Council of the European Union

Brussels, 12 December 2018
(OR. en)

14964/18
ADD 8

Interinstitutional File:
2016/0400(COD)

LIMITE

INST 472	AGRILEG 215
JUR 577	IND 380
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'I/A' ITEM NOTE

From:	Presidency
To:	Permanent Representatives Committee (Part 2)/Council
No. prev. doc.:	ST 5623/17; ST 5623/17 ADD1 REV1; ST 6933/18 ADD 8
No. Cion doc.:	COM(2016)799 FINAL; COM(2016) 799 FINAL/2
Subject:	Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union - General Approach - Section XII "Health and Food Safety"

XII. HEALTH AND FOOD SAFETY

136. 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[1]

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

In order to ensure uniform conditions for the implementation of Directive 89/108/EEC, implementing powers should be conferred on the Commission in order to determine 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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 **in order to supplement this Directive by** determining the purity criteria to be satisfied by those cryogenic media.";

[1] OJ L 40, 11.2.1989, p. 34

(2) Article 11 is replaced by the following:

"Article 11

'The Commission **may determine, by means of implementing acts […]** 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. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 12(2)**";

(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 Article[...] 4 […] shall be conferred for **a period of five years […]** from [the date of the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power[...] referred to in Article[...] 4 […] 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 ad**o**[...]pting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutionnal Agreement of **13 April 2016** on Better-Law-making of […]*.

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 […] 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, […] **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."

*** 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).**

137. 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[2]

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 […] 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 of **13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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2 OJ L 66, 13.3.1999, p.16.

There is no need to empower the Commission to adopt exceptions relating to the maximum radiation dose for foodstuffs in Directive 1999/2/EC. Therefore, the possibility to adopt those implementing measures in accordance with the regulatory procedure with scrutiny should be removed from Directive 1999/2/EC, without replacing it with an empowerment conferred in accordance with Article 290(1) or Article 291(2) of the Treaty.

Accordingly, Directive 1999/2/EC is amended as follows:

(1) in Article 5, paragraph 2 is **deleted. […]**

[…]

(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 7(2) and Article 14(3) shall be conferred for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in […] Article 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 ad**o**[...]pting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better-Law-making […]*.

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

6. A delegated act adopted pursuant to […] Article 7(2) and Article 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.".

138. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[3]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

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

[3] OJ L 18, 22.1.2000, p. 1.

"*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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 8(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 8(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

139. 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[4]

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 of **13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2001/18/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, **supplementing this Directive by** establishing the criteria and information requirements referred to in paragraph 1, as well as any appropriate requirements for a summary of the dossier, after consultation of the relevant Scientific Committee. The criteria and information requirements shall be such as to ensure a high level of safety of human health and the environment and shall be based on the available scientific evidence concerning such safety and on experience gained from the release of comparable GMOs.";

[4] OJ L 106, 17.4.2001, p.1

(b) paragraph 3 is replaced by the following:

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

(2) Article 21 is amended as follows:

(a) paragraph 2 is replaced by the following:

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

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

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

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

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

(4) Article 27 is replaced by the following:

" *Article 27*
Adaptation of the Annexes to technical progress

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

(5) the following Article 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegations of power referred to in Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

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

140. 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[5]

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 by specifying the principles and guidelines of good manufacturing practices for medicinal products.

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

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

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

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

[…]

(**2[…]**) in Article 46a, paragraph 2 is replaced by the following:

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

5 OJ L 311, 28.11.2001, p. 67.

(**3[…]**) in Article 47, the first paragraph is replaced by the following:

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

(**4[…]**) Article 120 is replaced by the following:

"Article 120

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

(**5**[...]) in Article 121, paragraph 2a is deleted;

(**6**[...]) Article 121a is replaced by the following:

"Article 121a

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

2. The power to adopt delegated acts referred to in Article 14(1), Article 22b, […] Article 46a, Article 47, Article 52b, Article 54a and Article 120 shall be conferred to the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 14(1), Article 22b, […] Article 46a, Article 47, Article 52b, Article 54a and Article 120 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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 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.";

(**7**[...]) Articles 121b and 121c are deleted.

141. 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[6]

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,
- 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.

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6 OJ L 147, 31.5.2001, 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 of **13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 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 **in order to supplement this Regulation by** 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 **in order to supplement this Regulation by** 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) **supplementing this Regulation by** 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 **supplementing this Regulation by** laying down detailed criteria to be taken in to 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 **supplementing this Regulation by** 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 **in order to supplement this Regulation by** 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 **in order to supplement this Regulation by** 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 6to 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 **in order to supplement this Regulation by** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in Article 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 adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act [adopted pursuant to Article 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.

142. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[7]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Directive 2002/32/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 **10a** […] amending those Annexes.
>
> Where, in the case of these amendments, imperative grounds of urgency so require, the procedure provided for in Article **10b** […] 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:
>
> "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.";

[7] OJ L 140, 30.5.2002, p. 10

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

"- is empowered to adopt delegated acts in accordance with Article 10a **supplementing this Directive in order** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 7(2) and Article 8(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

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

Article 10b

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

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

* OJ L 123, 12; 5; 2016, p. 1.";

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

143. Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[8]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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:

8 OJ L 183, 12.7.2002, p.51

(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 **in order to supplement this Directive by establishing** […] the purity criteria for substances listed in Annex II, except where such criteria apply pursuant to paragraph 3.";;

(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 **in order to supplement this Directive by** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 4(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 Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 4(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 **12**[...]a(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.

144. 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[9]

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 of **13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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:

(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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

[9] OJ L 33, 8.2.2003, p. 30.

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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to 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).".

145. 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[10]

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.

10 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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 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 **supplementing this Regulation by laying down** […] the procedure to be applied by the Authority to the requests for a scientific opinion;
>
> (b) implementing acts laying down the guidelines governing the scientific evaluation of substances, products or processes which are subject under **Union** […] legislation to a system of prior authorisation or entry on a positive list, in particular where **Union** […] legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2).";

(3) in Article 36(3), the first subparagraph is replaced by the following:

> "The Commission is empowered to adopt delegated acts in accordance with Article 57a **in order to supplement this Regulation by** establishing the criteria for 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 28(4), Article 29(6) and Article 36(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

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

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* OJ L 123, 12.5. 2016, p. 1.";

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

146. 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[11]

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

In order to ensure uniform conditions for the implementation of Council Directive 2003/99/EC, implementing powers should be conferred on the Commission in order to establish coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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.

[11] OJ L 325, 12.12.2003, p. 31

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 **may establish, by means of implementing acts […]** coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. Those **implementing […]** 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. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 12(2)**";

(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)[…] and Article 11 shall be conferred for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in Article[...] 4(4)[…] 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 adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article[...] 4(4)[…] 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.

147. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[12]

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 **of 13 April 2016** on Better Law-Making […]*. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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, **supplementing this Regulation by** establishing appropriate lower thresholds, in particular in respect of foods containing or consisting of GMOs, or taking account of advances in science and technology.";

12 OJ L 268, 18.10.2003, p. 1

(3) Article 14 is replaced by the following:

"Article 14
Delegated and implementing powers

1. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, **supplementing this Regulation by** 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, **supplementing this Regulation by** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegations of power referred to in Article 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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 12(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.

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

(9) in Article 35, paragraph 3 is deleted;

(10) in Article 47, paragraph 3 is deleted.

148. 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[13]

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 of **13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 1830/2003 is amended as follows:

13 OJ L 268, 18.10.2003, p. 24

(1) Article 8 is replaced by the following:

"*Article 8*
Unique identifiers

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

(2) the following Article 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 8 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

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

* 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.

149. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[14]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

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

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 21*a* amending Annex I in order to adapt feed additive categories and functional groups as a result of technological progress or scientific development.";

14 OJ L 268, 18.10.2003, p. 29

(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 21*a* **supplementing this Regulation by establishing** […] rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food.";

(4) in Article 16, paragraph 6 is replaced by the following:

"6. The Commission is empowered to adopt delegated acts in accordance with Article 21*a* 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 21*a* 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(6) and Article 21 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 3(5), Article 6(3), Article 7(5), Article 16(6) and Article 21 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

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

150. 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[15]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 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 **supplementing this Regulation by establishing** […] quality criteria for validated analytical methods referred to in point 4 of Annex II, including substances to be measured. Those delegated acts shall take into account available scientific evidence.";

(2) in Article 18, paragraph 1 is replaced by the following:

"1. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes following a request to the Authority for scientific and/or technical assistance.";

15 OJ L 309, 26.11.2003, p. 1

(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 17(3) and Article 18(1) shall be conferred on the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 17(3) and Article 18(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 17(3) and Article 18(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

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

151. 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[16]

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 **applicable for the reduction of prevalence of zoonoses and zoonotic agents**, **rules concerning the conditions for use of such methods,** specific rules on criteria relating to imports from third countries, the responsibilities and tasks of the Union 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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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.

In order to ensure uniform conditions for the implementation of the Regulation (EC) No 2160/2003, implementing powers should be conferred on the Commission in order to determine detailed rules that may be adopted concerning necessary documents and procedures as well as minimum requirements and certain specific control methods that shall not be used as a part of control programmes. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Accordingly, Regulation (EC) No 2160/2003 is amended as follows:

16 OJ L 325, 12.12.2003, p.1.

(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 **supplementing this Regulation by establishing** […] 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 **supplementing this Regulation by establishing** […]:

(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) […]

(d) […]"

The Commission may establish, by means of implementing acts:

(a) detailed rules that may be adopted concerning necessary documents and procedures as well as minimum requirements for the methods referred to in point (a) of the first subparagraph; and

(b) certain specific control methods that shall not be used as a part of control programmes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2)."

(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 **supplementing this Regulation by** establishing the rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2of 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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), **the first subparagraph of** Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4) and Article 13 shall be conferred for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in Article 3(1), (6), and (7), Article 5(6), **the first subparagraph of** 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 adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 3(1), (6), and (7), Article 5(6), **the first subparagraph of** 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.

152. 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[17]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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 **supplementing this Directive by** [...]establish**ing** 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:

"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).";

17 OJ L 102, 7.4.2004, p. 48.

(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 **supplementing this Directive by establishing** […] 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 8(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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 8(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.

153. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[18]

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, […] 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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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18 OJ L 139, 30.4.2004, p. 1

In order to ensure uniform conditions for the implementation of the Regulation (EC) No 852/2004, implementing powers should be conferred on the Commission to lay down 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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 **supplementing this Regulation by** 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;

(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 **shall lay down, by means of implementing acts, […]** 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. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2)**";

(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 experienced 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 **supplementing this Regulation by** 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) […] and Article 13(1) and (2) shall be conferred for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in Article 4(4), Article 6(3)(c) […] 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 adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6; A delegated act adopted pursuant to Article 4(4), Article 6(3)(c) […] 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.

154. 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[19]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 853/2004 is amended as follows:

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

"2. Food business operators shall not use any substance other than potable water — or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water — to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission. For that purpose the Commission is empowered to adopt delegated acts in accordance with Article 11a **supplementing this Regulation**. Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.";

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

"(a) The Commission is empowered to adopt delegated acts in accordance with Article 11a [amending paragraphs 1 and 2 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;

[19] 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 **supplementing this Regulation by** granting derogations from Annex II and III, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:

(a) to facilitate the […] implementation **of the requirements laid down in the Annexes in[…]**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 **facilitate work of** establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety.";

(5) Article 11 is amended as follows:

(a) the introductory phrase is replaced by the following:

"Without prejudice to the general application of Article 9 and Article 10(1), the Commission may lay down the following measures by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2);";

(b) 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of powers referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

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

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

155. […]

156. Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[20]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Accordingly, Regulation (EC) No 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 30*a* **supplementing this Regulation by** 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 **in order to supplement this Regulation**.";

(3) in Article 27, the second paragraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 30*a* 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 **supplementing this Regulation by** granting derogations from Annexes I, II and III for particular reasons, provided that such derogations do not affect the achievement of the objectives of this Regulation. ";

20 OJ L 35, 8.2.2005, p. 1.

(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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 5(3), Article 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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 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.

157. 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[21]

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 […]**.**
- […]

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

Accordingly, Regulation (EC) No 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 **supplementing this Regulation by** 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**[...]) the title of Section 2 of Chapter 1 is replaced by the following :

"Section 2

Exercise of the delegation";

(**3**[...]) 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.

21 OJ L 378, 27.12.2006, p. 1.

2. The power to adopt delegated acts referred to in Article 20(2) […] shall be conferred to the Commission for **a period of five years** […] from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 20(2) […] may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 20(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.

_____

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

(**4[…]**) Article 51 is deleted.

158. 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[22]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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:

22 OJ L 404, 30.12.2006, p.9

(1) Article 1 is amended as follows:

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

"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 **supplementing this Regulation by establishing […]** 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 **supplementing this Regulation by providing for […]** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by […]** updat**ing** […] **the** 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 **supplementing this Regulation by laying down […]** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 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).";

159. Regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[23]

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 **as regards** […] 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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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 **maximum** amounts of the vitamins or minerals added to food and as regards the conditions restricting or prohibiting the addition of a specific vitamin or mineral **to a food or a category of foods**. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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23 OJ L 404, 30.12.2006, p.26

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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 3(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 Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 3(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.

160. 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[24]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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24 OJ L 324, 10.12.2007, p. 121.

Accordingly, Regulation (EC) No 1394/2007 is amended as follows:

(1) Article 24 is replaced by the following:

"*Article 24*
Amendments 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.

2. The power to adopt delegated acts referred to in Article 24 shall be conferred to the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 24 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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 Council 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.

161. 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[25]

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

In order to ensure uniform conditions for the implementation of Directive 2009/32/EC, implementing powers should be conferred on the Commission in order to establish 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the protection of human health, imperative grounds of urgency so require.

Accordingly, Directive 2009/32/EC is amended as follows:

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25 OJ L 141, 6.6.2009, p. 3

(1) Article 4 is replaced by the following:

"*Article 4*

1. The Commission is empowered to adopt delegated acts in accordance with Article 5*a* 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.

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 the first subparagraph.

2. The Commission **may establish, by means of implementing acts: […]**

(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.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 6(2).

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 6 (2a) concerning the implementing acts adopted pursuant to point (c) of this paragraph.";

*** 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).**

[…]"

(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 5*a* 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 5*a* and 5*b* 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**(1)** and Article 5(3) shall be conferred on the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

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

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

6. A delegated act adopted pursuant to Article 4**(1)** and Article 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.

* OJ L 123, 12.05.2016, p.1.";

([…]**4**) […] Article 6 **is amended as follows:** […]

(a) 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.";

(b) 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.";

*** 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).**

(c) paragraphs 3 and 4 are deleted.

162. 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[26]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

26 OJ L 125, 21.5.2009, p.75.

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 19*a* amending:

(a) **parts B and C of** Annex[...] II **and Annexes** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 19 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 19 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.

* 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)."

163. 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[27]

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 **with the measures relating to the treatment of water.** […]

- […]
- […]
- […]
- […]
- […]

27 OJ L 164, 26.6.2009, p.45

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

In order to ensure uniform conditions for the implementation of Directive 2009/54/EC, implementing powers should be conferred on the Commission in order to determine:

- 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.

Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

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 **supplementing this Directive by laying down […]** 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 **supplementing this Directive by laying down […]** 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 **concerning amendments to […]** this Directive **which are considered necessary in order to address the situations mentioned in paragraph 1 and […]** 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:

"The Commission **may determine, by means of implementing acts, […]** the measures referred to in points (a) to (f) of the first paragraph. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).**

(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) [...] **and** Article 11(4) […] shall be conferred on the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 4(1), Article 9(4) **and** Article 11(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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Articles 4(1), Article 9(4)[…] **and** Article 11(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 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 amended as follows:** […]

(a) 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.";

*** 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).**

(b) Paragraph 3 is deleted.

164. 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[28]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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28 OJ L 309, 24.11.2009, p.71.

Accordingly, Directive 2009/128/EC is amended as follows:

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

"3. The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex I in order to take account of scientific and technical progress.";

(2) in Article 8, paragraph 7 is replaced by the following:

"7. The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex II in order to take account of scientific and technical progress.";

(3) in Article 14(4), the second subparagraph is replaced by the following:

"The Commission is empowered to adopt delegated acts in accordance with Article 20a amending Annex III in order to take account of scientific and technical progress.";

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

"The Commission shall be empowered to adopt delegated acts in accordance with Article 20a amending Annex IV in order to take account of scientific and technical progress.";

(5) the following Article 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 5(3), Article 8(7), Article 14(4) and Article 15(1) shall be conferred on the Commission for **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3. The delegation of power referred to in Article 5(3), Article 8(7), Article 14(4) and Article 15(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]*.

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.

(6) Article 21 pargraph 2 is deleted.

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* OJ L 123, 12; 5; 2016, p.1.".

165. 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[29]

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 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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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29 OJ L 152, 16.6.2009, p. 11.

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, **in order to supplement this Regulation by laying down** […]:
>
> (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, **supplementing this Regulation by laying down** […] the methological 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, **supplementing this Regulation by laying down rules on […]** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

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

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

6. A delegated act adopted pursuant to Article 13(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.

166. 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[30]

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 **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

30 OJ L 229, 1.9.2009, p. 1

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 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, **supplementing this Regulation by establishing** […] 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

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

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

6. A delegated act adopted pursuant to Article 6(2), 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.

167. 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)[31]

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;

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31 OJ L 300, 14.11.2009, p. 1.

- 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 conducted in accordance with the principles laid down in the Interinstitutional Agreement **of 13 April 2016** on Better Law-Making […]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In 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 **supplementing this Regulation by determining […]** 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 **supplementing this Regulation by laying down** […] 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 **supplementing this Regulation by laying down** […] 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 **supplementing this Regulation by laying down** […] 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by laying down […]**";

(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 **supplementing this Regulation by** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by laying down […]** 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 **supplementing this Regulation by** 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 **supplementing this Regulation by** 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 **a period of five years […]** from [the entry into force of this **Regulation […]**]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

3 The delegation of power referred to in Article 5(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 **of 13 April 2016** on Better Law-Making […]*.

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

6. A delegated act adopted pursuant to Article 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.