



Committee on the Environment, Public Health and Food Safety

2016/0400(COD)

4.9.2017

DRAFT POSITION IN THE FORM OF AMENDMENTS 1 - 123

Draft position in the form of amendments
Adina-Ioana Vălean

on the 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 EU

Proposal for a regulation
(COM(2016)0799 – C8-0524/2016 – 2016/0799(COD))

PA_LegPosition

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Legal Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part I – point 1 – paragraph 2 – point 1

Directive 2009/31/EC

Article 29 – paragraph 1

Text proposed by the Commission

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

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 29a amending the Annexes, ***in order to adapt to technical and scientific progress.***

Or. en

Justification

Necessary to ensure consistency with the wording used in the Commission proposal no COM(2016)0789, notably its Article 2(2).

Amendment 2

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part I – point 1 – paragraph 2 – point 2

Directive 2009/31/EC

Article 29a – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Article 29 shall be conferred on the Commission for ***an indeterminate*** period of time from [date of entry into force of this Omnibus].

Amendment

2. The power to adopt delegated acts referred to in Article 29 shall be conferred on the Commission for ***a*** period of ***five years*** from [date of entry into force of this Omnibus]. ***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.

Or. en

Justification

Alignment of the duration of the empowerment.

Amendment 3
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part I – point 1 – paragraph 2 – point 3
Directive 2009/31/EC
Article 30

Text proposed by the Commission

(3) Article 30 is *deleted*.

Amendment

(3) Article 30 is *replaced by the following*:

“Article 30

Committee procedure

1. The Commission shall be assisted by the Climate Change Committee established by Article 26 of Regulation (EU) No 525/2013 of the European Parliament and of the Council*. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council**.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.”

**** Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level***

relevant to climate change and repealing Decision No 280/2004/EC (OJ L 165, 18.6.2013, p. 13).

***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).*

Or. en

Justification

Necessary to ensure consistency with the wording used in the Commission proposal no COM(2016)0789, notably its Article 2(4).

Amendment 4 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part I – point 2 – paragraph 1**

Text proposed by the Commission

In order to ensure the accurate accounting of transactions under Decision No 406/2009/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Decision with requirements applicable to Member States' registries and the Central Administrator as regards the handling of transactions. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the

Amendment

In order to ensure the accurate accounting of transactions under Decision No 406/2009/EC **and that Member States meet the Union's greenhouse gas emission reduction commitments**, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Decision with requirements applicable to Member States' registries and the Central Administrator as regards the handling of transactions, **and with annual emissions allocations for 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

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

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts. This is also in line with the amendments EP is proposing for the Articles with the same purpose in the proposal for the Regulation on binding annual greenhouse emission reductions by Member States from 2021 to 2030 (COM(2016) 482 final) which will replace this Decision from 2020.

Amendment 5 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part I – point 2 – paragraph 2**

Text proposed by the Commission

Amendment

In order to ensure uniform conditions for the implementation of Decision No 406/2009/EC, implementing powers should be conferred on the Commission in order to determine the annual emission allocations. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

deleted

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 6
Adina-Ioana Vălean

Proposal for a regulation
Annex I – part I – point 2 – paragraph 3

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 7
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part I – point 2 – paragraph 4 – point 1 – point a
Decision No 406/2009/EC
Article 3 – paragraph 2 – subparagraphs 4 and 5

Text proposed by the Commission

Amendment

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

The Commission is empowered to adopt delegated acts in accordance with Article 12a to supplement this Decision by determining the annual emissions allocations for the period from 2013 to 2020 in terms of tonnes of carbon dioxide equivalent, when the relevant reviewed and verified emission data are available.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 8
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part I – point 2 – paragraph 4 – point 1 – point b

Decision No 406/2009/EC

Article 3 – paragraph 6

Text proposed by the Commission

(b) paragraph 6 *is deleted*;

Amendment

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

“The Commission is empowered to adopt delegated acts in accordance with Article 12a to supplement this Decision by establishing the modalities for such transfers.”;

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 9
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part I – point 2 – paragraph 4 – point 2

Decision No 406/2009/EC

Article 11 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The Commission is empowered to adopt delegated acts in accordance with Article 12a *to supplement this Decision in order to ensure the accurate accounting in accordance with* paragraphs 1 and 2 of this Article.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 10

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part I – point 2 – paragraph 4 – point 3

Decision No 406/2009/EC

Article 12a

Text proposed by the Commission

Article 12a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 11(3) shall be conferred on the Commission for ***an indeterminate*** period of ***time*** from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 11(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

Article 12a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article ***3(2) and (6) and Article*** 11(3) shall be conferred on the Commission for ***a*** period of ***five years*** from [date of entry into force of this Omnibus]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article ***3(2) and (6) and Article*** 11(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 11(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p.1.

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

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

6. A delegated act adopted pursuant to Article **3(2) and (6) and Article** 11(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p.1.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 11 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part I – point 2 – paragraph 4 – point 4
Decision No 406/2009/EC
Article 13 – paragraph 2

Text proposed by the Commission

(4) in Article 13, paragraph 2 is

Amendment

(4) in Article 13, paragraph 2 is

replaced by the following:

deleted.

“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.”

Or. en

Justification

Linked to amendments above - there is no more reference to this paragraph in the act.

Amendment 12

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part VI – point 53 – paragraph 1

Text proposed by the Commission

In order to update Regulation (EC) No 1221/2009 and to establish evaluation procedures, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Regulation and to supplement it with procedures for carrying out the peer evaluation of the EMAS Competent Bodies. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the 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.

Amendment

In order to update Regulation (EC) No 1221/2009 and to establish evaluation procedures, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend the Annexes to that Regulation and to supplement it with procedures for carrying out the peer evaluation of the EMAS Competent Bodies ***and to provide sectoral reference documents as well as guidance documents referring to registration of organisations and to harmonisation procedures.*** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 13
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 14
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 3 – point 1
Regulation (EC) No 1221/2009
Article 16 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

4. Guidance documents referring to

4. The Commission is empowered to adopt

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

delegated acts in accordance with Article 48a to supplement this Regulation by establishing guidance documents on the harmonisation procedures approved by the Forum of Competent Bodies.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 15 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 3 – point 2
Regulation (EC) No 1221/2009
Article 17 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 16 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 3 – point 3
Regulation (EC) No 1221/2009
Article 30 – paragraph 6 – subparagraph 1

Text proposed by the Commission

Amendment

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

6. The Commission ***is empowered to*** adopt ***delegated acts in accordance with Article 48a to supplement this Regulation by establishing guidance documents on the*** harmonisation procedures approved by the Forum of the Accreditation and Licensing Bodies.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 17
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 3 – point 4
Regulation (EC) No 1221/2009
Article 46 – paragraph 6

Text proposed by the Commission

Amendment

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

6. The Commission ***is empowered to adopt delegated acts in accordance with Article 48a to supplement this Regulation by adopting*** the sectoral reference documents referred to in paragraph 1 and the guide referred to in paragraph 4.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 18
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part VI – point 53 – paragraph 3 – point 6
Regulation (EC) No 1221/2009
Article 48a

Text proposed by the Commission

Article 48a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article **17(3)** and Article 48 shall be conferred on the Commission for **an indeterminate** period of **time** from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article **17(3)** and Article 48 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

Amendment

Article 48a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article **16(4)**, **Article 17(3)**, **Article 30(6)**, **Article 46(6)** and Article 48 shall be conferred on the Commission for a period of **five years** from [date of entry into force of this Omnibus]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Article **16(4)**, **Article 17(3)**, **Article 30(6)**, **Article 46(6)** and Article 48 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article **17(3)** and Article 48 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p. 1.

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

6. A delegated act adopted pursuant to Article **16(4), Article 17(3), Article 30(6), Article 46(6)** and Article 48 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 19 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part VII – point 59 – paragraph 4**

Text proposed by the Commission

In order to ensure uniform conditions for the implementation of Regulation (EC) No 2150/2002 concerning the production of results, the appropriate format for the transmission of results and the *contents* of the quality reports implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No

Amendment

In order to ensure uniform conditions for the implementation of Regulation (EC) No 2150/2002 concerning the production of results, the appropriate format for the transmission of results and the *structure and modalities* of the quality reports implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation

Justification

In line with amendment to Article aligning the wording to recent legislation in the area of statistics.

Amendment 20**Adina-Ioana Vălean****Proposal for a regulation****Annex I – Part VII – point 59 – paragraph 5 – point 1**

Regulation (EC) No 2150/2002

Article 1 – paragraph 5

Text proposed by the Commission

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

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

Amendment

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

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

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 21
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part VII – point 59 – paragraph 5 – point 2 – point a

Regulation (EC) No 2150/2002

Article 3 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 5b **to supplement this Regulation by defining** the quality and accuracy conditions.

Or. en

Justification

Clarification of empowerment (to supplement).

Amendment 22
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part VII – point 59 – paragraph 5 – point 4

Regulation (EC) No 2150/2002

Article 5a – paragraph 1

Text proposed by the Commission

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

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 5b **to amend this Regulation by adjusting it** to economic and technical developments in the collection and statistical processing of data, as well as the processing and the transmission of results and **by adapting** the specifications listed in the Annexes.

Or. en

Justification

Clarification of empowerment (i.e. to amend).

Amendment 23
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part VII – point 59 – paragraph 5 – point 4

Regulation (EC) No 2150/2002

Article 5b – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Article 1(5), Article 3(1) and (4) and Article 5a, shall be conferred on the Commission for ***an indeterminate*** period of time from [[date of entry into force of this Omnibus].

Amendment

2. The power to adopt delegated acts referred to in Article 1(5), Article 3(1) and (4), and Article 5a), shall be conferred on the Commission for ***a period of five years*** from [date of entry into force of this Omnibus]. ***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.***

Or. en

Justification

Alignment of the duration of the empowerment.

Amendment 24
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part VII – point 59 – paragraph 5 – point 5

Regulation (EC) No 2150/2002

Article 6 – paragraph 2 – point c

Text proposed by the Commission

(c) the ***contents*** of the quality reports as referred to in Section 7 of Annex I and Section 7 of Annex II.

Amendment

(c) the ***structure and modalities*** of the quality reports as referred to in Section 7 of Annex I and Section 7 of Annex II

Or. en

Justification

This amendment is consistent with other amendments to this legislative file as well as with more recent legislation in the area of statistics. The appropriate scope and intention of this paragraph seems to be to define structure and modalities of the report, which is clarified by the proposed amendment. In the spirit of good cooperation with the other institutions this amendment is also showing the effort of the European Parliament to find an agreement on this file by accepting the proposed procedure.

Amendment 25

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 91 – paragraph 1 – second indent

Text proposed by the Commission

Amendment

- to amend the Annexes to that Regulation
in certain cases;

- to amend the Annexes to that Regulation;

Or. en

Justification

Clarifying that the Annexes are always amended by delegated acts (in line with the new wording of Article 131).

Amendment 26

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 91 – paragraph 3 – point 1

Regulation (EC) No 1907/2006

Article 13 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 131a laying down test methods.

The Commission is empowered to adopt delegated acts in accordance with Article 131a *to supplement Regulation (EC) No 1907/2006 by* laying down test methods.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 27

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 91 – paragraph 3 – point 2

Regulation (EC) No 1907/2006

Article 41 – paragraph 7

Text proposed by the Commission

7. The Commission is empowered to adopt delegated acts in accordance with Article 131a, after consulting with the Agency, to **vary** the percentage of dossiers selected and to amend or **include** further criteria in paragraph 5.

Amendment

7. The Commission is empowered to adopt delegated acts in accordance with Article 131a, after consulting with the Agency, to **amend this Regulation by varying** the percentage of dossiers selected and **by updating or including** further criteria in paragraph 5.

Or. en

Justification

Clarification of empowerment (i.e. to amend).

Amendment 28

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 91 – paragraph 3 – point 4 a (new)

Regulation (EC) No 1907/2006

Article 73 – paragraph 2

Present text

2. A final decision **shall be taken** in accordance with **the procedure referred to in Article 133(4). The Commission shall send the draft amendment to the Member States at least 45 days before voting.**

Amendment

(4a) in Article 73, paragraph 2 is replaced by the following:

“2. A final decision to amend Annex XVII shall be taken by a delegated act that the Commission is empowered to adopt in accordance with Article 131a.”

Justification

Amending paragraph 2 in order to align the measure to delegated acts (there can be no reference to Article 133(4) (RPS) as it will be deleted from the act).

Amendment 29

Adina-Ioana Vălean

Proposal for a regulation**Annex I – Part IX – point 91 – paragraph 3 – point 6**

Regulation (EC) No 1907/2006

Article 131a

Text proposed by the Commission

Amendment

Article 131a

Article 131a

Exercise of the Delegation

Exercise of the Delegation

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

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

2. The power to adopt delegated acts referred to in Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(9) shall be conferred on the Commission for *an indeterminate* period of *time* from [date of entry into force of this Omnibus].

2. The power to adopt delegated acts referred to in Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(9) shall be conferred on the Commission for *a* period of *five years* from [date of entry into force of this Omnibus]. *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) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of

3. The delegation of power referred to in Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), **Article 73(2)**, Article 131 and Article 138(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the

the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 183

6. A delegated act adopted pursuant to Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), Article 131 and Article 138(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 183

6. A delegated act adopted pursuant to Article 13(2) and (3), Article 41(7), Article 58(1) and (8), Article 68(1) and (2), **Article 73(2)**, Article 131 and Article 138(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 30 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part IX – point 99 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

In addition, the Commission should be empowered to adopt acts in accordance with Article 290 of the Treaty to supplement this Regulation by authorising derogations from the prohibition on animal testing, in case a serious concern arises as regards the safety of an existing cosmetics ingredient.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 31
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part IX – point 99 – paragraph 3

Text proposed by the Commission

Amendment

In order to ensure uniform conditions for the implementation of the relevant provisions of Regulation (EC) No 1223/2009 concerning derogations in relation to animal testing, implementing powers should be conferred on the Commission to adopt decisions authorising derogations from the prohibition on animal testing. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. ***deleted***

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 32
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 99 – paragraph 4 – point 6

Regulation (EC) No 1223/2009

Article 18 – paragraph 2 – subparagraph 9

Text proposed by the Commission

The measures referred to in the sixth subparagraph shall be adopted by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 32(2).

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 31a by supplementing this Regulation by authorising the derogation referred to in the sixth subparagraph.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 33
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 99 – paragraph 4 – point 7

Regulation (EC) No 1223/2009

Article 20 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 31a establishing a list of common criteria for claims which may be used in respect of cosmetic products, after consulting the SCCS or other relevant authorities and taking into account the provisions of Directive 2005/29/EC.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 31a *to supplement this Regulation by* establishing a list of common criteria for claims which may be used in respect of cosmetic products, after consulting the SCCS or other relevant authorities and taking into account the provisions of Directive 2005/29/EC.

Or. en

Clarification of empowerment (i.e. to supplement).

Amendment 34

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part IX – point 99 – paragraph 4 – point 9

Regulation (EC) No 1223/2009

Article 31a

Text proposed by the Commission

Article 31a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), Article 20(2) and Article 31(1), (2) and (3) shall be conferred on the Commission for *an indeterminate* period of *time* from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16(8) and (9), Article 20(2) and Article 31(1), (2) and (3), may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union

Amendment

Article 31a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), **Article 18(2)**, Article 20(2) and Article 31(1), (2) and (3) shall be conferred on the Commission for *a* period of *five years* from [date of entry into force of this Omnibus]. ***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 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16(8) and (9), **Article 18(2)**, Article 20(2) and Article 31(1), (2) and (3), may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the

or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), Article 20(2) and Article 31(1), (2) and (3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 2(3), Article 13(8), Article 14(2), Article 15(1) and (2), Article 16 (8) and (9), **Article 18(2)**, Article 20(2) and Article 31(1), (2) and (3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 35

Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 143 – paragraph 1

Text proposed by the Commission

In order to achieve the objectives of Directive 2002/46/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Directive in order to adapt those Annexes to technical progress and to supplement that Directive as regards the purity criteria for substances listed in Annex II thereto, and the minimum amounts of vitamins and minerals that are to be present in food supplements. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Amendment

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

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 36
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 143 – paragraph 2

Text proposed by the Commission

Amendment

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.

deleted

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 37

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 143 – paragraph 3 – point 2

Directive 2002/46/EC

Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. The Commission is empowered to adopt delegated acts in accordance with Article 12a setting the minimum amounts of vitamins and minerals referred to in paragraph 3 of this Article.

4. The Commission is empowered to adopt delegated acts in accordance with Article 12a:

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).

(a) setting the minimum amounts of vitamins and minerals referred to in paragraph 3 of this Article;

(b) setting the maximum amounts of vitamins and minerals referred to in paragraphs 1 and 2 of this Article.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 38
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 143 – paragraph 3 – point 3
Directive 2002/46/EC
Article 12 – paragraph 3

Text proposed by the Commission

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

Amendment

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

“In order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, the Commission is empowered to adopt delegated acts in accordance with Article 12a, to supplement this Directive.

The Member State that has adopted safeguard measures may in that event retain them until those delegated acts have been adopted.”

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts. In the absence of a justification on the reasons for deletion of Article 12(3), it is proposed to maintain the content of that provision previously subjected to the Regulatory Procedure with Scrutiny, and to align it to delegated acts.

Amendment 39
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 143 – paragraph 3 – point 4

Text proposed by the Commission

Article 12a

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

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

3. The delegation of power referred to in Article 4(2) and (5) and Article 5(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.”

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

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

Amendment

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), Article 5(4), ***and Article 12(3)***, shall be conferred on the Commission for ***a*** period of ***five years*** from [date of entry into force of this Omnibus]. ***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 12(3)*** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.”

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

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

6. A delegated act adopted pursuant to Article 4(2) and (5), Article 5(4), and Article 12(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p. 1.

6. A delegated act adopted pursuant to Article 4(2) and (5), Article 5(4), **and Article 12(3)** shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 40 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part XII – point 144 – paragraph 2**

Text proposed by the Commission

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.

Amendment

deleted

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 41
Adina-Ioana Vălean

Proposal for a regulation
Annex I – part XII – point 144 – paragraph 3 – point 1
Directive 2002/98/EC
Article 27a – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in the first and third paragraphs of Article 29 shall be conferred for ***an indeterminate*** period of ***time*** from [date of entry into force of this omnibus].

Amendment

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 [date of entry into force of this omnibus]. ***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.***

Or. en

Justification

Alignment of the duration of the empowerment.

Amendment 42
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 144 – paragraph 3 – point 3 – point a
Directive 2002/98/EC
Article 29 – paragraph 1

Text proposed by the Commission

The Commission is empowered to adopt

Amendment

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.

delegated acts in accordance with Article 27a **to amend** the technical requirements set out in Annexes I to IV in order to adapt them to technical and scientific progress.

Or. en

Justification

Clarification of empowerment (i.e. to amend).

Amendment 43

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 144 – paragraph 3 – point 3 – point b

Directive 2002/98/EC

Article 29 – paragraph 2 – point i

Text proposed by the Commission

Amendment

(b) in the second paragraph, point (i) is deleted;

deleted

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 44

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 144 – paragraph 3 – point 3 – point d

Directive 2002/98/EC

Article 29 – paragraph 5

Text proposed by the Commission

Amendment

(d) the following fifth paragraph is added:

deleted

"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)."

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 45 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part XII – point 146 – paragraph 2 – point 2
Directive 2003/99/EC
Article 5 – paragraph 1

Text proposed by the Commission

1. If data collected through routine monitoring in accordance with Article 4 are not sufficient, the Commission is empowered to adopt delegated acts in accordance with Article 11a, laying down coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. Those delegated acts shall be adopted especially when specific needs are identified and when there is need to assess risks or to establish baseline values related to zoonoses or zoonotic agents at the level of Member States or at Union level.

Amendment

1. If data collected through routine monitoring in accordance with Article 4 are not sufficient, the Commission is empowered to adopt delegated acts in accordance with Article 11a ***to supplement this Directive*** by laying down coordinated monitoring programmes concerning one or more zoonoses or zoonotic agents. Those delegated acts shall be adopted especially when specific needs are identified and when there is need to assess risks or to establish baseline values related to zoonoses or zoonotic agents at the level of Member States or at Union level.

Or. en

Justification

Clarification of empowerment (i.e to supplement).

Amendment 46 **Adina-Ioana Vălean**

Proposal for a regulation

Annex I – Part XII – point 146 – paragraph 2 – point 3

Directive 2003/99/EC

Article 11

Text proposed by the Commission

(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.

Amendment

(3) Article 11 *is* replaced by the following:

“Article 11

Amendments to the Annexes and implementing measures

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.

Other implementing measures may be adopted in accordance with the regulatory procedure referred to in Article 12(2).

Or. en

Justification

The criteria inserted are new, however they make the empowerment more precise by explaining what could justify amending the Annexes (thus not just giving a “blank” empowerment). Since the Commission proposal has kept the last paragraph of Article 11 without any changes, it makes sense to add a deletion of the “transitional measures” mentioned in that paragraph (as transitional measures are no longer needed).

Amendment 47

Adina-Ioana Vălean

Proposal for a regulation

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Annex I – Part XII – point 147 – paragraph 1

Text proposed by the Commission

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.

Amendment

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 determining which food and feed falls within the scope of different sections of the 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, ***by establishing measures for operators to satisfy the competent authorities, measures necessary for operators to comply with the labelling requirements*** and by establishing specific rules concerning the information to be given by mass caterers providing food to the final consumer.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 48
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 3

Text proposed by the Commission

In order to ensure uniform conditions for the implementation of Regulation (EC) No 1829/2003, implementing powers should

Amendment

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.

be conferred on the Commission concerning rules to facilitate the uniform application of certain provisions. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 49 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 4 –point 1
Regulation (EC) No 1829/2003
Article 3 – paragraph 2

Text proposed by the Commission

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).***

Amendment

2. The Commission ***is empowered to adopt delegated acts in accordance with Article 34a to supplement this Regulation by determining*** whether a type of food falls within the scope of this Section.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 50
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 147 – paragraph 4 – point 2

Regulation (EC) No 1829/2003

Article 12 – paragraph 4

Text proposed by the Commission

4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, establishing appropriate lower thresholds, in particular in respect of foods containing or consisting of GMOs, or taking account of advances in science and technology.

Amendment

4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, ***to supplement 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.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 51
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 147 – paragraph 4 – point 3

Regulation (EC) No 1829/2003

Article 14

Text proposed by the Commission

Article 14

Delegated and implementing powers

1. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, ***adopting*** specific rules concerning the information to be given by mass caterers providing food to the final consumer. In order to take account of the specific situation of mass caterers, such rules may provide for adaptation of the requirements set out in Article 13(1)(e).

Amendment

Article 14

Delegated and implementing powers

1. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, ***to supplement this Regulation by establishing:***

(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) 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:

2. The Commission may adopt ***detailed rules to facilitate the uniform application of Article 13*** by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2).

(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).

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 52
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 4 – point 4
Regulation (EC) No 1829/2003
Article 15 – paragraph 2

Text proposed by the Commission

Amendment

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).***

2. The Commission ***is empowered to adopt delegated acts, in accordance with Article 34a, to supplement this Regulation by determining*** whether a type of feed falls within the scope of this Section.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 53
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 4 – point 5
Regulation (EC) No 1829/2003
Article 24 – paragraph 4

Text proposed by the Commission

Amendment

4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, establishing appropriate lower thresholds, in particular in respect of feed containing or consisting of GMOs, or taking account of advances in science and technology.

4. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, ***to supplement 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.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 54
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 4 – point 6

Text proposed by the Commission

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).

Amendment

Article 26

Delegated and implementing powers

1. The Commission is empowered to adopt delegated acts, in accordance with Article 34a, to supplement this Regulation by establishing:

(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.

2. The Commission may adopt detailed rules to facilitate the uniform application of Article 25 by means of implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 35(2).

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 55
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 147 – paragraph 4 –point 8
Regulation (EC) No 1829/2003
Article 34a

Article 34a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 12(4), Article 14(1a), Article 24(4) and Article 32, sixth paragraph, shall be conferred on the Commission for **an indeterminate** period of **time** from [date of entry into force of this Omnibus].

3. The delegations of power referred to in Article 12(4), Article 14(1a), Article 24(4) and Article 32, sixth paragraph, may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. As soon as it adopts a delegated act, the

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 3(2)**, Article 12(4), Article 14(1), **Article 15 (2)**, Article 24(4), **Article 26 (1)** and Article 32, sixth paragraph, shall be conferred on the Commission for **a** period of **five years** from [date of entry into force of this Omnibus]. ***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 3(2)**, Article 12(4), Article 14(1), **Article 15(2)**, Article 24(4), **Article 26(1)** and Article 32, sixth paragraph, may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. As soon as it adopts a delegated act, the

Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 12(4), Article 14(1a), Article 24(4) or Article 32, sixth paragraph, shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

* OJ L 123, 12.5.2016, p.1.

Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to **Article 3(2)**, Article 12(4), Article 14(**1**), **Article 15(2)**, Article 24(4), **Article 26(1)** 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.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 56 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part XII – point 151 – paragraph 1**

Text proposed by the Commission

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

Amendment

In order to achieve the objectives of Regulation (EC) No 2160/2003, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I, II and III to that Regulation and to supplement that Regulation as regards the Union targets for the reduction of the prevalence of zoonoses and zoonotic

agents, specific control methods, specific rules on criteria relating to imports from third countries, the responsibilities and tasks of the Union reference laboratories and certain responsibilities and tasks of the national reference laboratories. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

agents, specific control methods, specific rules on criteria relating to imports from third countries, the responsibilities and tasks of the Union reference laboratories, for ***approving methods for testing***, and ***as regards*** certain responsibilities and tasks of the national reference laboratories. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 57 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part XII – point 151 – paragraph 2**

Text proposed by the Commission

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.

Amendment

deleted

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 58

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 1 – point a

Regulation (EC) No 2160/2003

Article 4 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the Union targets for the reduction of the prevalence of zoonoses and zoonotic agents listed in Annex I, column 1, in the animal populations listed in Annex I, column 2, taking account, in particular, of:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning the Union targets for the reduction of the prevalence of zoonoses and zoonotic agents listed in Annex I, column 1, in the animal populations listed in Annex I, column 2, ***to supplement this Regulation***, taking account, in particular, of:

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 59

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 3

Regulation (EC) No 2160/2003

Article 8 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance ***with*** Article 13a concerning:

Amendment

1. The Commission is empowered to adopt delegated acts, ***to supplement this Regulation***, in accordance with Article 13a

concerning:

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 60

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 4

Regulation (EC) No 2160/2003

Article 9 – paragraph 4

Text proposed by the Commission

4. Without prejudice to Article 5(6), the Commission is empowered to adopt delegated acts in accordance with Article 13a, establishing the rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article.

Amendment

4. Without prejudice to Article 5(6), the Commission is empowered to adopt delegated acts in accordance with Article 13a, ***to supplement this Regulation, by*** establishing the rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 61

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 5

Regulation (EC) No 2160/2003

Article 10 – paragraph 5

Text proposed by the Commission

The authorisation may be withdrawn in accordance with the same procedure. ***and,*** without prejudice to Article 5(6), the

Amendment

The authorisation may be withdrawn in accordance with the same procedure. Without prejudice to Article 5(6), the

Commission is empowered to adopt delegated acts in accordance with Article 13a establishing specific rules concerning such criteria.

Commission is empowered to adopt delegated acts in accordance with Article 13a, ***to supplement this Regulation,*** establishing specific rules concerning such criteria.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 62

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 6 – point a

Regulation (EC) No 2160/2003

Article 11 – paragraph 2

Text proposed by the Commission

2. The Commission is empowered to adopt delegated acts in accordance with Article 13a ***laying*** down the responsibilities and tasks of the Union reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories.

Amendment

2. The Commission is empowered to adopt delegated acts in accordance with Article 13a, ***to supplement 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.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 63

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 6 – point b

Regulation (EC) No 2160/2003

Article 11 – paragraph 4

Text proposed by the Commission

Amendment

4. The Commission is empowered to adopt delegated acts in accordance with Article 13a laying down certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a).

4. The Commission is empowered to adopt delegated acts in accordance with Article 13a ***to supplement 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).

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 64

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 7

Regulation (EC) No 2160/2003

Article 12 – paragraph 3 – third subparagraph

Text proposed by the Commission

Amendment

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).***

The Commission ***is empowered to adopt delegated acts in accordance with Article 13a to supplement this Regulation by approving*** other methods for testing ***than those*** referred in ***the first and second subparagraph of this*** paragraph.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 65

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 8

Regulation (EC) No 2160/2003

Article 13

Text proposed by the Commission

Article 13

The Commission is empowered to adopt delegated acts in accordance with Article 13a amending elements concerning the relevant health certificates.

Other implementing *or transitional* measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).

Amendment

Article 13

Implementing measures

The Commission is empowered to adopt delegated acts in accordance with Article 13a ***to supplement this Regulation, by*** amending elements concerning the relevant health certificates.

Other implementing measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).

Or. en

Justification

Clarification of empowerment (i.e. to supplement). Since the Commission proposal has kept the last paragraph of Article 13 without any changes, it makes sense to add a deletion of the “transitional measures” mentioned in that paragraph (as transitional measures are no longer needed).

Amendment 66

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 151 – paragraph 3 – point 9

Regulation (EC) No 2160/2003

Article 13a

Text proposed by the Commission

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

2. The power to adopt delegated acts referred to in Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4) ***and Article 13*** shall be conferred for ***an***

Amendment

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

2. The power to adopt delegated acts referred to in Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4), ***Article 12(3) the third subparagraph,*** and Article

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

3. The delegation of powers referred to in Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), 11(2) and (4) and Article 13 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4) and Article 13 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the

13 shall be conferred for *a* period of *five years* from [date of entry into force of this Omnibus]. *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), Article 8(1), Article 9(4), Article 10(5), 11(2) and (4), **Article 12(3) the third subparagraph**, and Article 13 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 3(1), (6), and (7), Article 5(6), Article 8(1), Article 9(4), Article 10(5), Article 11(2) and (4), **Article 12(3) the third subparagraph**, 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

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.

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

or if, before the expiry of 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.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 67 **Adina-Ioana Vălean**

Proposal for a regulation **Annex I – Part XII – point 152 – paragraph 1**

Text proposed by the Commission

In order to achieve the objectives of Directive 2004/23/EC, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to supplement that Directive with traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality, *and* to supplement that Directive with certain technical requirements. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as

Amendment

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, *to establish procedures for ensuring traceability and for verifying the equivalent standards of quality and safety of imported tissues and cells*, and to supplement that Directive with certain technical requirements. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in

Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 68

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 152 – paragraph 2

Text proposed by the Commission

Amendment

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.

Deleted

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 69

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 152 – paragraph 3 – point 1

Text proposed by the Commission

5. The Commission is empowered to adopt delegated acts in accordance with Article 28a to establish traceability requirements for tissues and cells, **as well as** for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety.

Amendment

5. The Commission is empowered to adopt delegated acts in accordance with Article 28a **to supplement this Directive, by establishing** traceability requirements for tissues and cells, for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety, **as well as by establishing the procedures for ensuring traceability at Union level.**

Or. en

Justification

Amendments to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts, and to clarify the empowerment (i.e. to supplement).

Amendment 70
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 152 – paragraph 3 – point 1
Directive 2004/23/EC
Article 8 – paragraph 6

Text proposed by the Commission

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).";

Amendment

deleted

Or. en

Justification

Amendments to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts, and to clarify the empowerment (i.e. to supplement).

Amendment 71
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 152 – paragraph 3 – point 2
Directive 2004/23/EC
Article 9 – paragraph 4

Text proposed by the Commission

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).*

Amendment

4. The Commission is empowered to adopt delegated acts in accordance with Article 28a to supplement this Directive, by establishing the procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1.

Or. en

Justification

Amendments to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 72
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 152 – paragraph 3 – point 3
Directive 2004/23/EC
Article 28 – paragraph 2

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 28a with respect to the technical requirements referred to in points (a) to (i) of the first paragraph.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 28a **to supplement this Directive** with respect to the technical requirements referred to in points (a) to (i) of the first paragraph.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 73
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 152 – paragraph 3 – point 4

Directive 2004/23/EC

Article 28a

Text proposed by the Commission

Article 28a

Exercise of the delegation

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

2. The delegation of power referred to in Article 8(5) and in the second paragraph of Article 28 shall be conferred for an *indeterminate* period *of time* from the [date of entry into force of this omnibus].

3. The delegation of power referred to in Article 8(5) and in the second paragraph of Article 28 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better

Amendment

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), **Article 9(4)**, and in the second paragraph of Article 28 shall be conferred for *a* period *of five years* from the [date of entry into force of this omnibus]. ***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), **Article 9(4)**, and in the second paragraph of Article 28 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better

Law-Making of 13 April 2016*.

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

6. A delegated act adopted pursuant to Article 8(5) and in the second paragraph of Article 28 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

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

Law-Making of 13 April 2016*.

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

6. A delegated act adopted pursuant to Article 8(5), **Article 9(4)**, 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.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 74

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 153 – paragraph 2 – point 1

Regulation (EC) No 852/2004

Article 4 – paragraph 4 – introductory part

Text proposed by the Commission

4. The Commission is empowered to adopt delegated acts in accordance with Article 13a **adopting** the specific hygiene measures referred to in paragraph 3, in particular concerning:

Amendment

4. The Commission is empowered to adopt delegated acts in accordance with Article 13a **to supplement this Regulation by laying down** the specific hygiene measures referred to in paragraph 3, in particular concerning:

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 75
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 153 – paragraph 2 – point 2

Regulation (EC) No 852/2004

Article 6 – paragraph 3 – point c

Text proposed by the Commission

(c) by a delegated act that the Commission is empowered to adopt in accordance with Article 13a.

Amendment

(c) by a delegated act that the Commission is empowered to adopt in accordance with Article 13a ***to supplement this Regulation.***

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 76
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 153 – paragraph 2 – point 4

Regulation (EC) No 852/2004

Article 13 – paragraph 2

Text proposed by the Commission

2. The Commission is empowered to adopt delegated acts in accordance with Article 13a granting derogations from ***Annexes I and II***, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the ***following*** objectives of this Regulation:

Amendment

2. The Commission is empowered to adopt delegated acts in accordance with Article 13a ***to supplement this regulation by*** granting derogations from ***Annex I and II, in particular to facilitate the implementation of Article 5 for small businesses***, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the 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.

Or. en

Justification

This amendment is more true to the original wording of paragraph 2. Derogations should not affect any of the objectives of the Regulation. The wording proposed by the Commission does not make any sense, since it mixes up the reasons for derogations with the objectives of the Regulation (points (a) and (b) are not the objectives of the Regulation). In addition, point (b) is not present in the current wording of Article 13.

Amendment 77

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 153 – paragraph 2 – point 6

Regulation (EC) No 852/2004

Article 13a

Text proposed by the Commission

Article 13a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 4(4), Article 6(3)(c), **Article 12** and Article 13(1) and (2) shall be conferred for *an indeterminate* period of *time* from [date of entry into force of this Omnibus].

Amendment

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 [date of entry into force of this Omnibus]. ***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***

3. The delegation of powers referred to in Article 4(4), Article 6(3)(c), **Article 12** and Article 13(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6; A delegated act adopted pursuant to Article 4(4), Article 6(3)(c), **Article 12** and Article 13(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

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

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 adapting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016*.

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

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

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 78 **Adina-Ioana Vălean**

Proposal for a regulation

Annex I – Part XII – point 155 – paragraph 2 – point 2

Regulation (EC) No 854/2004

Article 17 – paragraph 2 – introductory part

Text proposed by the Commission

2. The Commission is empowered to adopt delegated acts in accordance with Article 18a granting derogations from Annexes I,II, III, IV, V and VI them, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the **following** objectives of this Regulation:

Amendment

2. The Commission is empowered to adopt delegated acts **to supplement this Regulation**, in accordance with Article 18a granting derogations from Annexes I,II, III, IV, V and VI them, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation, **in order to**:

Or. en

Justification

The amendment in Article 17(2) clarifies the empowerment (i.e. to supplement).

Amendment 79 **Adina-Ioana Vălean**

Proposal for a regulation

Annex I – Part XII – point 155 – paragraph 2 – point 3 – point a

Regulation (EC) No 854/2004

Article 18 – introductory part

Text proposed by the Commission

Without prejudice to the general application of **Article 16** and Article 17(1), the Commission **may** lay down the following measures **by means of implementing acts. Those implementing acts shall be adopted in accordance with**

Amendment

Without prejudice to the general application of Article 17(1), the Commission **is empowered to adopt delegated acts to supplement this Regulation** in accordance with Article 18a to lay down the following measures:

the procedure referred to in Article 12(2)";

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts. Reference to Article 16 is no longer needed, as that article is deleted according to the Commission proposal.

Amendment 80
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 155 – paragraph 2 – point 4
Regulation (EC) No 854/2004
Article 18a

Text proposed by the Commission

Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 17(1) and (2) shall be conferred *for an indeterminate* period of *time* from [date of entry into force of this Omnibus].

3. The delegation of powers referred to in Article 17(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power

Amendment

Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 17(1) and (2) **and in Article 18** shall be conferred **on the Commission for a period of five years** from [date of entry into force of this Omnibus]. **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 17(1) and (2) **and in Article 18** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of

specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant Article 17(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

* OJ L 123, 12.5.2016, p.1.

the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant Article 17(1) and (2) **and in Article 18** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

* OJ L 123, 12.5.2016, p.1.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 81
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 158 – paragraph 1 – intend 5 a (new)

Text proposed by the Commission

Amendment

- 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.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 82
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 158 – paragraph 3

Text proposed by the Commission

Amendment

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. ***deleted***

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with

Scrutiny to delegated acts.

Amendment 83

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 1 – point a

Regulation (EC) No 1924/2006

Article 1 – paragraph 2 – subparagraph 2

Text proposed by the Commission

In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning the labelling information for those non-prepackaged foodstuffs. National provisions may apply until the eventual adoption of those delegated acts.

Amendment

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, ***to supplement this Regulation***, concerning the labelling information for those non-prepackaged foodstuffs. National provisions may apply until the eventual adoption of those delegated acts.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 84

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 1 – point b

Regulation (EC) No 1924/2006

Article 1 – paragraph 4

Text proposed by the Commission

4. For generic descriptors (denominations) which have traditionally been used to

Amendment

4. For generic descriptors (denominations) which have traditionally been used to

indicate a particularity of a class of foods or beverages which could imply an effect on human health, food business operators concerned may apply for a derogation from paragraph 3. The application shall be sent to the national competent authority of a Member State which will forward it to the Commission without delay. The Commission shall adopt and make public the rules for food business operators according to which such applications shall be made, so as to ensure that the application is dealt with transparently and within a reasonable time. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning derogations from paragraph 3.

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 **to supplement this Regulation**, concerning derogations from paragraph 3.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 85

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 2 – point b

Regulation (EC) No 1924/2006

Article 3 – paragraph 2a (new)

Text proposed by the Commission

The Commission is empowered to adopt delegated acts in accordance with Article 24a derogating from point (d) of the second **subparagraph** of this Article in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet; the delegated acts shall include conditions for the application of the derogations, taking into account the special conditions present in Member States.

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 24a **to supplement this Regulation, by** derogating from point (d) of the second **paragraph** 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.

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 86
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 3 – point a – point i

Regulation (EC) No 1924/2006

Article 4 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 24a by 19 January 2009 establishing specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles.";

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 24a by 19 January 2009, **to supplement 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.";

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 87
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 3 – point a – point ii

Regulation (EC) No 1924/2006

Article 4 – paragraph 1 – subparagraph 6

Text proposed by the Commission

"The Commission is empowered to adopt delegated acts in accordance with Article

Amendment

"The Commission is empowered to adopt delegated acts in accordance with Article

24a concerning the update of nutrient profiles and their conditions of use to take into account relevant scientific developments. To this purpose, interested parties, in particular food business operators and consumer groups shall be consulted.";

24a *to supplement this Regulation*, concerning the update of nutrient profiles and their conditions of use to take into account relevant scientific developments. To this purpose, interested parties, in particular food business operators and consumer groups shall be consulted.";

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 88

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 3 – point b

Regulation (EC) No 1924/2006

Article 4 – paragraph 5

Text proposed by the Commission

5. The Commission is empowered to adopt delegated acts in accordance with Article 24a concerning measures determining the foods or categories of foods other than those referred to in paragraph 3 of this Article for which nutrition or health claims are to be restricted or prohibited in the light of scientific evidence.

Amendment

5. The Commission is empowered to adopt delegated acts in accordance with Article 24a *to supplement this Regulation*, concerning measures determining the foods or categories of foods other than those referred to in paragraph 3 of this Article for which nutrition or health claims are to be restricted or prohibited in the light of scientific evidence.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 89

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 5

Text proposed by the Commission

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).***

Amendment

3. After consulting the Authority, the Commission ***shall adopt, by means of delegated acts*** in accordance with Article 24a, 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. .

Or. en

Justification

Amendment to align measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts (wording suggested by the Legal Service).

Amendment 90
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 158 – paragraph 4 – point 5
Regulation (EC) No 1924/2006
Article 13 – paragraph 4

Text proposed by the Commission

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).***

Amendment

4. After consulting the Authority, the Commission ***shall adopt, by means of delegated acts*** in accordance with Article 24a, on its own initiative or following a request by a Member State, any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence. .

Or. en

Justification

Amendment to align measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts (wording suggested by the Legal Service).

Amendment 91

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 6 – point a

Regulation (EC) No 1924/2006

Article 17 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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)."*

Amendment

The Commission *is empowered to* adopt a final decision on the application, *to supplement this Regulation*, by means of *delegated acts in accordance with Article 24a.*

Or. en

Justification

Amendment to align measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 92

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 6 – point b

Regulation (EC) No 1924/2006

Article 17 – paragraph 3 – subparagraph 2 – point b

Text proposed by the Commission

(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*

Amendment

(b) before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the Commission *is empowered to* adopt measures for authorisation of the claim without restriction for use, *to supplement this Regulation*, by means of *delegated acts in accordance with Article 24a.*

the procedure referred to in Article 25(2).

Or. en

Justification

Amendment to align measures previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 93

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 7 – point a

Regulation (EC) No 1924/2006

Article 18 – paragraph 5 – subparagraph 1

Text proposed by the Commission

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)."*

Amendment

The Commission shall adopt delegated acts in accordance with Article 24a, to supplement this Regulation, concerning its decision on the application, where the Authority issues an opinion that does not support the inclusion of the claim in the list referred to in paragraph 4.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 94

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 7 – point b

Regulation (EC) No 1924/2006

Article 18 – paragraph 5 – subparagraph 2 – point b

Text proposed by the Commission

(b) before the expiry of the five-year

Amendment

(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).*

period, if the claim still meets the conditions laid down in this Regulation, the Commission *shall adopt delegated acts in accordance with Article 24a, to supplement this Regulation, for authorisation of the claim without restriction of use.*

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 95 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part XII – point 158 – paragraph 4 – point 8
Regulation (EC) No 1924/2006
Article 24a

Text proposed by the Commission

"Article 24a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 1(2) and (4), Article 3, Article 4(1) and (5) **and** Article 8(2) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

Amendment

"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), Article 8(2), **Article 13(3) and (4), Article 17(3) and (4), Article 18(5), and Article 28 paragraph 6(a)** shall be conferred on the Commission for **a** period of **five years** from [date of entry into force of this Omnibus]. **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**

3. The delegation of power referred to in Article 1(2) and (4), Article 3, Article 4(1) and (5) **and** Article 8(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 1(2) and (4), Article 3, Article 4(1) and (5) **and** Article 8(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

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), Article 8(2), **Article 13(3) and (4), Article 17(3) and (4),, Article 18(5), and Article 28 paragraph 6(a)** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 1(2) and (4), Article 3, Article 4(1) and (5), Article 8(2), **Article 13(3) and (4), Article 17(3) and (4),, Article 18(5), and Article 28 paragraph 6(a)** 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.";

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 96

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 158 – paragraph 4 – point 10 – point b

Regulation (EC) No 1924/2006

Article 28 – paragraph 6 – point a – point ii

Text proposed by the Commission

(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)***.

Amendment

(ii) after consulting the Authority, the Commission shall adopt ***delegated acts***, to ***supplement this Regulation***, by laying down the health claims authorised in this way, in accordance with ***Article 24a***.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 97

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 1

Text proposed by the Commission

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

Amendment

In order to achieve the objectives of Regulation (EC) No 1925/2006, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to amend Annexes I and II to that Regulation to adapt it to technical

and scientific progress and to amend Annex III to that Regulation to allow the use of vitamins, minerals and of certain other substances prohibited, restricted or under Union scrutiny **and** to supplement that Regulation by determining the additional foods or categories of foods to which vitamins and minerals may not be added, by determining the purity criteria for vitamin formulations and mineral substances and by determining the minimum amount by derogation from the significant amount for the presence of a vitamin or mineral in the food. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

and scientific progress and to amend Annex III to that Regulation to allow the use of vitamins, minerals and of certain other substances prohibited, restricted or under Union scrutiny , 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, **as well as by setting the maximum amounts of the vitamins or minerals added to food and to define the conditions restricting or prohibiting the addition of a specific vitamin or mineral.**.. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 98

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 2

Text proposed by the Commission

Amendment

In order to ensure uniform conditions for the implementation of Regulation (EC) No 1925/2006, implementing powers should be conferred on the Commission as regards the amounts of the vitamins or minerals added to food and as regards the conditions restricting or prohibiting the addition of a specific vitamin or mineral. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. **deleted**

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 99

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 2

Regulation (EC) No 1925/2006

Article 4 – paragraph 2

Text proposed by the Commission

Amendment

The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the additional foods or categories of foods to which vitamins and minerals may not be added in the light of scientific evidence and taking into account their nutritional value.

The Commission is empowered to adopt delegated acts in accordance with Article 13a ***to supplement this Regulation,*** concerning measures determining the additional foods or categories of foods to which vitamins and minerals may not be added in the light of scientific evidence and taking into account their nutritional value.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 100
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 3

Regulation (EC) No 1925/2006

Article 5 – paragraph 1

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the purity criteria for vitamin formulations and mineral substances listed in Annex II, except where purity criteria apply pursuant to paragraph 2 of this Article.

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 13a **to supplement this Regulation** concerning measures determining the purity criteria for vitamin formulations and mineral substances listed in Annex II, except where purity criteria apply pursuant to paragraph 2 of this Article.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 101
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 4 – point a

Regulation (EC) No 1925/2006

Article 6 – paragraph 1

Text proposed by the Commission

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

Amendment

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 **adopt delegated acts in accordance with Article 13a, to supplement this Regulation,** concerning those **maximum** amounts. 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

be those present in the foods when prepared for consumption according to the manufacturer's instructions.

present in the foods when prepared for consumption according to the manufacturer's instructions.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts, and clarification of empowerment (i.e. to supplement).

Amendment 102
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 4 – point a
Regulation (EC) No 1925/2006
Article 6 – paragraph 2

Text proposed by the Commission

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).***

Amendment

2. The Commission shall ***adopt delegated acts in accordance with Article 13a concerning the definition of*** any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods.

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 103
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 4 – point b
Regulation (EC) No 1925/2006
Article 6 – paragraph 6

Text proposed by the Commission

Amendment

6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011. The Commission is empowered to adopt delegated acts in accordance with Article 13a concerning measures determining the minimum amounts of vitamin or mineral in the food, including any lower amounts by derogation from the significant amounts, for specific foods or categories of foods.

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, ***to supplement this Regulation,*** concerning measures determining the minimum amounts of vitamin or mineral in the food, including any lower amounts by derogation from the significant amounts, for specific foods or categories of foods.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 104 **Adina-Ioana Vălean**

Proposal for a regulation

Annex I – Part XII – point 159 – paragraph 3 – point 5

Regulation (EC) No 1925/2006

Article 7 – paragraph 1

Text proposed by the Commission

1. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients. The Commission is empowered to adopt delegated acts in accordance with Article 13a derogating from this rule as regards a specific nutrient.

Amendment

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 ***to supplement this Regulation,*** derogating from this rule as regards a specific nutrient.

Or. en

Clarification of empowerment (i.e. to supplement).

Amendment 105
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 159 – paragraph 3 – point 7
Regulation (EC) No 1925/2006
Article 13a

Text proposed by the Commission

Article 13a

Exercise of the delegation

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

2. The power to adopt referred to in Article 3(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (5) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 3(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in *the Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts

Amendment

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(1), (2) and** (6), Article 7(1) and Article 8(2) and (5) shall be conferred on the Commission for an indeterminate period of time **of five years** from [date of entry into force of this Omnibus]. ***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(2)**, Article 6(6), Article 7(1) and Article 8(2) and (5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in *the Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts

already in force.

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

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

6. A delegated act adopted pursuant to Article 3(3), Article 4, Article 5(1), Article 6(6), Article 7(1) and Article 8(2) and (5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

already in force.

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

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

6. A delegated act adopted pursuant to Article 3(3), Article 4, Article 5(1), **Article 6(2)**, 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.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 106 **Adina-Ioana Vălean**

Proposal for a regulation
Annex I – Part XII – point 164 – paragraph 3 – point 5
Directive 2009/128/EC
Article 20a – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Article 5(3), Article 8(7), Article 14(4) and Article 15(1) shall be conferred on the Commission for ***an indeterminate*** period of ***time*** from the [date of entry into force of this Omnibus].

Amendment

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 [date of entry into force of this Omnibus]. ***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.***

Or. en

Justification

Alignment of the duration of the empowerment.

Amendment 107
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 164 – paragraph 3 – point 5 a (new)
Directive 2009/128/EC
Article 21 – paragraph 2

Text proposed by the Commission

Amendment

(5a) in Article 21, paragraph 2 is deleted

Or. en

Justification

This amendment deletes the paragraph referring to Regulatory Procedure of Scrutiny in Article 21 (which by an oversight was not deleted in the proposal by the Commission).

Amendment 108
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 165 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 109
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 165 – paragraph 2

Text proposed by the Commission

Amendment

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. **deleted**

Or. en

Justification

In line with amendments to Articles aligning measures previously submitted under Regulatory Procedure with Scrutiny to Delegated Acts.

Amendment 110
Adina-Ioana Vălean

Proposal for a regulation
Annex I – part XII – point 165 – paragraph 3 – point 1
Regulation (EC) No 470/2009
Article 13 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The Commission is empowered to adopt delegated acts, in accordance with Article 24a, concerning the adoption of:

2. The Commission is empowered to adopt delegated acts, in accordance with Article 24a, **to supplement this Regulation**, concerning the adoption of:

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 111

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 165 – paragraph 3 – point 2

Regulation (EC) No 470/2009

Article 18 – paragraph 1

Text proposed by the Commission

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).*

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)."*

Amendment

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 *is empowered to adopt delegated acts in accordance with Article 24a to supplement this Regulation by establishing* 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).

Where, in the case of risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 24b shall apply to delegated acts adopted pursuant to this Article."

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts, including with respect to the urgency procedure.

Amendment 112

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 165 – paragraph 3 – point 2

Text proposed by the Commission

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).***";

Amendment

Where, in the case of risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 24b shall apply to delegated acts adopted pursuant to this Article.";

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts, including with respect to the urgency procedure.

Amendment 113
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 165 – paragraph 3 – point 3
Regulation (EC) No 470/2009
Article 19 – paragraph 3 – subparagraph 2

Text proposed by the Commission

The Commission is empowered to adopt delegated act, in accordance with Article 24a, concerning the ***methological*** principles and scientific methods for establishing reference point for action.

Amendment

"The Commission is empowered to adopt delegated act, in accordance with Article 24a, ***to supplement this Regulation,*** concerning the ***methodological*** principles and scientific methods for establishing reference point for action.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 114
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 165 – paragraph 3 – point 4
Regulation (EC) No 470/2009
Article 24 – paragraph 4

Text proposed by the Commission

Amendment

4. The Commission is empowered to adopt delegated act, in accordance with Article 24a, concerning the application of this Article.

4. The Commission is empowered to adopt delegated act, in accordance with Article 24a, **to supplement this Regulation** concerning the application of this Article.

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 115
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 165 – paragraph 3 – point 5 – introductory sentence

Text proposed by the Commission

Amendment

(5) the following **Article** 24a *is* inserted under Title V:

(5) the following **Articles** 24a **and 24b are** inserted under Title V:

Or. en

Justification

Insertion of a reference to Article 24b (new) in line with the amendments below.

Amendment 116
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 165 – paragraph 3 – point 5
Regulation (EC) No 470/2009
Article 24a

Text proposed by the Commission

Amendment

Article 24a

Article 24a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 13(2), Article 19(3) and Article 24(4) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of this Omnibus].

3. The delegation of power referred to in Article 13(2), Article 19(3) and Article 24(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 13(2), Article 19(3) and Article 24(4) shall enter into force only if no objection has been expressed either by the

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 18**, Article 19(3) and Article 24(4) shall be conferred on the Commission for an indeterminate period of time **of five years** from [date of entry into force of this Omnibus]. ***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 18**, Article 19(3) and Article 24(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 13(2), **Article 18**, Article 19(3) and Article 24(4) shall enter into force only if no objection has been expressed either by

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.

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.

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.

Amendment 117 **Adina-Ioana Vălean**

Proposal for a regulation

Annex I – Part XII – point 165 – paragraph 3 – point 5

Regulation (EC) No 470/2009

Article 24b (new)

Text proposed by the Commission

Amendment

Article 24b

Urgency procedure

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

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 24a (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.

Or. en

Justification

Adding a new article, Article 24b, was necessary in line with the amendment of Article 18 third subparagraph above, where the urgency procedure for implementing acts is aligned to delegated acts.

Amendment 118
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 167 – paragraph 4 – point 14
Regulation (EC) No 1069/2009
Article 40 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission is empowered to adopt delegated acts in accordance with Article 51a concerning the conditions for:

Amendment

1. The Commission is empowered to adopt delegated acts in accordance with Article 51a, *to supplement this Regulation*, concerning the conditions for:

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 119
Adina-Ioana Vălean

Proposal for a regulation
Annex I – Part XII – point 167 – paragraph 4 – point 14
Regulation (EC) No 1069/2009
Article 40 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

2. The Commission shall adopt implementing acts concerning the following:

Amendment

2. The Commission shall adopt implementing acts, *to amend this Regulation*, concerning the following:

Justification

Clarification of empowerment (i.e. to amend).

Amendment 120
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 167 – paragraph 4 – point 15 – point a

Regulation (EC) No 1069/2009

Article 41 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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)."*

Amendment

The Commission *is empowered to adopt delegated acts in accordance with Article 51a to supplement this Regulation by laying down the conditions referred to in point (b).*

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 121
Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 167 – paragraph 4 – point 15 – point b

Regulation (EC) No 1069/2009

Article 41 – paragraph 3 – subparagraph 3

Text proposed by the Commission

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*

Amendment

The Commission *is empowered to adopt delegated acts in accordance with Article 51a to supplement this Regulation by laying down the requirements provided for in the first subparagraph.*

procedure referred to in Article 52(3).

Or. en

Justification

Amendment to align a measure previously submitted under Regulatory Procedure with Scrutiny to delegated acts.

Amendment 122

Adina-Ioana Vălean

Proposal for a regulation

Annex I – Part XII – point 167 – paragraph 4 – point 16 – point b

Regulation (EC) No 1069/2009

Article 42 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The Commission is empowered to adopt delegated acts in accordance with Article 51a **laying** down the following:

2. The Commission is empowered to adopt delegated acts in accordance with Article 51a, **to supplement this Regulation, by laying** down the following:

Or. en

Justification

Clarification of empowerment (i.e. to supplement).

Amendment 123

Adina-Ioana Vălean

Proposal for a regulation

Annex I – part XII – point 167 – paragraph 4 – point 20

Regulation (EC) No 1069/2009

Article 51a

Text proposed by the Commission

Amendment

Article 51a

Article 51a

Exercise of the delegation

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.

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

2. The delegation of power referred to in Article 5(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48, shall be conferred on the Commission for an indeterminate period of [date of entry into force of this Omnibus].

3 The delegation of power referred to in Article 5(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts

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) **and (2), the second subparagraph of Article 41(1), the third subparagraph of Article 41(3)**, the first subparagraph of Article 42(2), Article 43(3), paragraph 4 of Article 45, 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** [date of entry into force of this Omnibus]. **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), **and (2), the second subparagraph of Article 41(1), the third subparagraph of Article 41(3)**, the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts

designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016*.

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

6. A delegated act adopted pursuant to Article 5(1) and (2), Article 6(1), and (2), Article 7(4), Article 11(2), Article 15(1), Article 17(2), Article 18(3), Article 19(4), Article 20(11), Article 21(6), Article 27, Article 31(2), Article 32(3), Article 40(1), the first subparagraph of Article 42(2), Article 43(3), the first subparagraph of paragraph 7 and paragraph 8 of Article 48 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016*.

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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), ***and (2), the second subparagraph of Article 41(1), the third subparagraph of Article 41(3)***, 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.

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

Or. en

Justification

Alignment of the duration of the empowerment and updating the references in line with previous amendments.