 are replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending Annexes I and II. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of the 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 and the procedures based on HACCP principles 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) new scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs.

The amendments referred to in the first subparagraph shall concern:

(a) hygiene provisions for primary production and associated operations;

(b) requirements for food premises and equipments;

(c) provisions applicable to foodstuffs, including transport, wrapping and packaging;

(d) heat treatment of foodstuffs;

- (e) handling of food waste;
- (f) requirements for water supply;
- (g) hygiene and training of persons working in food-handling areas.

2. The Commission is empowered to adopt delegated acts in accordance with Article 13a granting derogations from Annexes I and II , 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 implementation of Article 5 for small businesses;

(b) to establishments producing, handling or processing raw material which is intended for the production of highly refined food products which have undergone a treatment ensuring its safety.";

(6) the following Article 13a is 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(4), Article 6(3)(c), Article 12 and Article 13(1) and (2) shall be conferred for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of powers referred to in Article 4(4), Article 6(3)(c), Article 12 and Article 13(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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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(4), Article 6(3)(c), Article 12 and Article 13(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.";

(5) in Article 14, paragraph 3 is deleted.

**156. 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>161</sup>**

In order to achieve the objectives of Regulation (EC) No 853/2004, the power to adopt acts in accordance with Article 290 of the Treaty 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 placing certain food of animal origin on the market in Sweden or Finland and in respect of derogations from the 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 on Better Law-Making of 13 April 2016. 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. 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 in order to update the requirements set out in those paragraphs], taking into account changes in Member States' control programmes or of the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004.";

(3) Article 9 is deleted;

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<sup>161</sup> OJ L 139, 30.4.2004, p. 55

(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 the 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 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 their implementation by small businesses;

(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 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) paragraphs 1, 5, 6, 7 and 8 are deleted.

(6) the following Article 11a 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 for an indeterminate period of time from [date of entry into force of this Omnibus].

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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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.

**157. Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>162</sup>**

In order to achieve the objectives of Regulation (EC) No 854/2004, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II, III, IV, V and VI to that Regulation and to supplement that Regulation by granting derogation to those Annexes. 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 on Better Law-Making of 13 April 2016. 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>162</sup> OJ L 139, 30.4.2004, p. 206

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

(1) Article 16 is deleted;

(2) in Article 17, paragraphs 1 and 2 are replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending Annexes I, II, III, IV, V and VI. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of the 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) technological developments and their practical consequences and consumer expectations with regard to food composition;

(i) scientific advice, particularly new risk assessments;

(ii) changes in patterns of consumption.

The amendments referred to in the first subparagraph shall concern:

(a) the tasks of the competent authorities;

(b) the organisation of official controls, in particular their frequency and distribution of responsibilities;

(c) the involvement of slaughterhouse staff in official controls;

(d) actions following controls;

(e) specific requirements for meat inspection;

(f) requirements on specific hazards;

(g) specific listing requirements for establishments in third countries;

(h) criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;

(i) circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis;

(j) rules concerning the content of tests for official veterinarians and official auxiliaries;

(k) rules for laboratory testing;

(1) analytical limits for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;

2. The Commission is empowered to adopt delegated acts in accordance with Article 18a granting derogations from Annexes I,II, III, IV, V and VI them, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the following objectives of this Regulation:

(i) to facilitate the implementation of the requirements laid down in the Annexes in small businesses;

(ii) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(iii) to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints.";

(3) Article 18 is amended as follows:

(a) the introductory phrase is replaced by the following:

"Without prejudice to the general application of Article 16 and Article 17(1), the Commission may lay down the following measures by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2):";

(b) paragraphs 3, 4, 7, 8 and 15 are deleted.

(4) the following Article 18a 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(1) and (2) shall be conferred for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of powers referred to in Article 17(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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016\*.

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 Article 17(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";

(5) In Article 19, paragraph 3 is deleted.

#### **158. Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene<sup>163</sup>**

In order to achieve the objectives of Regulation (EC) No 183/2005, the power to adopt acts in accordance with Article 290 of the Treaty 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 approving 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 on Better Law-Making of 13 April 2016. 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 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 defining the criteria and targets referred to in points (a) and (b).";

(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.";

(3) in Article 27, the second paragraph is replaced by the following:

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<sup>163</sup> OJ L 35, 8.2.2005, p. 1.

"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*

The Commission is empowered to adopt delegated acts in accordance with Article 30a 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 30a 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), Article 10(3), Article 27 and Article 28 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of the Omnibus].

3. The delegation of power referred to in Article 5(3), Article 10(3), 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 on Better Law-Making of 13 April 2016\*.

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 10(3), 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.";

(5) in Article 31, paragraph 3 is deleted.



**159. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>164</sup>**

In order to achieve the objectives of Regulation (EC) No 1901/2006, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation:

- by specifying further the grounds for granting deferrals of the initiation or completion of certain measures and
- with provisions regarding the imposition of financial penalties.

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 on Better Law-Making of 13 April 2016. 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 1901/2006 is amended as follows:

(1) in Article 20, paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 50a defining further the grounds for granting a deferral, on the basis of the experience acquired as a result of the operation of paragraph 1.";

(2) in Article 49, paragraph 3 is replaced by the following:

"3. The Commission may impose financial penalties in the form of fines or periodic penalty payments for the infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004.

The Commission is empowered to adopt delegated acts in accordance with Article 50a laying down:

- (a) a list of obligations under this Regulation, the infringement of which may be subject to financial penalties;
- (b) procedures for the exercise of powers to impose fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and confidentiality;
- (c) rules on duration of procedure and limitation periods;

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<sup>164</sup>

OJ L 378, 27.12.2006, p. 1.

- (d) elements to be taken into account by the Commission when setting the level of fines and periodic penalty payments, their maximum amounts, as well as the conditions and method for their collection.

For the conduct of the investigation the Commission may cooperate with national competent authorities and shall rely on resources provided by the Agency.

The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payments imposed.";

- (3) the title of Section 2 of Chapter 1 is replaced by the following :

*"Section 2*  
**Exercise of the delegation";**

- (4) after the title of Section 2 of Chapter 1 the following Article 50a is inserted:

*"Article 50a*

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 20(2) and Article 49(3) shall be conferred to the Commission for an indeterminate period from [date of entry into force of this omnibus].
3. The delegation of power referred to in Article 20(2) and Article 49(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 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 on Better Law-Making of 13 April 2016\*.
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 20(2) and Article 49(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.";

(5) Article 51 is deleted.

**160. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods<sup>165</sup>**

In order to achieve the objectives of Regulation (EC) No 1924/2006, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annex to that Regulation in order to adapt it to technical progress and to supplement that Regulation as regards:

- the nutrition information for non-prepackaged foodstuffs put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale;
- derogations from authorisation procedures linked to the use of trade marks, brand names or fancy names;
- derogations concerning cases of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet;
- specific nutrient profiles, which food or certain categories of food must comply with in order to bear nutrition or health claims;
- measures determining the foods or categories of foods for which nutrition or health claims are to be restricted or prohibited.

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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1924/2006, implementing powers should be conferred on the Commission as regards the adoption of the Union list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health and their conditions of use, any changes or any additions to that list, and as regards final decisions on applications for authorisations of claims. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1924/2006 is amended as follows:

(1) Article 1 is amended as follows:

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

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<sup>165</sup> OJ L 404, 30.12.2006, p.9

"In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the labelling information for those non-prepackaged foodstuffs. National provisions may apply until the eventual adoption of those delegated acts.";

(b) paragraph 4 is replaced by the following:

"4. For generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, food business operators concerned may apply for a derogation from paragraph 3. The application shall be sent to the national competent authority of a Member State which will forward it to the Commission without delay. The Commission shall adopt and make public the rules for food business operators according to which such applications shall be made, so as to ensure that the application is dealt with transparently and within a reasonable time. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning derogations from paragraph 3.";

(2) Article 3 is amended as follows:

(a) in the second subparagraph, point (d) is replaced by the following:

"(d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general;"

(b) the following subparagraph is added:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a derogating from point (d) of the second subparagraph of this Article in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet; the delegated acts shall include conditions for the application of the derogations, taking into account the special conditions present in Member States.";

(3) Article 4 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the first subparagraph is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 24a by 19 January 2009 establishing specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles.";

(ii) the sixth subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the update of nutrient profiles and their conditions of use to take into account relevant scientific developments. To this purpose, interested parties, in particular food business operators and consumer groups shall be consulted.";

(b) paragraph 5 is replaced by the following:

"5. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning measures determining the foods or categories of foods other than those referred to in paragraph 3 of this Article for which nutrition or health claims are to be restricted or prohibited in the light of scientific evidence.";

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

"2. The Commission is empowered to adopt delegated acts in accordance with Article 24a amending the Annex, after consulting the Authority, where appropriate. Where appropriate, the Commission shall involve interested parties, in particular food business operators and consumer groups, in order to evaluate the perception and understanding of the claims in question.";

(5) in Article 13, paragraphs 3 and 4 are replaced by the following:

"3. The Commission shall, after consulting the Authority, adopt a Union list of permitted claims as referred to in paragraph 1 and all necessary conditions for the use of those claims by 31 January 2010 at the latest by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).

4. The Commission shall, after consulting the Authority, on the Commission's own initiative or following a request by a Member State adopt any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

(6) Article 17(3) is amended as follows:

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

"The Commission shall adopt a final decision on the application by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

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

"(b) before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the Commission shall adopt measures for authorisation of the claim without restriction for use by means of implementing

act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

(7) Article 18(5) is amended as follows:

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

"Where the Authority issues an opinion that does not support the inclusion of the claim in the list referred to in paragraph 4, the Commission shall adopt a decision on the application by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

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

"(b) before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the Commission shall adopt measures for authorisation of the claim without restriction of use by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

(8) the following Article 24a 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 1(2) and (4), Article 3, Article 4(1) and (5) and Article 8(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 1(2) and (4), Article 3, Article 4(1) and (5) 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 on Better Law-Making of 13 April 2016\*.

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 1(2) and (4), Article 3, Article 4(1) and (5) 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.";

(9) in Article 25, paragraph 3 is deleted;

(10) Article 28 is amended as follows:

(a) in paragraph 4, point (b) is deleted;

(b) in paragraph 6(a), point (ii) is replaced by the following:

"(ii) after consulting the Authority, the Commission shall, by means of implementing act, adopt a decision concerning the health claims authorised in this way. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 25(2).";

#### **161. Regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods<sup>166</sup>**

In order to achieve the objectives of Regulation (EC) No 1925/2006, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Regulation to adapt it to technical and scientific progress and to amend Annex III to that Regulation to allow the use of vitamins, minerals and of certain other substances prohibited, restricted or under Union scrutiny and to supplement that Regulation by determining the additional foods or categories of foods to which vitamins and minerals may not be added, by determining the purity criteria for vitamin formulations and mineral substances and by determining the minimum amount by derogation from the significant amount for the presence of a vitamin or mineral in the 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1925/2006, implementing powers should be conferred on the Commission as regards the amounts of the vitamins or minerals added to food and as regards the conditions

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<sup>166</sup> OJ L 404, 30.12.2006, p.26

restricting or prohibiting the addition of a specific vitamin or mineral. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1925/2006 is amended as follows:

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

“3. The Commission is empowered to adopt delegated acts in accordance with Article 13a amending the lists in Annexes I and II in order to adapt them to technical progress.

Where in the case of the removal of a vitamin or a mineral from the lists referred to in paragraph 1 of this Article, imperative ground of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.

Prior to making these amendments, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups.”;

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

“The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the additional foods or categories of foods to which vitamins and minerals may not be added in the light of scientific evidence and taking into account their nutritional value.”;

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

“1. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the purity criteria for vitamin formulations and mineral substances listed in Annex II, except where purity criteria apply pursuant to paragraph 2 of this Article.”;

(4) Article 6 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

“1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts. The Commission shall set those amounts by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 14(2). The Commission may, to this end submit a draft of measures for the maximum amounts by 19 January 2009. For concentrated and dehydrated products, the maximum amounts set shall be those present in the foods when prepared for consumption according to the manufacturer’s instructions.

2. The Commission shall define any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 14(2).”;



(b) paragraph 6 is replaced by the following:

“6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the minimum amounts of vitamin or mineral in the food, including any lower amounts by derogation from the significant amounts, for specific foods or categories of foods.”;

(5) in Article 7, paragraph 1 is replaced by the following:

“1. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients. The Commission is empowered to adopt delegated acts in accordance with Article 13a derogating from this rule as regards a specific nutrient.”;

(6) Article 8 is amended as follows:

(a) paragraph 2 is replaced by the following:

“2. On its own initiative or on the basis of information provided by Member States, the Commission is empowered to adopt delegated acts in accordance with Article 13a to amend Annex III in order to include the substance or ingredient referred to in paragraph 1 of this Article. Such delegated act shall follow, in each case, an assessment of available information by the Authority and shall comply with the following conditions:

- (a) if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:
  - (i) be placed in Annex III, Part A, and its addition to foods or its use in the manufacture of foods shall be prohibited; or
  - (ii) be placed in Annex III, Part B, and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein;
- (b) if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.

Where in the case of an inclusion of the substance or the ingredient in Annex III, Part A or B, imperative ground of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.”;

(b) paragraph 5 is replaced by the following:

“5. Within four years from the date a substance has been listed in Annex III, Part C and taking into account the opinion of the Authority on any file submitted for evaluation as mentioned in paragraph 4 of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 13a amending Annex III to allow

the use of a substance listed in Annex III, Part C, or to list it in Annex III, Part A or B, as appropriate.

Where in the case of an inclusion of the substance or the ingredient in Annex III, Part A or B, imperative ground of urgency so require, the procedure provided for in Article 13b shall apply to delegated acts adopted pursuant to this Article.”;

(7) the following Articles 13a and 13b 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 referred to in Article 3(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (5) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (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 Inter-Institutional Agreement on Better Law-Making of 13 April 2016\*.

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(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (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 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 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) in Article 14, paragraphs 3 and 4 are deleted.

**162. 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>167</sup>**

In order to achieve the objectives of Regulation (EC) No 1394/2007, the power to adopt acts in accordance with Article 290 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 1394/2007 is amended as follows:

(1) Article 24 is replaced by the following:

*"Article 24*  
**Amendments of 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 25a 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.

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<sup>167</sup> OJ L 324, 10.12.2007, p. 121.

2. The power to adopt delegated acts referred to in Article 24 shall be conferred to the Commission for an indeterminate period from [date of entry into force of this omnibus].

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 on Better Law-Making of 13 April 2016\*.

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.

**163. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients<sup>168</sup>**

In order to achieve the objectives of Directive 2009/32/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annex I to that Directive in order to adapt it to the technical progress and to supplement that Directive in respect of the methods of analysis necessary to verify compliance with the purity criteria and procedure for taking samples and the methods of analysis of the extraction solvents listed in Annex I to that Directive and maximum permitted limits of mercury and cadmium in those solvents. 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts,

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<sup>168</sup> OJ L 141, 6.6.2009, p. 3

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 2009/32/EC is amended as follows:

(1) Article 4 is replaced by the following:

*"Article 4*

1. The Commission is empowered to adopt delegated acts in accordance with Article 5a concerning amending Annex I in the light of scientific and technical progress in the field of the use of solvents, their conditions of use and maximum residue limits.

2. The Commission is empowered to adopt delegated acts in accordance with Article 5a establishing

(a) the methods of analysis necessary to verify compliance with the general and specific purity criteria provided for in Article 3;

(b) the procedure for taking samples and the methods for qualitative and quantitative analysis of the extraction solvents listed in Annex I and used in foodstuffs or food ingredients;

(c) if necessary, specific purity criteria for the extraction solvents listed in Annex I, and in particular maximum permitted limits of mercury and cadmium in the extraction solvents.

3. Where, in order to protect human health, imperative grounds of urgency so require, the procedure provided for in Article 5b shall apply to delegated acts adopted pursuant to paragraph 1 and to point (c) of paragraph 2.";

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

"3. Where imperative grounds of urgency so require, the Commission is empowered to adopt delegated acts in accordance with Article 5a concerning amendments to this Directive which are considered necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health.

Any Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force in its territory.";

(3) the following Articles 5a and 5b are 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 4 and Article 5(3) shall be conferred on the Commission for an indeterminate period of time from the [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 4 and Article 5(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 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 Inter-institutional Agreement on Better Law-Making of 13 April 2016\*.

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 and Article 5(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.

#### *Article 5b*

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, 12.2016, p.1.";

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

**164. Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms<sup>169</sup>**

In order to achieve the objectives of Directive 2009/41/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the annexes to that Directive to adapt them to technical progress and to list types of GMMs to which the Directive does not apply if their safety is established in accordance with the criteria set out in 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 on Better Law-Making of 13 April 2016. 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 2009/41/EC is amended as follows:

(1) Article 19 is replaced by the following:

*"Article 19*

The Commission is empowered to adopt delegated acts in accordance with Article 19a amending:

- (a) Annexes II, III, IV and V in order to adapt them to technical progress;
- (b) Part C of Annex II in order to establish and update the list of types of GMMs referred to in Article 3(1), point (b).";

(2) the following Article 19a is inserted:

*"Article 19a*

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 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 19 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.

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<sup>169</sup>

OJ L 125, 21.5.2009, p.75.

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 on Better Law-Making of 13 April 2016\*.

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 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 20, paragraph 2 is deleted;

(4) in Annex II, Part B, point (1) is replaced by the following:

"1. Introduction

Types of GMMs listed in Part C pursuant to Article 19 are excluded from the scope of this Directive. GMMs will be added to the list on a case-by-case basis and exclusion will relate only to each clearly identified GMM. This exclusion applies only when the GMM is used under conditions of contained use. It does not apply to the deliberate release of GMMs. For a GMM to be listed in Part C, it must be proved that it meets the criteria given below.";

(5) Annex II, Part C, is replaced by the following:

"Part C

Types of GMMs which meet the criteria listed in Part B:

... (to be completed pursuant to Article 19)."



**165. Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters<sup>170</sup>**

In order to achieve the objectives of Directive 2009/54/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend that Directive in order to ensure the protection of public health and to supplement that Directive as regards the following:

- limits for the concentrations of constituents of natural mineral waters;
- any necessary provisions for the indication on the labelling of high levels of certain constituents;
- the conditions of use of ozone-enriched air for the treatment of natural mineral water, information on the treatments of natural mineral water;
- methods of analysis to determine the absence of pollution of natural mineral waters;
- the sampling procedures and methods of analysis necessary for checking the microbiological characteristics of natural mineral waters.

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 on Better Law-Making of 13 April 2016<sup>171</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.

Accordingly, Directive 2009/54/EC is amended as follows:

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

“The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the measures referred to in points b(i) and (c)(i) of the first subparagraph.”;

(2) in Article 9(4), the second subparagraph is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the measures referred to in point (d) of the first subparagraph.”;

(3) in Article 11(4), the first and second subparagraphs are replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 13a amending this Directive in order to ensure the protection of public health.

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

(4) in Article 12, the second paragraph is replaced by the following:

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<sup>170</sup>

OJ L 164, 26.6.2009, p.45

“The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the measures referred to in points (a) to (f) of the first paragraph.”;

(5) the following Articles 13a and 13b are inserted:

*“Article 13a*

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), Article 9(4), Article 11(4) and Article 12, shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].
3. The delegation of power referred to in Article 4(1), Article 9(4), Article 11(4) 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 Inter-Institutional Agreement on Better Law-Making of 13 April 2016\*.
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 4(1), Article 9(4), Article 11(4) and Article 12 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 13b*

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 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) Article 14 is deleted.

**166. 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>171</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 of the Treaty 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 on Better Law-Making of 13 April 2016. 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 2009/128/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 20a is inserted:

*"Article 20a*  
**Exercise of the delegation**

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<sup>171</sup> OJ L 309, 24.11.2009, p.71.

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 an indeterminate period of time from the [date of entry into force of this Omnibus].
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 on Better Law-Making of 13 April 2016\*.
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 the Council.

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\* OJ L 123, 12; 5; 2016, p.1.".

**167. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council**<sup>172</sup>

In order to achieve the objectives of Regulation (EC) No 470/2009, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplementing that Regulation with scientific methods for establishing reference points for action, rules on actions in case of confirmed presence of a prohibited non-authorised substance, as well as the methodological principles for the risk assessment and risk management recommendations and rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or a

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<sup>172</sup> OJ L 152, 16.6.2009, p. 11.

maximum residue limit established for a pharmacologically active substance in one or more species for other species. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of the relevant provisions of Regulation (EC) No 470/2009, implementing powers should be conferred on the Commission concerning reference points for action for residues from pharmacologically active substances. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 470/2009 is amended as follows:

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

"2. The Commission is empowered to adopt delegated acts, in accordance with Article 24a, concerning the adoption of:

(a) the methodological principles for the risk assessment and risk management recommendations referred to in Articles 6 and 7, including technical requirements in accordance with internationally agreed standards;

(b) rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or a maximum residue limit established for a pharmacologically active substance in one or more species for other species, as referred to in Article 5. Those rules shall specify how and under what circumstances scientific data on residues in a particular foodstuff or in a species or more species may be used for setting a maximum residue limit in other foodstuffs, or other species.";

(2) Article 18 is replaced by the following:

*"Article 18*  
**Reference points for action**

When it is deemed necessary in order to ensure the functioning of controls of food of animal origin imported or placed on the market in accordance with Regulation (EC) No 882/2004, the Commission may establish, by means of implementing act, reference points for action for residues from pharmacologically active substances which are not subject to a classification in accordance with Article 14(2)(a), (b) or (c). Those implementing acts shall be adopted in accordance with the procedure referred to in Article 26(2).

The reference points for action shall be reviewed regularly in the light of new scientific data relating to food safety, the outcome of the investigations and analytical tests referred to in Article 24 and technological progress.

On duly justified imperative grounds of urgency relating to the protection of human health, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 26 (2a).";

(3) in Article 19(3), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated act, in accordance with Article 24a, concerning the methodological principles and scientific methods for establishing reference point for action.";

(4) in Article 24, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated act, in accordance with Article 24a, concerning the application of this Article.";

(5) the following Article 24a is inserted under Title V:

*"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 13(2), Article 19(3) and Article 24(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 13(2), Article 19(3) and Article 24(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 on Better Law-Making of 13 April 2016\*.

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(2), Article 19(3) and Article 24(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.";

(6) in Article 25, paragraph 3 is deleted;

(7) Article 26 is amended as follows:

(a) the following paragraph 2a is inserted:

"Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 of the European Parliament and of the Council\*, in conjunction with Article 5 thereof, 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)";

(b) paragraphs 3 and 4 are deleted.

**168. Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC<sup>173</sup>**

In order to achieve the objectives of Regulation (EC) No 767/2009, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Regulation in order to adapt them to technical progress and to supplement that Regulation with a list of categories of feed materials. 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 on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 767/2009, implementing powers should be conferred on the Commission in order to

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<sup>173</sup> OJ L 229, 1.9.2009, p. 1

clarify whether a certain product constitutes feed, updating the list of intended uses and setting the maximum content of chemical impurities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 767/2009 is amended as follows:

(1) in Article 6(2), the second and third subparagraphs are replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 27a amending Annex III.

Where imperative grounds of urgency so require, the procedure provided for in Article 27b shall apply to delegated acts adopted pursuant to this Article.”;

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

“2. The Commission may adopt implementing acts in order to clarify whether a certain product constitutes feed for the purposes of this Regulation. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).”;

(3) in Article 10, paragraph 5 is replaced by the following:

“5. Within six months of receipt of a valid application or, where appropriate, after receiving the opinion of the Authority, the Commission shall adopt implementing acts updating the list of intended uses if the conditions laid down in paragraph 2 are met. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).”;

(4) in Article 17(4), the second subparagraph is replaced by the following:

“The Commission is empowered to adopt delegated acts in accordance with Article 27a, concerning the establishment of the list of categories of feed materials referred to in paragraph 2(c).”;

(5) in Article 20(2), the second subparagraph is replaced by the following:

“2. The Commission is empowered to adopt delegated acts in accordance with Article 27a amending Annex VIII.”;

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

“3. Amendments to the Community Catalogue setting the maximum content of chemical impurities as referred to in point 1 of Annex I or levels of botanical purity as referred to in point 2 of Annex I or levels of moisture content as referred to in point 6 of Annex I or particulars replacing the compulsory declaration as referred to in Article 16(1)(b), shall be adopted by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).”;

(7) in Article 27, paragraph 1 is replaced by the following:



“1. The Commission is empowered to adopt delegated acts in accordance with Article 27a amending the Annexes in order to adapt them in light of scientific and technological developments.”;

(8) the following Articles 27a and 27b are 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 6(2), Article 17(4), Article 20(2) and Article 27(1) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 6(2), Article 17(4), Article 20(2) and Article 27(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 on Better Law-Making of 13 April 2016\*.

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), Article 17(4), Article 20(2) and Article 27(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 27b*

**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 27a(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.”;

(9) in Article 28, paragraphs 4, 5 and 6 are deleted;

(10) in Article 32, paragraph 4 is deleted.

**169. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)<sup>174</sup>**

In order to achieve the objectives of Regulation (EC) No 1069/2009, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Regulation as regards:

- an end point in the manufacturing chain;
- the determination of serious transmissible diseases;
- the conditions designed to prevent the spread of diseases transmissible to humans or animals;
- the risk categories in order to take into account scientific progress as regards the assessment of the level of risk;
- checks and controls of uses of animal by-products and derived products and conditions for feeding;
- derogations for research and other specific purposes;
- certain measures relating to collection, transport and disposal;
- authorisation of alternative methods of use or disposal of animal by-products or derived products;
- certain measures relating to collection and identification;
- certain measures relating to category and transport;
- certain measures relating to collection, transport and traceability;
- certain measures relating to registration and approval;
- the placing on the market of animal by-products and derived products destined for feeding to farmed animals;
- the placing on the market and use of organic fertilisers and soil improvers;
- certain measure relating to other derived products;
- certain measures relating to the import and transit products;
- purposes for exports of category 1 material, Category 2 material and products derived therefrom;
- controls for dispatch to other Member States.

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

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<sup>174</sup> OJ L 300, 14.11.2009, p. 1.

conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. 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 order to ensure uniform conditions for the implementation of Regulation (EC) No 1069/2009, implementing powers should be conferred on the Commission concerning certain documentation, parameters for the manufacturing process and testing requirements applicable to the end product. models for health certificates, commercial documents and declarations which are to accompany consignments, specifying the conditions under which it can be stated that the animal by- products or derived products concerned have been collected or manufactured in accordance with the requirements of this Regulation Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 1069/2009 is amended as follows:

(1) Article 5 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 51a to amend the endpoint in the manufacturing chain for the products referred to in points (a) and (b) of the third subparagraph of this paragraph, taking into account scientific and technical developments.

Where imperative grounds of urgency so require, the Commission is empowered to adopt delegated acts in accordance with Article 51b to amend the endpoint in the manufacturing chain for the products referred to in points (a) and (b) of the third subparagraph of this paragraph, taking into account scientific and technical developments.";

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

"The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning an end point in the manufacturing chain, beyond which derived products referred to in this paragraph are no longer subject to the requirements of this Regulation.";

(2) Article 6 is amended as follows:

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

"The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the measures referred to in point (b)(ii) of the first subparagraph.";

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

"The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the measures referred to in the first subparagraph.";

(3) in Article 7, paragraph 4 is replaced by the following:

"4. The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the measures referred to in paragraphs 2 and 3.";

(4) in Article 11, paragraph 2 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(b) the second subparagraph is deleted;

(5) Article 15 is amended as follows:

(a) the title is replaced by the following:

**"Delegated powers"**

(b) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(ii) the second subparagraph is deleted;

(6) in Article 17(2), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down the conditions referred to in the first subparagraph.";

(7) in Article 18, paragraph 3 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(b) the second subparagraph is deleted;

(8) in Article 19, paragraph 4 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(b) the second subparagraph is deleted.

(9) in Article 20, paragraph 11 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"Following receipt of the opinion of the EFSA, the Commission is empowered to adopt delegated acts in accordance with Article 51a as regards the following:";

(b) the second subparagraph is deleted;

(10) in Article 21, paragraph 6 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(b) the second subparagraph is deleted;

(11) Article 27 is amended as follows:

(a) the title of Article 27 is replaced by the following:

**"Delegated powers";**

(b) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the following measures related to this Section and to Section 1 of this Chapter:";

(c) the second subparagraph is deleted;

(12) in Article 31, paragraph 2 is replaced by the following:

"2.The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning measures relating to the public and animal health conditions for the collection, processing and treatment of animal by-products and derived products referred to in paragraph 1.";

(13) in Article 32, paragraph 3 is amended as follows:

(a) in the first subparagraph, the introductory phrase is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down measures relating to the following:";

(b) the second subparagraph is deleted;

(14) Article 40 is replaced with the following:

*"Article 40*

**Delegated and implementing powers**

1. The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the conditions for:

- (a) the placing on the market of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c);
- (b) the safe sourcing and movement of material to be used under conditions which exclude risks to public and animal health;
- (c) the safe use of derived products which pose a risk to public or animal health.

2. The Commission shall adopt implementing acts concerning the following:

- (a) documentation as referred to in the first subparagraph of Article 37(2);
- (b) parameters for the manufacturing process as referred to in the first paragraph of Article 38, in particular as regards the application of physical or chemical treatments to the material used;
- (c) testing requirements applicable to the end product.

Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).";

(15) Article 41 is amended as follows:

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

"The Commission shall adopt implementing acts laying down the conditions referred to in point (b) of the first subparagraph. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).";

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

"The Commission shall adopt implementing acts laying down the requirements provided for in the first subparagraph. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).";

(16) Article 42 is amended as follows:

- (a) the title is replaced by the following:

"Delegated and implementing powers";

- (b) paragraph 2 is replaced by the following:

"2. The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down the following:

- (a) conditions for the import and transit of Category 1 and Category 2 materials and for products derived therefrom;
- (b) restrictions regarding public or animal health applicable to imported Category 3 material or products derived therefrom which may be laid down by reference to the lists of third countries or parts of third countries drawn up in accordance with Article 41(4) or for other public or animal health purposes;
- (c) conditions for the manufacture of animal by-products or derived products in establishments or plants in third countries; such conditions may include the arrangements for controls of such establishments or plants by the competent authority concerned and may exempt certain types of establishments or plants handling animal by-products or derived products from approval or registration as referred to in point (b) of the second subparagraph of Article 41(3).

The Commission shall adopt implementing acts establishing models for health certificates, commercial documents and declarations which are to accompany consignments, specifying the conditions under which it can be stated that the animal by- products or derived products concerned have been collected or manufactured in accordance with the requirements of this Regulation. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).";

(17) in Article 43(3), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the rules referred to in the first subparagraph.";

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

"4. The Commission may adopt implementing acts laying down detailed arrangements for implementing this Article, including rules concerning the reference methods for microbiological analyses. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).";

(19) in Article 48, paragraphs 7 and 8 are replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 51a laying down the following:

- (a) a specified time period for the decision of the competent authority as referred to in paragraph 1;
- (b) supplementary conditions for the dispatch of animal by-products or derived products referred to in paragraph 4;
- (c) models for the health certificates which have to accompany consignments sent in accordance with paragraph 5.

The Commission shall adopt implementing acts laying down the conditions under which animal by-products or derived products intended to be used for exhibitions, artistic activities, for diagnostic, educational or research purposes may be sent to other Member States, by way of derogation from paragraph 1 to 5 of this Article. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 52(3).

8. The Commission is empowered to adopt delegated acts in accordance with Article 51a specifying the conditions subject to which the competent authorities may allow derogations from paragraphs 1 to 4 as regards the following:

(a) the dispatch of manure transported between two points located on the same farm or between farms located in the border regions of Member States sharing a common border;

(b) the dispatch of other animal by-products transported between establishments or plants located in the border regions of Member States sharing a common border; and

(c) the transport of a dead pet animal for incineration to an establishment or plant located in the border region of another Member State sharing a common border.  
";

(20) the following Articles 51a and 51b are inserted:

*"Article 51a*

**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 delegation of power referred to in Article 5(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48, shall be conferred on the Commission for an indeterminate period of [date of entry into force of this Omnibus].
- 3 The delegation of power referred to in Article 5(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48 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 on Better Law-Making of 13 April 2016\*.
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(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48 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 51b*

**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 51a(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 the Council.

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

(21) in Article 52, paragraphs 4, 5 and 6 are deleted.

### **XIII. TAXATION AND CUSTOMS UNION**

#### **170. 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>175</sup>**

Under Article 15 of Decision No 70/2008/EC the Commission is empowered to extent certain time limits in accordance with Council Decision 1999/468/EC<sup>176</sup>. That empowerment has never been exercised and is no longer needed. Therefore, it is not necessary to adapt it to Article 290 of the Treaty. Instead, the empowerment should be revoked and Articles 15 and 16 of the Decision should be deleted.

Accordingly, in Decision No 70/2008/EC, Articles 15 and 16 are deleted.

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<sup>175</sup> OJ L 23, 26.1.2008, p. 21.

<sup>176</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).