Official Journal of the European Union

L 279

Volume 62

English edition

Legislation

31 October 2019

Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

([1]) Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/1819

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include vinegar as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance vinegar, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for vinegar for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. Vinegar was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether vinegar gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that vinegar does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include vinegar in Annex I to Regulation (EU) No 528/2012. As vinegar is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. Vinegar should be included in that Annex only insofar as it falls within the definition of 'food' referred to in point (u) of Article 3(1) of that Regulation and insofar it contains less than 10 % acetic acid. This is consistent with the fact that vinegar only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food.

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to vinegar for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).
([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of vinegar for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	Vinegar (*)	Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food).	CAS No 8028-52-2

(*) The date of approval of vinegar for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'.

COMMISSION DELEGATED REGULATION (EU) 2019/1820

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include *Saccharomyces cerevisiae* as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance *Saccharomyces cerevisiae*, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for *Saccharomyces cerevisiae* for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. *Saccharomyces cerevisiae* was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether *Saccharomyces cerevisiae* gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that *Saccharomyces cerevisiae* does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include *Saccharomyces cerevisiae* in Annex I to Regulation (EU) No 528/2012. As *Saccharomyces cerevisiae* is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. *Saccharomyces cerevisiae* should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that *Saccharomyces cerevisiae* only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).
([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to *Saccharomyces cerevisiae* for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of *Saccharomyces cerevisiae* for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	*Saccharomyces cerevisiae* (yeast) (*)	Excluding *Saccharomyces cerevisiae* that is not food or feed.	CAS No 68876-77-7

(*) The date of approval of *Saccharomyces cerevisiae* for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'.

COMMISSION DELEGATED REGULATION 2019/1821

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include powdered egg as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance powdered egg, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for powdered egg for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. Powdered egg was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether powdered egg gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that powdered egg does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include powdered egg in Annex I to Regulation (EU) No 528/2012. As powdered egg is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. Powdered egg should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that powdered egg only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).

([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to powdered egg for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of powdered egg for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	Powdered egg (*)	Excluding powdered egg that is not food or feed.	

(*) The date of approval of powdered egg for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'.

COMMISSION DELEGATED REGULATION (EU) 2019/1822

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include honey as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance honey, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for honey for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. Honey was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether honey gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that honey does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include honey in Annex I to Regulation (EU) No 528/2012. As honey is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. Honey should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that honey only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to honey for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).
([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of honey for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	Honey (*)	Excluding honey that is not food or feed.	CAS No 8028-66-8

(*) The date of approval of honey for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'

COMMISSION DELEGATED REGULATION (EU) 2019/1823

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include D-fructose as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance D-fructose, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for D-fructose for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. D-fructose was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether D-fructose gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012. The opinion of the Agency ([5]) concluded that D-fructose does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).

([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

(4) Taking into account the opinion of the Agency, it is appropriate to include D-fructose in Annex I to Regulation (EU) No 528/2012. As D-fructose is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. D-fructose should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that D-fructose only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

(5) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to D-fructose for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of D-fructose for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'200-333-3	D-Fructose (*)	Excluding D-fructose that is not food or feed.	CAS No 57-48-7

(*) The date of approval of D-fructose for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'.

COMMISSION DELEGATED REGULATION (EU) 2019/1824

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include cheese as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance cheese, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for cheese for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. Cheese was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether cheese gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that cheese does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include cheese in Annex I to Regulation (EU) No 528/2012. As cheese is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. Cheese should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that cheese only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).

([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to cheese for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of cheese for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	Cheese (*)	Excluding cheese that is not food or feed.	

(*) The date of approval of cheese for product-type 19 for the purposes of Article 89(3) is 1 June 2021.'.

COMMISSION DELEGATED REGULATION (EU) 2019/1825

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include concentrated apple juice as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 28(1) thereof,

Whereas:

(1) The active substance concentrated apple juice, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ([2]).

(2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ([3]) for concentrated apple juice for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. Concentrated apple juice was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ([4]).

(3) On 31 January 2017 the Commission asked the Agency for an opinion on whether concentrated apple juice gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.

(4) The opinion of the Agency ([5]) concluded that concentrated apple juice does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is appropriate to include concentrated apple juice in Annex I to Regulation (EU) No 528/2012. As concentrated apple juice is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. Concentrated apple juice should be included in that Annex only in so far it falls within the definition in point (2) of Part I of Annex I to Council Directive 2001/112/EC ([6]).

(6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to concentrated apple juice for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

---

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([3]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([4]) Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).

([5]) Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

([6]) Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of concentrated apple juice for product-type 19 is 1 June 2021.

Article 3

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

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

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
'Not available	Concentrated apple juice (*)	Excluding concentrated apple juice that does not fall within the definition in point (2) of Part I of Annex I to Council Directive 2001/112/EC (**) .	

(*) The date of approval of concentrated apple juice for product-type 19 for the purposes of Article 89(3) is 1 June 2021.

(**) Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).'.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1826

of 25 October 2019

entering a name in the register of protected designations of origin and protected geographical indications ('Kaimiškas Jovarų alus' (PGI))

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Lithuania's application to register the name 'Kaimiškas Jovarų alus' was published in the *Official Journal of the European Union* ([2]).

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Kaimiškas Jovarų alus' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Kaimiškas Jovarų alus' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 2.1. – Beer, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ([3]).

Article 2

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

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

Done at Brussels, 25 October 2019.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ C 217, 28.6.2019, p. 5.
([3]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION DELEGATED REGULATION (EU) 2019/1827

of 30 October 2019

amending Directive 2014/23/EU of the European Parliament and of the Council in respect of the threshold for concessions

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts ([1]), and in particular the second subparagraph of Article 9(4) thereof,

Whereas:

(1) By Decision 2014/115/EU ([2]), the Council approved the Protocol amending the Agreement on Government Procurement ([3]) ('the Agreement') concluded in the framework of the World Trade Organization. The Agreement is a plurilateral instrument and its purpose is to mutually open government procurement markets among its parties. It applies to any procurement contract with a value that reaches or exceeds the amounts ('thresholds') set in it and expressed as special drawing rights.

(2) One of the objectives of Directive 2014/23/EU is to allow the contracting entities and the contracting authorities, which apply that Directive, to comply at the same time with the obligations laid down in the Agreement. In accordance with Article 9(1) of Directive 2014/23/EU, every two years the Commission is to verify that the threshold for concessions set out in Article 8(1) of that Directive corresponds to the threshold established in the Agreement. Given that the value of the threshold calculated in accordance with Article 9(1) of Directive 2014/23/EU is different from the value of the threshold set out in Article 8(1) of that Directive, it is necessary to revise this threshold.

(3) Directive 2014/23/EU should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 8(1) of Directive 2014/23/EU, 'EUR 5 548 000' is replaced by 'EUR 5 350 000'.

Article 2

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

It shall apply from 1 January 2020.

([1]) OJ L 94, 28.3.2014, p. 1.
([2]) Council Decision 2014/115/EU of 2 December 2013 on the conclusion of the Protocol Amending the Agreement on Government Procurement (OJ L 68, 7.3.2014, p. 1).
([3]) OJ L 68, 7.3.2014, p. 2.

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

Done at Brussels, 30 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION DELEGATED REGULATION (EU) 2019/1828

of 30 October 2019

amending Directive 2014/24/EU of the European Parliament and of the Council in respect of the thresholds for public supply, service and works contracts, and design contests

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC ([1]), and in particular the second subparagraph of Article 6(5) thereof,

Whereas:

(1) By Decision 2014/115/EU ([2]), the Council approved the Protocol amending the Agreement on Government Procurement ([3]) ('the Agreement') concluded in the framework of the World Trade Organization. The Agreement is a plurilateral instrument and its purpose is to mutually open government procurement markets among its parties. It applies to any procurement contract with a value that reaches or exceeds the amounts ('thresholds') set in it and expressed as special drawing rights.

(2) One of the objectives of Directive 2014/24/EU is to allow the contracting authorities, which apply that Directive, to comply at the same time with the obligations laid down in the Agreement. In accordance with Article 6(1) of Directive 2014/24/EU, every two years the Commission is to verify that the thresholds for public contracts and design contests set out in points (a), (b) and (c) of Article 4 of that Directive correspond to the thresholds established in the Agreement. Given that the value of the thresholds calculated in accordance with Article 6(1) of Directive 2014/24/EU is different from the value of the thresholds set out in points (a), (b) and (c) of Article 4 of that Directive, it is necessary to revise these thresholds. In accordance with Article 6(2) of Directive 2014/24/EU, the thresholds established in Article 13 of that Directive are to be aligned with the thresholds set out in points (a) and (c) of Article 4 of that Directive.

(3) Directive 2014/24/EU should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Directive 2014/24/EU is amended as follows:

(1) Article 4 is amended as follows:

(a) in point (a), 'EUR 5 548 000' is replaced by 'EUR 5 350 000';

(b) in point (b), 'EUR 144 000' is replaced by 'EUR 139 000';

(c) in point (c), 'EUR 221 000' is replaced by 'EUR 214 000';

(2) the first paragraph of Article 13 is amended as follows:

(a) in point (a), 'EUR 5 548 000' is replaced by 'EUR 5 350 000';

(b) in point (b), 'EUR 221 000' is replaced by 'EUR 214 000'.

([1]) OJ L 94, 28.3.2014, p. 65.
([2]) Council Decision 2014/115/EU of 2 December 2013 on the conclusion of the Protocol Amending the Agreement on Government Procurement (OJ L 68, 7.3.2014, p. 1).
([3]) OJ L 68, 7.3.2014, p. 2.

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 30 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION DELEGATED REGULATION (EU) 2019/1829

of 30 October 2019

amending Directive 2014/25/EU of the European Parliament and of the Council in respect of the thresholds for supply, service and works contracts, and design contests

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC ([1]), and in particular the second subparagraph of Article 17(4) thereof,

Whereas:

(1) By Decision 2014/115/EU ([2]), the Council approved the Protocol amending the Agreement on Government Procurement ([3]) ('the Agreement') concluded in the framework of the World Trade Organization. The Agreement is a plurilateral instrument and its purpose is to mutually open government procurement markets among its parties. It applies to any procurement contract with a value that reaches or exceeds the amounts ('thresholds') set in it and expressed as special drawing rights.

(2) One of the objectives of Directive 2014/25/EU is to allow the contracting entities, which apply that Directive, to comply at the same time with the obligations laid down in the Agreement. In accordance with Article 17(1) of Directive 2014/25/EU, every two years the Commission is to verify that the thresholds for contracts and design contests set out in points (a) and (b) of Article 15 of that Directive correspond to the thresholds established in the Agreement. Given that the value of the thresholds calculated in accordance with Article 17(1) of Directive 2014/25/EU is different from the value of the thresholds set out in points (a) and (b) of Article 15 of that Directive, it is necessary to revise these thresholds.

(3) Directive 2014/25/EU should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 15 of Directive 2014/25/EU is amended as follows:

(1) in point (a), 'EUR 443 000' is replaced by 'EUR 428 000';

(2) in point (b), 'EUR 5 548 000' is replaced by 'EUR 5 350 000'.

([1]) OJ L 94, 28.3.2014, p. 243.
([2]) Council Decision 2014/115/EU of 2 December 2013 on the conclusion of the Protocol Amending the Agreement on Government Procurement (OJ L 68, 7.3.2014, p. 1).
([3]) OJ L 68, 7.3.2014, p. 2.

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 30 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION DELEGATED REGULATION (EU) 2019/1830

of 30 October 2019

amending Directive 2009/81/EC of the European Parliament and of the Council in respect of the thresholds for supply, service and works contracts

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC ([1]), and in particular the second subparagraph of Article 68(1) thereof,

Whereas:

(1) By Decision 2014/115/EU ([2]), the Council approved the Protocol amending the Agreement on Government Procurement ([3]) ('the Agreement') concluded in the framework of the World Trade Organization. The Agreement is a plurilateral instrument and its purpose is to mutually open government procurement markets among its parties. It applies to any procurement contract with a value that reaches or exceeds the amounts ('thresholds') set in it and expressed as special drawing rights.

(2) One of the objectives of Directive 2014/25/EU of the European Parliament and of the Council ([4]) is to allow the contracting entities and the contracting authorities, which apply that Directive, to comply at the same time with the obligations laid down in the Agreement. In accordance with Article 17 of Directive 2014/25/EU every two years the Commission is to verify that the thresholds set out in points (a) and (b) of Article 15 of that Directive correspond to the thresholds established in the Agreement and is to, where necessary, revise them.

(3) The thresholds laid down in Directive 2014/25/EU have been revised. In accordance with Article 68(1) of Directive 2009/81/EC, the thresholds laid down in that Directive are to be aligned to the revised thresholds laid down in Directive 2014/25/EU.

(4) Directive 2009/81/EC should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 8 of Directive 2009/81/EC is amended as follows:

(1) in point (a), 'EUR 443 000' is replaced by 'EUR 428 000';

(2) in point (b), 'EUR 5 548 000' is replaced by 'EUR 5 350 000'.

([1]) OJ L 216, 20.8.2009, p. 76.
([2]) Council Decision 2014/115/EU of 2 December 2013 on the conclusion of the Protocol Amending the Agreement on Government Procurement (OJ L 68, 7.3.2014, p. 1).
([3]) OJ L 68, 7.3.2014, p. 2.
([4]) Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 30 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2019/1831

of 24 October 2019

establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work ([1]), and in particular Article 3(2) thereof,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights ([2]), proclaimed at Gothenburg on 17 November 2017, states that every worker has the right to a healthy, safe and well-adapted work environment. The right to a high level of protection for health and safety at work, and to a working environment that is adapted to workers' professional needs and enables them to participate in the labour market for an extended period also includes protection from exposure to chemical agents at work.

(2) The Commission clearly emphasised the need to continue improving workers' protection from exposure to dangerous chemicals at work in its communication 'Safer and Healthier Work for All'. ([3])

(3) Pursuant to Directive 98/24/EC, the Commission is to propose European Union (EU) objectives in the form of indicative occupational exposure limit values (IOELVs) to be set at EU level, to protect workers from risks arising from exposure to hazardous chemicals.

(4) Article 3(2) of Directive 98/24/EC empowers the Commission to establish or revise IOELVs, taking into account the availability of measurement techniques based on measures adopted in accordance with the procedure laid down in Article 17 of Council Directive 89/391/EEC ([4]).

(5) Article 3(1) of Directive 98/24/EC states that the Commission shall evaluate, through an independent scientific assessment of the latest available scientific data, the relationship between the health effects of hazardous chemical agents and the level of occupational exposure.

(6) The Commission is assisted in this task by the Scientific Committee on Occupational Exposure Limits for Chemical Agents (SCOEL), set up by Commission Decision 2014/113/EU. ([5])

(7) Under Directive 98/24/EC, 'occupational exposure limit value' means, unless otherwise specified, the limit of the time-weighted average of the concentration of a chemical agent in the air within a worker's breathing zone, in relation to a specified reference period.

(8) IOELVs are health-based occupational exposure limit values, derived from the most recent scientific data available and adopted by the Commission, taking into account the availability of measurement techniques. They are threshold levels of exposure below which, in general, no detrimental effects are expected for any given chemical agent after short-term or daily exposure over a working lifetime. They constitute EU objectives and are designed to help employers determine and assess risks and implement preventive and protective measures, in accordance with Directive 98/24/EC.

([1]) OJ L 131, 5.5.1998, p. 11.
([2]) European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en
([3]) Communication from the Commission 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' COM/2017/012 final. http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709
([4]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).
([5]) Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

(9) In accordance with SCOEL recommendations, IOELVs are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain chemical agents, to shorter reference periods, in general 15 minutes time-weighted average (short-term exposure limit values), to take account of the effects arising from short-term exposure.

(10) For any chemical agent for which an IOELV has been set at EU level, Member States are required to establish a national occupational exposure limit value. In doing so, they are required to take into account the EU limit value, determining the nature of the national limit value in accordance with national legislation and practice.

(11) IOELVs are an important part of the general arrangements for protecting workers against the health risks arising from exposure to hazardous chemicals.

(12) In accordance with Article 3 of Directive 98/24/EC, SCOEL has assessed the relationship between the health effects of the chemical agents listed in the 10 entries in the Annex to this Directive and the level of occupational exposure. Similarly, for all these chemical agents it has recommended establishing IOELVs for the inhalation route of exposure in relation to a reference period of eight hours time-weighted average. It is therefore appropriate to lay down long-term exposure limit values for all these agents in the Annex to this Directive.

(13) For some of these chemical agents, i.e. aniline, trimethylamine, 2-phenylpropane (cumene), sec-butyl acetate, 4-aminotoluene, isobutyl acetate, isoamyl alcohol, n-butyl acetate and phosphoryl trichloride, SCOEL also recommended establishing short-term exposure limit values.

(14) For certain substances, it is necessary to take into account the possibility of penetration through the skin in order to ensure the best possible level of protection. Among the chemical agents listed in the entries in the Annex to this Directive, SCOEL identified the possibility of significant uptake through the skin for aniline, 2-phenylpropane (cumene) and 4-aminotoluene. It is therefore appropriate to include in the Annex to this Directive notations indicating the possibility of significant uptake through the skin for these chemical agents, in addition to the IOELVs.

(15) One of the chemical agents, 2-phenylpropane (cumene), is currently listed in the Annex to Commission Directive 2000/39/EC ([6]). SCOEL has recommended establishing a new IOELV for this substance. It is therefore appropriate to include a revised limit value for 2-phenylpropane (cumene) in the Annex to this Directive and to delete the corresponding entry from the Annex to Directive 2000/39/EC.

(16) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ([7]), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(17) As regards this Directive, the Commission considers it justified to send such documents in the form of a table showing the correlation between the national measures and this Directive, given that for some agents national occupational exposure limit values already exist in national legislation, and given the variety and the technical nature of national legal instruments for establishing occupational exposure limit values.

(18) The Advisory Committee on Safety and Health at Work was consulted in accordance with Article 3(2) of Directive 98/24/EC and gave its opinions on 6 December 2017 and 31 May 2018. The Committee acknowledged that there were currently challenges as regards the availability of measurement methodologies that could be used to demonstrate compliance with the proposed limit values for phosphoryl trichloride and isoamyl alcohol, and that efforts should be made to ensure that suitable techniques were available by the end of the transposition period.

(19) The measures for which this Directive provides are in accordance with the opinion of the Technical Progress Committee established under Article 17 of Directive 89/391/EEC.

([6]) Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 142, 16.6.2000, p. 47).

([7]) OJ C 369, 17.12.2011, p. 14.

HAS ADOPTED THIS DIRECTIVE:

Article 1

A fifth list of EU indicative occupational exposure limit values is established for the chemical agents listed in the Annex.

Article 2

Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex, taking into account the EU limit values.

Article 3

In the Annex to Directive 2000/39/EC, the reference to cumene is deleted with effect from 20 May 2021.

Article 4

1. The Member States shall adopt and publish, by 20 May 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall forthwith communicate to the Commission the text of those provisions and shall accompany their notification with one or more explanatory documents in the form of tables showing the correlation between the provisions and this Directive.

When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main national legal provisions which they adopt in the field covered by this Directive.

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

EC No [1]	CAS No [2]	Name of the chemical agent	Limit values				Notation [3]
			8 hours [4]		Short-term [5]		
			mg/m³ [6]	ppm [7]	mg/m³ [6]	ppm [7]	
200-539-3	62-53-3	Aniline [8]	7,74	2	19,35	5	skin
200-817-4	74-87-3	Chloromethane	42	20	-	-	-
200-875-0	75-50-3	Trimethylamine	4,9	2	12,5	5	-
202-704-5	98-82-8	2-Phenylpropane (Cumene) [8]	50	10	250	50	skin
203-300-1	105-46-4	sec-Butyl acetate	241	50	723	150	-
203-403-1	106-49-0	4-aminotoluene	4,46	1	8,92	2	skin
203-745-1	110-19-0	Isobutyl acetate	241	50	723	150	-
204-633-5	123-51-3	Isoamyl alcohol	18	5	37	10	-
204-658-1	123-86-4	n-Butyl acetate	241	50	723	150	-
233-046-7	10025-87-3	Phosphoryl trichloride	0,064	0,01	0,12	0,02	-

(1) EC No: European Community (EC) number, the European Union's numerical identifier for substances.
(2) CAS No: Chemical Abstract Service Registry Number.
(3) A *skin notation* assigned to the occupational exposure limit value indicates the possibility of significant uptake through the skin.
(4) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
(5) Short-term exposure limit (STEL). A limit value which must not be exceeded. The period to which it relates is 15 minutes, unless otherwise specified.
(6) mg/m³: milligrams per cubic metre of air. For chemicals in gas or vapour phase, the limit value is expressed at 20 °C and 101,3 kPa.
(7) ppm: parts per million by volume in air (ml/m³).
(8) During exposure monitoring, account should be taken of relevant biological monitoring values as suggested by the Scientific Committee on Occupational Exposure Limits for Chemicals Agents (SCOEL).

COMMISSION DIRECTIVE 2019/1832

of 24 October 2019

amending Annexes I, II and III to Council Directive 89/656/EEC as regards purely technical adjustments

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace ([1]), and in particular Article 9 thereof,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights ([2]), proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to a healthy, safe and well-adapted working environment. The workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes the use of personal protective equipment at the workplace if risks cannot be avoided or sufficiently limited by other means, measures, methods or procedures of work organisation.

(2) The implementation of the directives related to the health and safety of workers at work, including Directive 89/656/EEC, was the subject of an *ex-post* evaluation, referred to as a REFIT evaluation. The evaluation looked at the directives' relevance, at research and at new scientific knowledge in the various fields concerned. The REFIT evaluation, referred to in the Commission Staff Working Document ([3]), concludes, among other things, that the use of personal protective equipment concerns approximately 40 % of the EU's workforce, as risks at the workplace cannot be avoided by any other means, and that there is a need to address difficulties in implementing Directive 89/656/EEC.

(3) In its Communication 'Safer and Healthier Work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy' ([4]), the Commission reiterated that while the REFIT evaluation of the Union's *acquis* on occupational health and safety confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground. The Commission emphasises the particular need to consider the definition of personal protective equipment and its use by different services and sectors, as set out in Article 2 of Directive 89/656/EEC.

(4) Directive 89/656/EEC lays down minimum requirements for the use of personal protective equipment used by workers at work, which is to be used when the risks concerned cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation. To facilitate the establishment of the general rules required pursuant to Article 6 of Directive 89/656/EEC, Annexes I, II and III to Directive 89/656/EEC provide non-binding guidelines intended to facilitate and support the selection of appropriate personal protective equipment for the risks, activities and sectors concerned.

([1]) OJ L 393, 30.12.1989, p. 18.
([2]) European Pillar of Social Rights, 2017, https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf
([3]) SWD(2017) 10 final
([4]) COM(2017) 12

(5) Regulation (EU) 2016/425 of the European Parliament and of the Council ([5]) lays down the provisions regarding the design, manufacture and marketing of personal protective equipment. Regulation (EU) 2016/425 modified the risk categorisation of products, to enable employers to understand and thus to deploy personal protective equipment, as further explained in the Personal Protective Equipment Guidelines ([6]) that clarify procedures and matters referred to in Regulation (EU) 2016/425. It is considered appropriate to update Annexes I, II and III to Directive 89/656/EEC in order to ensure consistency with the risk classification laid down in Regulation (EU) 2016/425 and to align them with terminologies used and types of personal protective equipment referred to in Regulation (EU) 2016/425.

(6) Article 4(1) of Directive 89/656/EEC foresees that employers must provide personal protective equipment that complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to that Article, employers who provide that personal protective equipment to their workers must ensure that such personal protective equipment fulfils the requirements laid down in Regulation (EU) 2016/425.

(7) Annex I to Directive 89/656/EEC sets out a specimen risk survey table for the use of personal protective equipment and sets out types of risks that could occur in workplaces in relation to different parts of the body to be protected by personal protective equipment. Annex I should be amended to take account of new types of risks that appear in workplaces and to ensure consistency with the risk classification and the terminology used, in particular in Regulation (EU) 2016/425.

(8) Annex II to Directive 89/656/EEC, which sets out a non-exhaustive guide list of types of personal protective equipment, should be amended to take account of the new types of risks identified in Annex I to that directive. Annex II should also be amended to include examples of personal protective equipment currently available on the market in conformity with Regulation (EU) 2016/425 and the terminology used in that Regulation.

(9) Annex III to Directive 89/656/EEC sets out a non-exhaustive guide list of activities and sectors of activity that could require the provision of personal protective equipment, bringing together the risk classifications set out in Annex I to that directive and the types of personal protective equipment described in Annex II to that directive. Annex III to Directive 89/656/EEC should be restructured to ensure consistency between the terminology and classifications used across the three annexes and with Regulation (EU) 2016/425. This will enable employers from different sectors and industries to better identify and provide personal protective equipment that corresponds to specific activities and the specific types of risks that workers are exposed to, as indicated by the risk assessment.

(10) The Advisory Committee for Safety and Health at Work was consulted on the measures resulting from the adoption of the Commission's Communication 'Safer and Healthier Work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy' that are required to keep the Union's occupational health and safety legislation effective and fit-for-purpose.

(11) In its 'Opinion on the Modernisation of Six OSH Directives to Ensure Healthier and Safer Work for All' ([7]), adopted on 6 December 2017, the Advisory Committee for Safety and Health at Work recommends that Directive 89/656/EEC should be amended to enhance its relevance and effectiveness.

(12) In a subsequent 'Opinion on technical updates to the annexes of the Personal Protective Equipment Directive (89/656/EEC)' ([8]), adopted on 31 May 2018, the Advisory Committee for Safety and Health at Work recommends that specific updates to Annex I, II and III to Directive 89/656/EEC, taking into account the latest technological developments in the field and ensuring consistency with Regulation (EU) 2016/425, should be carried out.

(13) In preparing the current update of Annexes I, II and III to Directive 89/656/EEC, the Commission was assisted by experts representing Member States, who provided technical and scientific support.

([5]) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).
([6]) PPE Regulation Guidelines – Guide to application of Regulation (EU) 2016/425 on personal protective equipment, https://ec.europa.eu/docsroom/documents/29201
([7]) Advisory Committee for Safety and Health at Work Doc. 1718/2017
([8]) Advisory Committee for Safety and Health at Work Doc. 443/18

(14) In accordance with the Joint Political Declaration on explanatory documents [9], adopted by the Member States and the Commission on 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(15) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 17 of Council Directive 89/391/EEC [10],

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I, II and III to Directive 89/656/EEC are replaced by the text in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

[9] OJ C 369, 17.12.2011, p. 14.
[10] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

ANNEX

(1) Annex I to Directive 89/656/EEC is replaced by the following:

'ANNEX I

RISKS IN RELATION TO THE BODY PARTS TO BE PROTECTED BY PPE (*)

(*) This list of risks/parts of the body cannot be expected to be exhaustive.

The risk assessment will determine the need to provide a PPE and its characteristics according to the provisions of this Directive.

RISKS

			PHYSICAL													**CHEMICAL** (including nanomaterial) (*)					**BIOLOGICAL AGENTS** (contained in)				**OTHER RISKS**		
			MECHANICAL							NOISE	THERMAL		ELECTRICAL		RADIATION		AEROSOLS	LIQUIDS		GASES AND VAPOURS	AEROSOLS	LIQUIDS		MATERIALS, PERSONS, ANIMALS, ETC.	DROWNING	OXYGEN deficiency	NON-VISIBILITY
			(1)	(2)	(3)	(4)	(5)	(6)	(7)		Heat and/or fire	Cold	Electric shock (8)	Static electricity	Non-ionizing (9)	Ionizing	Solid (10)	Liquid (11)	Immersion	Splashes, sprays, jets		Solids and liquids	Direct and indirect contact	Splashes, sprays, jets	Direct and indirect contact			
PARTS OF THE BODY TO BE PROTECTED	Head	Cranium																									
		Whole head																									
	Ears																										
	Eyes																										
	Face																										
	Respiratory system																										
	Hands																										
	Arms (parts)																										
	Foot																										
	Legs (parts)																										
	Skin																										
	Trunk/Abdomen																										
	Partial body																										
	Whole body																										

(1) Impact caused by falling or ejected objects, collision with an obstacle and high-pressure jets
(2) Falls due to slipping
(3) Falls from a height
(4) Vibration
(5) Static compression of parts of the body
(6) Mechanical injuries (abrasion, perforation, cuts, bites, wounds or stabs)
(7) Entanglement and trapping
(8) Direct or indirect contact
(9) Including sunlight (other than direct observation)
(10) Dusts, fumes, smokes and fibres
(11) Mists and fogs

(*) See Recommendation 2011/696/EU on the definition of nanomaterial'

(2) Annex II to Directive 89/656/EEC is replaced by the following:

'ANNEX II

NON-EXHAUSTIVE LIST OF TYPES OF PERSONAL PROTECTIVE EQUIPMENT WITH REGARD TO THE RISKS THEY PROVIDE PROTECTION AGAINST

Equipment for HEAD PROTECTION

— Helmets and/or caps/balaclavas/headgears against:
  — Impacts caused by falling or ejected object
  — Collision with an obstacle
  — Mechanical risks (perforation, abrasion)
  — Static compression (lateral crushing)
  — Thermal risks (fire, heat, cold, hot solids including molten metals)
  — Electric shock and live working
  — Chemical risks
  — Non-ionizing radiation (UV, IR, solar or welding radiation)
— Hairnets against risk of entanglement

Equipment for HEARING PROTECTION

— Earmuffs (including e.g. earmuffs attached to a helmet, active noise reduction earmuffs, earmuffs with electrical audio input)
— Earplugs (including e.g. level-dependent earplugs, earplugs adapted to the individual)

Equipment for EYE AND FACE PROTECTION

— Spectacles, goggles and face shields (prescription lenses where appropriate) against:
  — Mechanical risks
  — Thermal risks
  — Non-ionizing radiation (UV, IR, solar or welding radiation)
  — Ionizing radiation
  — Solid aerosols and liquids of chemical and biological agents

Equipment for RESPIRATORY PROTECTION

— Filtering devices against:
  — Particles
  — Gases
  — Particles and gases
  — Solid and/or liquid aerosols
— Insulating devices, including with an air supply
— Self-rescue devices
— Diving equipment

Equipment for HAND AND ARM PROTECTION

— Gloves (including mittens and arm protection) against:
  — Mechanical risks
  — Thermal risks (heat, flame and cold)

  - Electric shock and live working (antistatic, conductive, insulating)
  - Chemical risks
  - Biological agents
  - Ionizing radiation and radioactive contamination
  - Non-ionizing radiation (UV, IR, solar or welding radiation)
  - Vibration risks
- Finger stalls

Equipment for FOOT AND LEG PROTECTION and anti-slip protection

- Footwear (e.g. shoes, including in certain circumstances clogs, boots that may have steel toe-caps) to protect against:
  - Mechanical risks
  - Slipping risks
  - Thermal risks (heat, flame and cold)
  - Electric shock and live working (antistatic, conductive, insulating)
  - Chemicals risks
  - Vibration risks
  - Biological risks
- Removable instep protectors against mechanical risks
- Kneepads against mechanical risks
- Gaiters against mechanical, thermal and chemical risks and biological agents
- Accessories (e.g. spikes, crampons)

SKIN PROTECTION — BARRIER CREAMS ([1])

- There could be barrier creams to protect against:
  - Non ionizing radiation (UV, IR, solar or welding radiation)
  - Ionizing radiation
  - Chemicals
  - Biological agents
  - Thermal risks (heat, flame and cold)

Equipment for BODY PROTECTION/OTHER SKIN PROTECTION

- Personal protective equipment for protection against falls from a height, such as retractable type fall arresters, full body harnesses, sit harnesses, belts for work positioning and restraint and work positioning lanyards, energy absorbers, guided-type fall arresters including an anchor line, rope adjustment devices, anchor devices that are not designed to be permanently fixed and that do not require fastening works before use, connectors, lanyards, rescue harness
- Protective clothing, including whole body (i.e. suits, overalls) protection and partial body (i.e. gaiters, trousers, jackets, waistcoats, aprons, kneepads, hoods, balaclavas) protection against:
  - Mechanical risks
  - Thermal risks (heat, flame and cold)
  - Chemicals

([1]) In certain circumstances, as a result of the risk assessment, barrier creams could be used together with other PPE with the aim of protecting workers' skin from related risks. Barrier creams are PPE under the scope of Directive 89/656/EEC as this type of equipment can be considered in certain circumstances as "additional or accessory" within the meaning of Article 2 of Directive 89/656/EEC. However, barrier creams are not PPE according to the definition in Article 3(1) of Regulation (EU) 2016/425.

— Biological agents
— Ionizing radiation and radioactive contamination
— Non-ionizing radiation (UV, IR, solar or welding radiation)
— Electric shock and live working (antistatic, conductive, insulating)
— Entanglement and trapping
— Lifejackets for prevention of drowning and buoyancy aids
— PPE for signalling the user's presence visually'

(3) Annex III to Directive 89/656/EEC is replaced by the following:

'ANNEX III

NON-EXHAUSTIVE LIST OF ACTIVITIES AND SECTORS OF ACTIVITY WHICH MAY REQUIRE THE PROVISION OF PERSONAL PROTECTIVE EQUIPMENT (*)

(*) The risk assessment will determine the need to provide a PPE and its characteristics according to the provisions of this Directive

I. **PHYSICAL RISKS**

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
PHYSICAL — MECHANICAL			
Impact caused by falling or ejected objects, collision with an obstacle and high-pressure jets	Cranium **Protective helmet**	— Work on, underneath or in the vicinity of scaffolding and elevated workplaces — Carcase Work and road work — Formwork's erection and stripping — Scaffolding's assembly and installation — Assembly and installation works — Demolitions — Blasting works — Work in pits, trenches, shafts and tunnels — Work in the vicinity of lifts, lifting gear, cranes, and conveyors — Works in underground workings, quarries, open diggings — Work with industrial furnaces, containers, machinery, silos, bunkers and pipelines — Slaughtering and Cutting line at slaughterhouses — Load handling or Transport and storage — Forest work — Work on steel bridges, steel building construction, steel hydraulic structures, blast furnaces, steel works and rolling mills, large containers, large pipelines, boiler plants and power stations — Earth and rock works — Work with bolt-driving tools — Work with blast furnaces, direct reduction plants, steelworks, rolling mills, metalworks, forging, drop forging and casting — Work involving travelling on bicycles and mechanically propelled bikes	— Building construction — Civil engineering construction — Machinery manufacturing, installation and maintenance — Shipbuilding — Mining works — Energy production — Infrastructure construction and maintenance — Iron and Steel industry — Slaughterhouses — Railway shunting work — Harbours, transport and logistics — Forest Industry

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
	Eyes and/or face **Spectacles, goggles and face shields**	— Welding, grinding and separating work — Manual hammering — Caulking and chiselling — Rock working and processing — Work with bolt-driving tools — Work on stock removing machines for small chippings — Drop forging — The removal and breaking up of fragments — Spraying of abrasive substances — Use of brush cutter or chainsaw — Dental and surgical procedures	— Building construction — Civil engineering construction — Machinery manufacturing, installation and maintenance — Shipbuilding — Mining works — Energy production — Infrastructure construction and maintenance — Iron and Steel industries — Metal and Wood industries — Stone carving — Gardening — Healthcare — Forestry
	Foot and leg (parts) **Footwear (shoes/boots, etc.) with safety or protective toecap** **Footwear with metatarsal protection**	— Carcase Work and road work — Erection and stripping of formwork — Scaffolding's assembly and installation — Demolitions — Blasting works — Working and processing of rock — Slaughtering and Cutting line works — Transport and storage — Work with moulds in the ceramics industry — Work with frozen meat blocks and preserved foods packaging — Flat glass products and container glassware manufacture, working and processing — Conversion and maintenance work — Forest works — Work with concrete and prefabricated parts involving formwork erection and stripping — Work in contractors' yards and warehouses — Roof work — Work on steel bridges, steel building construction, masts, towers, lifts, steel hydraulic structures, blast furnaces, steelworks and rolling mills, large containers, large pipelines, cranes, boiler plants and power stations — Furnace construction, heating and ventilation installation and metal assembly work — Work with blast furnaces, direct reduction plants, steelworks, rolling mills, metal works, forging, drop forging, hot pressing and drawing plants — Work in quarries and open diggings, coal stock removal	— Building construction — Civil engineering construction — Machinery manufacturing, installation and maintenance — Shipbuilding — Mining works — Energy production — Infrastructure construction and maintenance — Iron and Steel industry — Slaughterhouses — Logistic Companies — Manufacturing Industry — Glass Industry — Forest Industry

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
		— Work with moulds in the ceramics industry — Lining of kilns in the ceramics industry — Railway shunting work	
Falls due to slipping	Foot **Slip-resistant footwear**	— Works on slippery surfaces — Works on humidity environments	— Building construction — Civil engineering construction — Shipbuilding — Slaughterhouse — Cleaning — Food industries — Gardening — Fishing industry
Falls from a height	Whole body **PPE designed to prevent or arrest falls from height**	— Work on scaffolding — Assembly of prefabricated parts — Works on masts — Roof work — Work on vertical or slope surfaces — Work in high crane cabs — Work in high cabs of warehouse stacking and retrieval equipment — Work in high sections of drilling towers — Work in shafts and sewers	— Building construction — Civil engineering construction — Shipbuilding — Infrastructure maintenance
Vibration	Hands **Protective Gloves**	— Works with hand-guided tools	— Manufacturing industries — Building work — Civil Engineering work
Static compression of parts of the body	Knee (leg parts) **Kneepads**	— Installation of blocks, tiles and pavers on the floor	— Building construction — Civil engineering construction
	Foot **Footwear with toecaps**	— Demolitions — Load handling	— Building construction — Civil engineering construction — Transport and storage — Maintenance
Mechanical injuries (abrasion, perforation, cuts, bites, wounds or stabs)	Eyes and/or face **Spectacles, goggles, face shields**	— Works with hand-guided tools — Welding and forging — Grinding and separating work — Chiselling — Rock working and processing — Work on stock removing machines for small chippings — Drop forging — The removal and breaking up of fragments — Spraying of abrasive substances	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Energy production — Infrastructure maintenance — Iron and Steel industries — Metal and Wood industries — Stone carving

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
		— Use of brush cutter or chainsaw	— Gardening — Forestry
	Hands **Mechanical protective gloves**	— Works with steel framework — Handling of sharp-edged objects, other than machines where there is a danger of the gloves being caught — Regular cutting using a hand knife for production and slaughtering — Changing the knives of cutting machines — Forest works — Gardening work	— Building construction — Civil engineering construction — Shipbuilding — Infrastructure maintenance — Manufacturing industries — Food industry — Slaughter — Forest industry
	Forearms **Arm protection**	— Boning and cutting	— Food industry — Slaughter
	Trunk/Abdomen/ Leg **Protective apron, gaiters** **Penetration resistance trousers (cut-resistant trousers)**	— Regular cutting using a hand knife for production and slaughtering — Forest works	— Food industry — Slaughter — Forest industry
	Foot **Penetration resistance footwear**	— Carcase works and road works — Demolition — Formwork's erection and stripping — Forest works	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Forest industry
Entanglement and trapping	Whole body **Protective clothing for use where there is a risk of entanglement with moving parts**	— Entangle oneself in parts of machines — Get caught in parts of machines — Get caught with garment in parts of machines — Get swept away	— Machine building — Manufacture of heavy-duty machines — Engineering — Construction — Agriculture
		PHYSICAL — NOISE	
Noise	Ears **Hearing protectors**	— Work with metal presses — Work with pneumatic drills — The work of ground staff at airports — Works with power tools — Blasting works — Pile-driving work — Wood and textile working	— Metal Industry — Manufacturing industry — Building construction — Civil engineering construction — Aeronautical industry — Mining works

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
PHYSICAL — THERMAL			
Heat and/or fire	Face/Whole head **Welding head-shields, helmets/caps against heat or fire, protective hoods against heat and/or flame**	— Work in presence of high temperatures, radiating heat or fire — Work with or in the vicinity of molten substances — Work with welding plastics guns	— Iron and Steel Industry — Metal Industry — Maintenance services — Manufacturing Industry
	Trunk/abdomen/legs **Protective apron, gaiters**	— Welding and forging — Casting	— Iron and Steel Industry — Metal Industry — Maintenance services — Manufacturing industry
	Hand **Protective gloves against heat and/or flame**	— Welding and forging — Work in presence of high temperatures, radiating heat or fire — Work with or in the vicinity of molten substances	— Iron and Steel Industry — Metal Industry — Maintenance services — Manufacturing industry
	Forearms **Sleeves**	— Welding and forging — Work with or in the vicinity of molten substances	— Iron and Steel Industry — Metal Industry — Maintenance services — Manufacturing industry
	Foot **Footwear against heat and/or flame**	— Work with or in the vicinity of molten substances	— Iron and Steel Industry — Metal Industry — Maintenance services — Manufacturing industry
	Whole/partial body **Protective clothing against heat and/or flame**	— Work in presence of high temperatures, radiating heat or fire	— Iron and Steel Industry — Metal Industry — Forest Industry
Cold	Hand **Protective gloves against cold** Foot **Footwear against cold**	— Work in the open air in extreme cold conditions — Work in deep-freeze rooms — Work with cryogenic liquids	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Food Industry — Agriculture and fisheries sector
	Whole/partial body including head **Protective clothing against cold**	— Work in the open air in cold weather conditions — Work in deep-freeze rooms	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Food Industry — Agriculture and fisheries sector — Transport and storage

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
		PHYSICAL — ELECTRICAL	
Electric shock (direct or indirect contact)	Whole head **Electrically insulating helmets** Hands **Electrically insulating gloves** Foot **Electrically insulating footwear** Whole body/ Hands/Foot **Conductive PPE intended to be worn by skilled persons during live working at a nominal power system voltage up to 800 kV AC and 600 kV DC**	— Live working or close to live parts under electrical tension — Work on electrical system	— Energy production — Transmission and distribution of electrical energy — Industrial facilities maintenance — Building construction — Civil engineering construction
Static electricity	Hands **Antistatic gloves** Foot **Antistatic/ conductive footwear** Whole body **Antistatic clothing**	— Handling plastic and rubber — Pouring, collecting or loading into a container — Work near to highly charged elements such as conveyor belts — Handling explosives	— Manufacturing industry — Feed industry — Bagging and packing plants — Production, storage or transport of explosives
		PHYSICAL — RADIATION	
Non-ionizing radiation, including sunlight (other than direct observation)	Head **Caps and helmets**	— Work in open air	— Fishing and agriculture — Building construction — Civil engineering construction
	Eyes **Protective spectacles, goggles and face shields**	— Work with radiant heat — Furnace operations — Work with laser — Work in open air — Welding and gas cutting — Glass blowing — Germicidal lamps	— Iron and Steel Industries — Manufacturing industry — Fishing and agriculture
	Whole body (skin) **PPE against** **Natural and artificial UV**	— Work in the open air — Electrical welding — Germicidal lamps — Xenon lamps	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Energy production — Infrastructure maintenance — Fishing and agriculture

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
			— Forest industry — Gardening — Food industry — Plastic industry — Printing industry
Ionizing radiation	Eyes **Protective spectacles/goggles against ionizing radiation** Hands **Protective gloves against ionizing radiation**	— Operating in X-ray facilities — Operating in the area of medical radio diagnosis — Work with radioactive products	— Healthcare — Veterinary care — Radioactive waste plant — Energy production
	Trunk/abdomen/ partial body **Protective apron against x-rays /Coat/Vest/Skirt against x-rays**	— Operating in X-ray facilities — Operating in the area of medical radio diagnosis	— Healthcare — Veterinary care — Dental care — Urology — Surgery — Interventional radiology — Laboratories
	Head **Headwear & Caps** **PPE for protection against e.g. development of brain tumours**	— Medical X-ray work places and facilities	— Healthcare — Veterinary care — Dental care — Urology — Surgery — Interventional radiology
	Partial body **PPE for thyroid protection** **PPE for gonads protection**	— Operating in X-ray facilities — Operating in the area of medical radio diagnosis	— Healthcare — Veterinary care
	Whole body **Protective clothing against ionizing radiation**	— Operating in the area of medical radio diagnosis — Work with radioactive products	— Energy production — Radioactive waste plant

II. **CHEMICAL RISKS (including nanomaterial)**

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
		CHEMICAL — AEROSOLS	
Solid (dusts, fumes, smokes, fibres, and nano-material)	Respiratory system **Respiratory protective devices against particles**	— Demolition — Blasting works — Sanding and Polishing of surfaces — Work in presence of asbestos — Use of materials consisting of/containing nanoparticles — Welding — Chimney sweeper — Work on the lining of furnaces and ladles where there may be dust — Work in the vicinity of blast furnace taps where there may be heavy metal fumes — Work in the vicinity of the blast furnace charge	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Iron and Steel industries — Metal and Wood industries — Automotive industry — Stone carving — Pharmaceuticals industry — Healthcare services — Preparation of cytostatics
	Hands **Chemical Protective gloves and barrier cream as an additional/ accessory protection**	— Work in presence of asbestos — Use of materials consisting of/containing nanoparticles	— Building construction — Civil engineering construction — Shipbuilding — Industrial facilities maintenance
	Whole body **Protective clothing against solid particles**	— Demolition — Work in presence of asbestos — Use of materials consisting of/containing nanoparticles — Chimney sweeper — Preparation of plant protection products	— Building construction — Civil engineering construction — Shipbuilding — Industrial facilities maintenance — Agriculture
	Eyes **Spectacles/goggles and face shields**	— Woodworking — Road work	— Mining industry — Metal and wood industry — Civil engineering construction
Liquid (mists and fogs)	Respiratory system **Respiratory protective devices against particles**	— Surface treatment (e.g. varnishing/painting, abrasive blasting) — Surface cleaning	— Metal Industry — Manufacturing Industry — Automotive sector
	Hands **Chemical protective gloves**	— Surface treatment — Surface cleaning — Work with liquid sprays — Works with acids and caustic solutions, disinfectants and corrosive cleaning substances	— Metal Industry — Manufacturing industry — Automotive sector
	Whole body **Chemical protective clothing**	— Surface treatment — Surface cleaning	— Metal Industry — Manufacturing industry — Automotive sector

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
		CHEMICAL — LIQUIDS	
Immersion Splashes, sprays and jets	Hands **Chemical protective gloves,**	— Work with liquid sprays — Works with acids and caustic solutions, disinfectants and corrosive cleaning products — Processing of coating materials — Tanning — Work in hairdressers and beauty salons	— Textile and clothing industry — Cleaning industry — Automobile industry — Beauty and hairdressing sectors
	Forearms **Chemical protective sleeves**	— Works with acids and caustic solutions, disinfectants and corrosive cleaning products	— Cleaning — Chemical industry — Cleaning industry — Automobile industry
	Foot **Chemical protective boots**	— Work with liquid sprays — Works with acids and caustic solutions, disinfectants and corrosive cleaning products	— Textile and clothing industry — Cleaning industry — Automobile industry
	Whole body **Chemical protective clothing**	— Work with liquid sprays — Works with acids and caustic solutions, disinfectants and corrosive cleaning products	— Cleaning — Chemical industry — Cleaning industry — Automobile industry — Agriculture
		CHEMICAL — GASES AND VAPOURS	
Gases and vapours	Respiratory system **Respiratory protective devices against gases**	— Surface treatment (e.g. varnishing/painting, abrasive blasting) — Surface cleaning — Work in fermentation and distilling rooms — Work inside tanks and digesters — Work in containers, restricted areas and gas-fired industrial furnaces where there may be gas or insufficient oxygen — Chimney sweeper — Disinfectants and corrosive cleaning substances — Work in the vicinity of gas converters and blast furnace gas pipes	— Metal Industry — Automotive sector — Manufacturing industry — Cleaning industry — Alcoholic drinks production — Wastewater treatment plants — Waste treatment plant — Chemical Industry — Petrochemical industry
	Hands **Chemical protective gloves**	— Surface treatment — Surface cleaning — Work in fermentation and distilling rooms — Work inside tanks and digesters — Work in containers, restricted areas and gas-fired industrial furnaces where there may be gas or insufficient oxygen	— Metal Industry — Automotive sector — Manufacturing industry — Alcoholic drinks production — Wastewater treatment plants — Waste treatment plant — Chemical Industry — Petrochemical industry

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
	Whole body **Chemical protective clothing**	— Surface treatment — Surface cleaning — Work in fermentation and distilling rooms — Work inside tanks and digesters — Work in containers, restricted areas and gas-fired industrial furnaces where there may be gas or insufficient oxygen	— Metal Industry — Automotive sector — Manufacturing industry — Alcoholic drinks production — Wastewater treatment plants — Waste treatment plant — Chemical Industry — Petrochemical industry
	Eyes **Spectacles, goggles and face shields**	— Spray painting — Woodworking — Mining operations	— Automotive sector — Manufacturing industry — Mine industry — Chemical Industry — Petrochemical industry

III. **BIOLOGICAL AGENTS**

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
BIOLOGICAL AGENTS (contained in) - AEROSOLS			
Solids and liquids	Respiratory system **Respiratory protective devices against particles**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry — Biochemical production
	Hands **Protective gloves against microorganisms** Whole/partial body **Protective clothing against biological agents** Eyes and/or face **Protective spectacles, goggles and face shields**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
BIOLOGICAL AGENTS (contained in) - LIQUIDS			
Direct and indirect contact	Hands **Protective gloves against microorganisms** Whole/partial body **Protective clothing against biological agents** Eyes and/or face **Protective goggles and face shields**	— Work that involve contact with human body and animal fluids and tissues (bites, stings) — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry — Forest industry
Splashes, sprays and jets	Hands **Protective gloves against microorganisms**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry
	Forearms **Protective sleeves against microorganisms**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry
	Foot/legs **Protective over boots and gaiters**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
	Whole body **Protective clothing against biological agents**	— Work that involve contact with human body and animal fluids and tissues — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry
BIOLOGICAL AGENTS (contained in) – MATERIALS, PERSONS, ANIMALS, ETC.			
Direct and indirect contact	Hands **Protective gloves against microorganisms** Whole/partial body **Protective clothing against biological agents** Eyes and/or face **Protective goggles and face shields**	— Work that involve contact with human body and animal fluids and tissues (bites, stings) — Work in presence of biological agent	— Healthcare — Veterinary clinics — Clinical analysis laboratories — Research Laboratories — Retirement homes — Homes assistances — Wastewater treatment plants — Waste treatment plant — Food Industry — Forest industry

IV. **OTHER RISKS**

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
Non-visibility	Whole body **PPE for signalling the user's presence visually**	— Work in proximity of movement of vehicles — Asphalt works and road marking — Railway works — Driving means of transport — Work of ground staff at airport	— Building construction — Civil engineering construction — Shipbuilding — Mining works — Transport services and passengers transports
Oxygen deficiency	Respiratory system **Insulating respiratory protectives devices**	— Work in confined spaces — Work in fermentation and distilling rooms — Work inside tanks and digesters — Work in containers, restricted areas and gas-fired industrial furnaces where there may be gas or insufficient oxygen — Work in shafts, sewers and other underground areas connected with sewage	— Alcoholic drinks production — Civil engineering construction — Chemical Industry — Petrochemical industry
	Respiratory system **Diving equipment**	— Underwater works	— Civil engineering construction

Risks	Body part affected Type of PPE	Examples of activities where the use of the corresponding type of PPE may be necessary (*)	Industry and Sectors
Drowning	Whole body **Life jacket**	— Work on or near water — Work in the sea — Work in an airplane	— Fishing industry — Aeronautical industry — Building construction — Civil engineering construction — Shipbuilding — Docks and harbours'

COMMISSION DIRECTIVE (EU) 2019/1833

of 24 October 2019

amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament and of the Council as regards purely technical adjustments

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ([1]), and in particular Article 19 thereof,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights ([2]), proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to a healthy, safe and well-adapted working environment. The workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes protection from exposure to biological agents at work.

(2) The implementation of the directives related to the health and safety of workers at work, including Directive 2000/54/EC, was the subject of an *ex-post* evaluation, referred to as a REFIT evaluation. The evaluation looked at the directives' relevance, at research and at new scientific knowledge in the various fields concerned. The REFIT evaluation, referred to in the Commission Staff Working Document ([3]), concludes, among other things, that the classified list of biological agents in Annex III to Directive 2000/54/EC needs to be amended in light of scientific and technical progress and that consistency with other relevant directives should be enhanced.

(3) In its Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' ([4]), the Commission reiterated that while the REFIT evaluation of the Union's *acquis* on occupational health and safety confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground. The Commission emphasises the particular need to update the list of biological agents in Annex III to Directive 2000/54/EC.

(4) Directive 2000/54/EC lays down rules to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. Directive 2000/54/EC applies to activities in which workers are exposed, or are potentially exposed, to biological agents as a result of their work, and states the measures to be taken in the case of any activity likely to involve a risk of exposure to biological agents, to determine the nature, degree and duration of workers' exposure to biological agents.

(5) Since the results of a risk assessment can show an unintended exposure to biological agents, there could be other work activities not included in Annex I to Directive 2000/54/EC that should also be taken into consideration. Therefore, the indicative list of activities set out in Annex I to Directive 2000/54/EC should be amended to include an introductory phrase in order to clarify the non-exhaustive nature of the list.

([1]) OJ L 262, 17.10.2000, p. 21.
([2]) European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en
([3]) SWD(2017) 10 final.
([4]) COM(2017) 12.

(6) Annex III to Directive 2000/54/EC sets out the list of biological agents known to infect humans, classified according to their level of risk of infection. In line with introductory note 6 in that Annex, the list should be amended to take into account the latest state of knowledge as regards scientific development that have brought about significant changes since the list was last updated, particularly as regards the taxonomy, nomenclature, classification and characteristics of biological agents, and the existence of new biological agents.

(7) Annexes V and VI to Directive 2000/54/EC lay down the containment measures and levels for laboratories, animal facilities and industry. Annexes V and VI should be amended and restructured in order to be aligned with and to take into account the containment and other protective measures included in Directive 2009/41/EC of the European Parliament and of the Council ([5]).

(8) In preparing the current update of Annexes I, III V and VI to Directive 2000/54/EC, consideration was given to the need to maintain the existing levels of protection for workers who are or who are potentially exposed to biological agents through their work, and to ensure that the amendments only take into account scientific developments in the area, requiring adjustments at the workplace that are merely technical in nature.

(9) The Advisory Committee for Safety and Health at Work was consulted on the measures resulting from the adoption of the Commission's Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' that are required to keep the Union's occupational health and safety legislation effective and fit-for-purpose.

(10) In its 'Opinion on the Modernisation of Six OSH Directives to Ensure Healthier and Safer Work for All' ([6]), adopted on 6 December 2017, the Advisory Committee for Safety and Health at Work recommends that Directive 2000/54/EC should be amended to enhance its relevance and effectiveness.

(11) In a subsequent 'Opinion on technical updates to the annexes of the Biological Agents Directive (2000/54/EC)' ([7]), adopted on 31 May 2018, the Advisory Committee for Safety and Health at Work recommends that specific updates should be made to Annex I, III, V and VI, reflecting the latest technological and scientific developments in the field.

(12) In preparing the current update of Annexes I, III, V and VI to Directive 2000/54/EC, the Commission was assisted by experts representing Member States, who provided technical and scientific support.

(13) In accordance with the Joint Political Declaration on explanatory documents ([8]), adopted by the Member States and the Commission on 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(14) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 17 of Council Directive 89/391/EEC ([9]),

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I, III, V and VI to Directive 2000/54/EC are replaced by the text in the Annex to this Directive.

([5]) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).
([6]) Advisory Committee for Safety and Health at Work Doc. 1718/2017.
([7]) Advisory Committee for Safety and Health at Work Doc. 434/18.
([8]) OJ C 369, 17.12.2011, p. 14.
([9]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

(1) Annex I to Directive 2000/54/EC is replaced by the following:

'ANNEX I

INDICATIVE LIST OF ACTIVITIES

(Article 4(2))

Preliminary note

Where the result of the risk assessment, carried out in accordance with Article 3 and Article 4(2) of this Directive, shows an unintentional exposure to biological agents, there may be other work activities, not included in this Annex, which should be considered.

1. Work in food production plants.
2. Work in agriculture.
3. Work activities where there is contact with animals and/or products of animal origin.
4. Work in healthcare, including isolation and post-mortem units.
5. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
6. Work in refuse disposal plants.
7. Work in sewage purification installations.'.

(2) Annex III to Directive 2000/54/EC is replaced by the following:

'ANNEX III

COMMUNITY CLASSIFICATION

Article 2, second paragraph, and Article 18

INTRODUCTORY NOTES

1. In line with the scope of the Directive, only agents which are known to infect humans are to be included in the classified list.

   Where appropriate, indicators are given of the toxic and allergic potential of these agents.

   Animal and plant pathogens which are known not to affect man are excluded.

   In drawing up this list of classified biological agents consideration has not been given to genetically modified micro-organisms.

2. The list of classified agents is based on the effect of those agents on healthy workers.

   No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding.

   Additional risk to such workers should be considered as part of the risk assessment required by the Directive.

   In certain industrial processes, certain laboratory work or certain work with animals involving actual or potential exposure to biological agents of groups 3 or 4, any technical precautions taken must comply with Article 16 of the Directive.

3. Biological agents which have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified in group 1.

   For genera where more than one species is known to be pathogenic to man, the list will include those species which are known to be the most frequently responsible for diseases, together with a more general reference to the fact that other species of the same genus may affect health.

   When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains known to be non-pathogenic are excluded.

4. Where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to assessment appropriate for risk in the workplace.

   This is the case, for example, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements of the taxonomy and nomenclature of agents at the time the list was prepared.

6. The list of classified biological agents reflects the state of knowledge at the time that it was devised.

   It will be updated as soon as it no longer reflects the latest state of knowledge.

7. Member States are to ensure that all viruses which have already been isolated in humans and which have not been assessed and allocated in this Annex are classified in group 2 as a minimum, except where Member States have proof that they are unlikely to cause disease in humans.

8. Certain biological agents classified in group 3 which are indicated in the appended list by two asterisks (**), may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

   Member States shall assess the containment measures to be applied to such agents, taking account of the nature of specific activities in question and of the quantity of the agent involved, with a view to determining whether, in particular circumstances, some of these measures may be dispensed with.

9. The requirements as to containment consequent on the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

10. This list also gives a separate indication in cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 years.

    These indications are shown by the following letters:

    A: Possible allergic effects

    D: List of workers exposed to this biological agent to be kept for more than 10 years after the end of last known exposure

    T: Toxin production

    V: Effective vaccine available and registered within the EU

    The application of preventive vaccination should take account of the code of practice given in Annex VII.

BACTERIA

and similar organisms

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of "spp." refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
Actinomadura madurae	W	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actinomyces spp.	2	
Aggregatibacter actinomycetemcomitans (Actinobacillus actinomycetemcomitans)	2	
Anaplasma spp.	2	
Arcanobacterium haemolyticum (Corynebacterium haenolyticum)	2	
Arcobacter butzleri	2	
Bacillus anthracis	3	T
Bacteroides fragilis	2	
Bacteroides spp.	2	
Bartonella bacilliformis	2	
Bartonella quintana (Rochalimaea quintana)	2	
Bartonella (Rochalimaea) spp.	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	
Bordetella pertussis	2	T, V
Bordetella spp.	2	
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp.	2	
Brachyspira spp.	2	
Brucella abortus	3	
Brucella canis	3	
Brucella inopinata	3	
Brucella melitensis	3	
Brucella suis	3	
Burkholderia cepacia	2	
Burkholderia mallei (Pseudomonas mallei)	3	
Burkholderia pseudomallei (Pseudomonas pseudomallei)	3	D

Biological agent	Classification	Notes
Campylobacter fetus subsp. *fetus*	2	
Campylobacter fetus subsp. *venerealis*	2	
Campylobacter jejuni subsp. *doylei*	2	
Campylobacter jejuni subsp. *jejuni*	2	
Campylobacter spp.	2	
Cardiobacterium hominis	2	
Cardiobacterium valvarum	2	
Chlamydia abortus (Chlamydophila abortus)	2	
Chlamydia caviae (Chlamydophila caviae)	2	
Chlamydia felis (Chlamydophila felis)	2	
Chlamydia pneumoniae (Chlamydophila pneumoniae)	2	
Chlamydia psittaci (Chlamydophila psittaci) (avian strains)	3	
Chlamydia psittaci (Chlamydophila psittaci) (other strains)	2	
Chlamydia trachomatis (Chlamydophila trachomatis)	2	
Clostridium botulinum	2	T
Clostridium difficile	2	T
Clostridium perfringens	2	T
Clostridium tetani	2	T, V
Clostridium spp.	2	
Corynebacterium diphtheriae	2	T, V
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	T
Corynebacterium ulcerans	2	T
Corynebacterium spp.	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia spp.	2	
Eikenella corrodens	2	
Elizabethkingia meningoseptica (Flavobacterium meningosepticum)	2	
Enterobacter aerogenes (Klebsiella mobilis)	2	
Enterobacter cloacae subsp. *cloacae (Enterobacter cloacae)*	2	
Enterobacter spp.	2	
Enterococcus spp.	2	
Erysipelothrix rhusiopathiae	2	
Escherichia coli (with the exception of non-pathogenic strains)	2	
Escherichia coli, verocytotoxigenic strains (e.g. O157:H7 or O103)	3 (*)	T
Fluoribacter bozemanae (Legionella)	2	
Francisella hispaniensis	2	

Biological agent	Classification	Notes
Francisella tularensis subsp. *holarctica*	2	
Francisella tularensis subsp. *mediasiatica*	2	
Francisella tularensis subsp. *novicida*	2	
Francisella tularensis subsp. *tularensis*	3	
Fusobacterium necrophorum subsp. *funduliforme*	2	
Fusobacterium necrophorum subsp. *necrophorum*	2	
Gardnerella vaginalis	2	
Haemophilus ducreyi	2	
Haemophilus influenzae	2	V
Haemophilus spp.	2	
Helicobacter pylori	2	
Helicobacter spp.	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae subsp. *ozaenae*	2	
Klebsiella pneumoniae subsp. *pneumoniae*	2	
Klebsiella pneumoniae subsp. *rhinoscleromatis*	2	
Klebsiella spp.	2	
Legionella pneumophila subsp. *fraseri*	2	
Legionella pneumophila subsp. *pascullei*	2	
Legionella pneumophila subsp. *pneumophila*	2	
Legionella spp.	2	
Leptospira interrogans (all serovars)	2	
Leptospira interrogans spp.	2	
Listeria monocytogenes	2	
Listeria ivanovii subsp. *ivanovii*	2	
Listeria invanovii subsp. *londoniensis*	2	
Morganella morganii subsp. *morganii (Proteus morganii)*	2	
Morganella morganii subsp. *sibonii*	2	
Mycobacterium abscessus subsp. *abscessus*	2	
Mycobacterium africanum	3	V
Mycobacterium avium subsp. *avium (Mycobacterium avium)*	2	
Mycobacterium avium subsp. *paratuberculosis (Mycobacterium paratuberculosis)*	2	
Mycobacterium avium subsp. *silvaticum*	2	
Mycobacterium bovis	3	V
Mycobacterium caprae (Mycobacterium tuberculosis subsp. *caprae)*	3	
Mycobacterium chelonae	2	
Mycobacterium chimaera	2	
Mycobacterium fortuitum	2	

Biological agent	Classification	Notes
Mycobacterium intracellulare	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3 (*)	
Mycobacterium pinnipedii	3	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3 (*)	
Mycobacterium xenopi	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Mycoplasma spp.	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Neorickettsia sennetsu (Rickettsia sennetsu, Ehrlichia sennetsu)	2	
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Nocardia spp.	2	
Orientia tsutsugamushi (Rickettsia tsutsugamushi)	3	
Pasteurella multocida subsp. *gallicida (Pasteurella gallicida)*	2	
Pasteurella multocida subsp. *multocida*	2	
Pasteurella multocida subsp. *septica*	2	
Pasteurella spp.	2	
Peptostreptococcus anaerobius	2	
Plesiomonas shigelloides	2	
Porphyromonas spp.	2	
Prevotella spp.	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens (Proteus inconstans)	2	

Biological agent	Classification	Notes
Providencia rettgeri (Proteus rettgeri)	2	
Providencia spp.	2	
Pseudomonas aeruginosa	2	T
Rhodococcus hoagii (Corynebacterium equii)	2	
Rickettsia africae	3	
Rickettsia akari	3 (*)	
Rickettsia australis	3	
Rickettsia canadensis	2	
Rickettsia conorii	3	
Rickettsia heilongjiangensis	3 (*)	
Rickettsia japonica	3	
Rickettsia montanensis	2	
Rickettsia typhi	3	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia sibirica	3	
Rickettsia spp.	2	
Salmonella enterica (choleraesuis) subsp. *arizonae*	2	
Salmonella Enteritidis	2	
Salmonella Paratyphi A, B, C	2	V
Salmonella Typhi	3 (*)	V
Salmonella Typhimurium	2	
Salmonella (other serovars)	2	
Shigella boydii	2	
Shigella dysenteriae (Type 1)	3 (*)	T
Shigella dysenteriae, other than Type 1	2	
Shigella flexneri	2	
Shigella sonnei	2	
Staphylococcus aureus	2	T
Streptobacillus moniliformis	2	
Streptococcus agalactiae	2	
Streptococcus dysgalactiae subsp. *equisimilis*	2	
Streptococcus pneumoniae	2	T, V
Streptococcus pyogenes	2	T
Streptococcus suis	2	
Streptococcus spp.	2	
Treponema carateum	2	
Treponema pallidum	2	

Biological agent	Classification	Notes
Treponema pertenue	2	
Treponema spp.	2	
Trueperella pyogenes	2	
Ureaplasma parvum	2	
Ureaplasma urealyticum	2	
Vibrio cholerae (including El Tor)	2	T, V
Vibrio parahaemolyticus (Benecka parahaemolytica)	2	
Vibrio spp.	2	
Yersinia enterocolitica subsp. *enterolitica*	2	
Yersinia enterocolitica subsp. *palearctica*	2	
Yersinia pestis	3	
Yersinia pseudotuberculosis	2	
Yersinia spp.	2	

(*) See paragraph 8 of the introductory notes.

VIRUSES (*)

(*) See paragraph 7 of the introductory notes.

NB: Viruses have been listed according to their order (O), family (F) and genus (G).

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Bunyavirales (O)		
Hantaviridae (F)		
Orthohantavirus (G)		
Andes orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Bayou orthohantavirus	3	
Black Creek Canal orthohantavirus	3	
Cano Delgadito orthohantavirus	3	
Choclo orthohantavirus	3	
Dobrava-Belgrade orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
El Moro Canyon orthohantavirus	3	
Hantaan orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Laguna Negra orthohantavirus	3	
Prospect Hill orthohantavirus	2	
Puumala orthohantavirus (Hantavirus species causing Nephropathia Epidemica [NE])	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Seoul orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Sin Nombre orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Other hantaviruses known to be pathogenic	2	
Nairoviridae (F)		
Orthonairovirus (G)		
Crimean-Congo haemorrhagic fever orthonairovirus	4	
Dugbe orthonairovirus	2	
Hazara orthonairovirus	2	
Nairobi sheep disease orthonairovirus	2	
Other nairoviruses known to be pathogenic	2	
Peribunyaviridae (F)		
Orthobunyavirus (G)		
Bunyamwera orthobunyavirus (Germiston virus)	2	
California encephalitis orthobunyavirus	2	
Oropouche orthobunyavirus	3	
Other orthobunyaviruses known to be pathogenic	2	
Phenuiviridae (F)		
Phlebovirus (G)		
Bhanja phlebovirus	2	
Punta Toro phlebovirus	2	
Rift Valley fever phl**e**bovirus	3	
Sandfly fever Naples phlebovirus (Toscana Virus)	2	
SFTS phlebovirus (Severe Fever with Thrombocytopenia Syndrome-Virus)	3	
Other phleboviruses known to be pathogenic	2	
Herpesvirales (O)		
Herpesviridae (F)		
Cytomegalovirus (G)		
Human betaherpesvirus 5 (Cytomegalovirus)	2	
Lymphocryptovirus (G)		
Human gammaherpesvirus 4 (Epstein-Barr virus)	2	
Rhadinoovirus (G)		
Human gammaherpesvirus 8	2	D
Roseolovirus (G)		
Human betaherpesvirus 6A (Human B-lymphotropic virus)	2	
Human betaherpesvirus 6B	2	
Human betaherpesvirus 7	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Simplexvirus (G)		
Macacine alphaherpesvirus 1 (Herpesvirus simiae, Herpes B virus)	3	
Human alphaherpesvirus 1 (Human herpesvirus 1, Herpes simplex virus type 1)	2	
Human alphaherpesvirus 2 (Human herpesvirus 2, Herpes simplex virus type 2)	2	
Varicellovirus (G)		
Human alphaherpesvirus 3 (Herpesvirus varicella-zoster)	2	V
Mononegavirales (O)		
Filoviridae (F)		
Ebolavirus (G)	4	
Marburgvirus (G)		
Marburg marburgvirus	4	
Paramyxoviridae (F)		
Avulavirus (G)		
Newcastle disease virus	2	
Henipavirus (G)		
Hendra henipavirus	4	
Nipah henipavirus	4	
Morbillivirus (G)		
Measles morbillivirus	2	V
Respirovirus (G)		
Human respirovirus 1 (Parainfluenza virus 1)	2	
Human respirovirus 3 (Parainfluenza virus 3)	2	
Rubulavirus (G)		
Mumps rubulavirus	2	V
Human rubulavirus 2 (Parainfluenza virus 2)	2	
Human rubulavirus 4 (Parainfluenza virus 4)	2	
Pneumoviridae (F)		
Metapneumovirus (G)		
Orthopneumovirus (G)		
Human orthopneumovirus (Respiratory syncytial virus)	2	
Rhabdoviridae (F)		
Lyssavirus (G)		
Australian bat lyssavirus	3 (**)	V
Duvenhage lyssavirus	3 (**)	V
European bat lyssavirus 1	3 (**)	V
European bat lyssavirus 2	3 (**)	V

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Lagos bat lyssavirus	3 (**)	
Mokola lyssavirus	3	
Rabies lyssavirus	3 (**)	V
Vesiculovirus (G)		
Vesicular stomatitis virus, Alagoas vesiculovirus	2	
Vesicular stomatitis virus, Indiana vesiculovirus	2	
Vesicular stomatitis virus, New Jersey vesiculovirus	2	
Piry vesiculovirus (Piry virus)	2	
Nidovirales (O)		
Coronaviridae (F)		
Betacoronavirus (G)		
Severe acute respiratory syndrome-related coronavirus (SARS-virus)	3	
Middle East respiratory syndrome coronavirus (MERS-virus)	3	
Other *Coronaviridae* known to be pathogenic	2	
Picornavirales (O)		
Picornaviridae (F)		
Cardiovirus (G)		
Saffold virus	2	
Cosavirus (G)		
Cosavirus A	2	
Enterovirus (G)		
Enterovirus A	2	
Enterovirus B	2	
Enterovirus C	2	
Enterovirus D, Human Enterovirus type 70 (Acute haemorrhagic conjunctivitis virus)	2	
Rhinoviruses	2	
Poliovirus, type 1 and 3	2	V
Poliovirus, type 2 ([1])	3	V
Hepatovirus (G)		
Hepatovirus A (Hepatitis A virus, Human Enterovirus type 72)	2	V
Kobuvirus (G)		
Aichivirus A (Aichi virus 1)	2	
Parechovirus (G)		
Parechoviruses A	2	
Parechoviruses B (Ljungan virus)	2	
Other *Picornaviridae* known to be pathogenic	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Unassigned (O)		
Adenoviridae (F)	2	
Astroviridae (F)	2	
Arenaviridae (F)		
Mammarenavirus (G)		
Brazilian mammarenavirus	4	
Chapare mammarenavirus	4	
Flexal mammarenavirus	3	
Guanarito mammarenavirus	4	
Junín mammarenavirus	4	
Lassa mammarenavirus	4	
Lujo mammarenavirus	4	
Lymphocytic choriomeningitis mammarenavirus, neurotropic strains	2	
Lymphocytic choriomeningitis mammarenavirus (other strains)	2	
Machupo mammarenavirus	4	
Mobala mammarenavirus	2	
Mopeia mammarenavirus	2	
Tacaribe mammarenavirus	2	
Whitewater Arroyo mammarenavirus	3	
Caliciviridae (F)		
Norovirus (G)		
Norovirus (Norwalk virus)	2	
Other *Caliciviridae* known to be pathogenic	2	
Hepadnaviridae (F)		
Orthohepadnavirus (G)		
Hepatitis B virus	3 (**)	V, D
Hepeviridae (F)		
Orthohepevirus (G)		
Orthohepevirus A (Hepatitis E virus)	2	
Flaviviridae (F)		
Flavivirus (G)		
Dengue virus	3	
Japanese encephalitis virus	3	V
Kyasanur Forest disease virus	3	V
Louping ill virus	3 (**)	
Murray Valley encephalitis virus (Australia encephalitis virus)	3	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Omsk haemorrhagic fever virus	3	
Powassan virus	3	
Rocio virus	3	
St. Louis encephalitis virus	3	
Tick-borne encephalitis virus		
Absettarov virus	3	
Hanzalova virus	3	
Hypr virus	3	
Kumlinge virus	3	
Negishi virus	3	
Russian spring-summer encephalitis ([a])	3	V
Tick-borne encephalitis virus Central European subtype	3 (**)	V
Tick-borne encephalitis virus Far Eastern Subtype	3	
Tick-borne encephalitis virus Siberian subtype	3	V
Wesselsbron virus	3 (**)	
West Nile fever virus	3	
Yellow fever virus	3	V
Zika virus	2	
Other flaviviruses known to be pathogenic	2	
Hepacivirus (G)		
Hepacivirus C (Hepatitis C virus)	3 (**)	D
Orthomyxoviridae (F)		
Gammainfluenzavirus (G)		
Influenza C virus	2	V ([c])
Influenzavirus A (G)		
Highly Pathogenic Avian Influenza Viruses HPAIV (H5), e.g. H5N1	3	
Highly Pathogenic Avian Influenza Viruses HPAIV (H7), e.g. H7N7, H7N9	3	
Influenza A virus	2	V ([c])
Influenza A virus A/New York/1/18 (H1N1) (Spanish flu 1918)	3	
Influenza A virus A/Singapore/1/57 (H2N2)	3	
Low Pathogenic Avian Influenza Virus (LPAI) H7N9	3	
Influenzavirus B (G)		
Influenza B virus	2	V ([c])
Thogoto virus (G)		
Dhori virus (Tick-borne *orthomyxoviridae*: Dhori)	2	
Thogoto virus (Tick-borne *orthomyxoviridae*: Thogoto)	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Papillomaviridae (F)	2	D ([d])
Parvoviridae (F)		
Erythroparvovirus (G)		
Primate erythroparvovirus 1 (Human parvovirus, B 19 virus)	2	
Polyomaviridae (F)		
Betapolyomavirus (G)		
Human polyomavirus 1 (BK virus)	2	D ([d])
Human polyomavirus 2 (JC virus)	2	D ([d])
Poxviridae (F)		
Molluscipoxvirus (G)		
Molluscum contagiosum virus	2	
Orthopoxvirus (G)		
Cowpox virus	2	
Monkeypox virus	3	V
Vaccinia virus (incl. Buffalopox virus ([e]), Elephantpox virus ([f]), Rabbitpox virus ([g]))	2	
Variola (major and minor) virus	4	V
Parapoxvirus (G)		
Orf virus	2	
Pseudocowpox virus (Milkers' node virus, parapoxvirus bovis)	2	
Yatapoxvirus (G)		
Tanapox virus	2	
Yaba monkey tumor virus	2	
Reoviridae (F)		
Seadornavirus (G)		
Banna virus	2	
Coltivirus (G)	2	
Rotaviruses (G)	2	
Orbivirus (G)	2	
Retroviridae (F)		
Deltaretrovirus (G)		
Primate T-lymphotropic virus 1 (Human T-cell lymphotropic virus, type 1)	3 (**)	D
Primate T-lymphotropic virus 2 (Human T-cell lymphotropic virus, type 2)	3 (**)	D
Lentivirus (G)		
Human immunodeficiency virus 1	3 (**)	D
Human immunodeficiency virus 2	3 (**)	D
Simian Immunodeficiency Virus (SIV) ([h])	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Togaviridae (F)		
Alphavirus (G)		
Cabassouvirus	3	
Eastern equine encephalomyelitis virus	3	V
Bebaru virus	2	
Chikungunya virus	3 (**)	
Everglades virus	3 (**)	
Mayaro virus	3	
Mucambo virus	3 (**)	
Ndumu virus	3 (**)	
O'nyong-nyong virus	2	
Ross River virus	2	
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3 (**)	
Venezuelan equine encephalomyelitis virus	3	V
Western equine encephalomyelitis virus	3	V
Other alphaviruses known to be pathogenic	2	
Rubivirus (G)		
Rubella virus	2	V
Unassigned (F)		
Deltavirus (G)		
Hepatitis delta virus ([b])	2	V, D

(*) See paragraph 7 of the introductory notes.
([1]) Classification according to WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.
(**) See paragraph 8 of the introductory notes.
([a]) Tick-borne encephalitis.
([b]) Hepatitis delta virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus. Vaccination against hepatitis B virus will therefore protect workers who are not affected by hepatitis B virus against hepatitis delta virus.
([c]) Only for types A and B.
([d]) Recommended for work involving direct contact with these agents.
([e]) Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
([f]) Variant of cowpox virus.
([g]) Variant of Vaccinia.
([h]) At present there is no evidence of disease in humans caused by the other retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.

PRION DISEASE AGENTS

Biological agent	Classification	Notes
Agent of Creutzfeldt-Jakob disease	3 (*)	D [a]
Variant Agent of Creutzfeldt-Jakob disease	3 (*)	D [a]
Agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs	3 (*)	D [a]
Agent of Gerstmann-Sträussler-Scheinker syndrome	3 (*)	D [a]
Agent of Kuru	3 (*)	D [a]
Agent of Scrapie	2	

(*) See paragraph 8 of the introductory notes.
[a] Recommended for work involving direct contact with these agents.

PARASITES

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of "spp." refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
Acanthamoeba castellani	2	
Ancylostoma duodenale	2	
Angiostrongylus cantonensis	2	
Angiostrongylus costaricensis	2	
Anisakis simplex	2	A
Ascaris lumbricoides	2	A
Ascaris suum	2	A
Babesia divergens	2	
Babesia microti	2	
Balamuthia mandrillaris	3	
Balantidium coli	2	
Brugia malayi	2	
Brugia pahangi	2	
Brugia timori	2	
Capillaria philippinensis	2	
Capillaria spp.	2	
Clonorchis sinensis (Opisthorchis sinensis)	2	
Clonorchis viverrini (Opisthirchis viverrini)	2	
Cryptosporidium hominis	2	
Cryptosporidium parvum	2	
Cyclospora cayetanensis	2	
Dicrocoelium dentriticum	2	

Biological agent	Classification	Notes
Dipetalonema streptocerca	2	
Diphyllobothrium latum	2	
Dracunculus medinensis	2	
Echinococcus granulosus	3 (*)	
Echinococcus multilocularis	3 (*)	
Echinococcus oligarthrus	3 (*)	
Echinococcus vogeli	3 (*)	
Entamoeba histolytica	2	
Enterobius vermicularis	2	
Enterocytozoon bieneusi	2	
Fasciola gigantica	2	
Fasciola hepatica	2	
Fasciolopsis buski	2	
Giardia lamblia (Giardia duodenalis, Giardia intestinalis)	2	
Heterophyes spp.	2	
Hymenolepis diminuta	2	
Hymenolepis nana	2	
Leishmania aethiopica	2	
Leishmania braziliensis	3 (*)	
Leishmania donovani	3 (*)	
Leishmania guyanensis (Viannia guyanensis)	3 (*)	
Leishmania infantum (Leishmania chagasi)	3 (*)	
Leishmania major	2	
Leishmania mexicana	2	
Leishmania panamensis (Viannia panamensis)	3 (*)	
Leishmania peruviana	2	
Leishmania tropica	2	
Leishmania spp.	2	
Loa loa	2	
Mansonella ozzardi	2	
Mansonella perstans	2	
Mansonella streptocerca	2	
Metagonimus spp.	2	
Naegleria fowleri	3	
Necator americanus	2	
Onchocerca volvulus	2	
Opisthorchis felineus	2	

Biological agent	Classification	Notes
Opisthorchis spp.	2	
Paragonimus westermani	2	
Paragonimus spp.	2	
Plasmodium falciparum	3 (*)	
Plasmodium knowlesi	3 (*)	
Plasmodium spp. (human and simian)	2	
Sarcocystis suihominis	2	
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Strongyloides stercoralis	2	
Strongyloides spp.	2	
Taenia saginata	2	
Taenia solium	3 (*)	
Toxocara canis	2	
Toxocara cati	2	
Toxoplasma gondii	2	
Trichinella nativa	2	
Trichinella nelsoni	2	
Trichinella pseudospiralis	2	
Trichinella spiralis	2	
Trichomonas vaginalis	2	
Trichostrongylus orientalis	2	
Trichostrongylus spp.	2	
Trichuris trichiura	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	2	
Trypanosoma brucei rhodesiense	3 (*)	
Trypanosoma cruzi	3 (*)	
Wuchereria bancrofti	2	

(*) See paragraph 8 of the introductory notes.

FUNGI

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of "spp." refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
Aspergillus flavus	2	A
Aspergillus fumigatus	2	A
Aspergillus spp.	2	
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Blastomyces gilchristii	3	
Candida albicans	2	A
Candida dubliniensis	2	
Candida glabrata	2	
Candida parapsilosis	2	
Candida tropicalis	2	
Cladophialophora bantiana (Xylohypha bantiana, Cladosporium bantianum, trichoides)	3	
Cladophialophora modesta	3	
Cladophialophora spp.	2	
Coccidioides immitis	3	A
Coccidioides posadasii	3	A
Cryptococcus gattii (Filobasidiella neoformans var. bacillispora)	2	A
Cryptococcus neoformans (Filobasidiella neoformans var. neoformans)	2	A
Emmonsia parva var. *parva*	2	
Emmonsia parva var. *crescens*	2	
Epidermophyton floccosum	2	A
Epidermophyton spp.	2	
Fonsecaea pedrosoi	2	
Histoplasma capsulatum	3	
Histoplasma capsulatum var. farciminosum	3	
Histoplasma duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp.	2	A
Nannizzia spp.	2	
Neotestudina rosatii	2	
Paracoccidioides brasiliensis	3	A
Paracoccidioides lutzii	3	
Paraphyton spp.	2	
Rhinocladiella mackenziei	3	

Biological agent	Classification	Notes
Scedosporium apiospermum	2	
Scedosporium prolificans (inflatum)	2	
Sporothrix schenckii	2	
Talaromyces marneffei (Penicillium marneffei)	2	A
Trichophyton rubrum	2	A
Trichophyton tonsurans	2	A
Trichophyton spp.	2'	

(3) Annex V to Directive 2000/54/EC is replaced by the following:

'ANNEX V

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

(Articles 15(3) and 16(1)(a) and (b))

Preliminary note

The measures contained in this Annex shall be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned.

In the table, "Recommended" means that the measures should in principle be applied, unless the results of the assessment referred to in Article 3(2) indicate otherwise.

A. Containment measures	B. Containment levels		
	2	3	4
Workplace			
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. The workplace is to be sealable to permit fumigation	No	Recommended	Yes
Facilities			
3. Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
Equipment			
4. Input air and extract air to the workplace are to be filtered using (HEPA [1]) or likewise	No	Yes, on extract air	Yes, on input and extract air
5. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
6. Surfaces impervious to water and easy to clean	Yes, for bench and floor	Yes, for bench, floor and other surfaces determined by risk assessment	Yes, for bench, walls, floor and ceiling

A. Containment measures	B. Containment levels		
	2	3	4
7. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
System of work			
8. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock ([2])
9. Efficient vector control, for example rodents and insects	Recommended	Yes	Yes
10. Specified disinfection procedures	Yes	Yes	Yes
11. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
12. Personnel should shower before leaving the contained area	No	Recommended	Recommended
Waste			
13. Validated inactivation process for the safe disposal of animal carcases	Recommended	Yes, on or off site	Yes, on site
Other measures			
14. A laboratory is to contain its own equipment	No	Recommended	Yes
15. An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes'

([1]) HEPA: High efficiency particulate air
([2]) Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(4) Annex VI to Directive 2000/54/EC is replaced by the following:

'ANNEX VI

CONTAINMENT FOR INDUSTRIAL PROCESSES

(Article 4(1) and Article 16(2)(a))

Preliminary note

In the table, "Recommended" means that the measures should in principle be applied, unless the results of the assessment referred to in Article 3(2) indicate otherwise.

Group 1 biological agents

For work with group 1 biological agents including live attenuated vaccines, the principles of good occupational safety and hygiene should be observed.

Groups 2, 3 and 4 biological agents

It may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of a process.

A. Containment measures	B. Containment levels		
	2	3	4
General			
1. Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Recommended	Yes
7. The controlled area should be sealable to permit fumigation	No	Recommended	Yes
Facilities			
8. Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
Equipment			
9. Input air and extract air to the controlled area should be HEPA ([1]) filtered	No	Recommended	Yes
10. The controlled area should be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
11. The controlled area should be adequately ventilated to minimise air contamination	Recommended	Recommended	Yes
System of work			
12. Closed systems ([2]) should be located within a controlled area	Recommended	Recommended	Yes, and purpose-built
13. Biohazard signs should be posted	Recommended	Yes	Yes
14. Access should be restricted to nominated personnel only	Recommended	Yes	Yes, via an airlock ([3])

A. Containment measures	B. Containment levels		
	2	3	4
15. Personnel should shower before leaving the controlled area	No	Recommended	Yes
16. Personnel should wear protective clothing	Yes, work clothing	Yes	Yes, complete change
Waste			
17. Effluent from sinks and showers should be collected and inactivated before release	No	Recommended	Yes
18. Effluent treatment before final discharge	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means'

([1]) HEPA: High efficiency particulate air
([2]) Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).
([3]) Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

COMMISSION DIRECTIVE (EU) 2019/1834

of 24 October 2019

amending Annexes II and IV to Council Directive 92/29/EEC as regards purely technical adaptations

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels ([1]), and in particular Article 8 thereof,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights ([2]), proclaimed at Gothenburg on 17 November 2017, states that every worker has the right to a healthy, safe and well-adapted working environment. The workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes improved medical treatment on board vessels.

(2) The implementation of the directives related to the health and safety of workers at work, including Directive 92/29/EEC, was the subject of an *ex post* evaluation, referred to as REFIT evaluation. The evaluation looked at the directives' relevance, at research and at new scientific knowledge in the various fields concerned. The REFIT evaluation, referred to in the Commission Staff Working Document ([3]), concludes, among other things, that the list of mandatory medical supplies in Annex II of Directive 92/29/EEC needs to be updated and that coherence with international instruments should be enhanced.

(3) In its Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' ([4]), the Commission reiterated that while the REFIT evaluation of the Union's *acquis* on occupational safety and health confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground. The Commission emphasises the particular need to update the list of mandatory medical supplies in Annex II to Directive 92/29/EEC.

(4) Directive 92/29/EEC lays down minimum safety and health requirements for improved medical treatment for persons carrying out an occupation on board a vessel. It lists the medical supplies required on board and addresses how responsibilities are assigned, information and training, and inspection.

(5) Annex II to Directive 92/29/EEC contains a non-exhaustive list of medical supplies required on board, including medicines, medical equipment and antidotes. The requirements as regards the medical supplies vary according to the category of vessel as defined in Annex I of that Directive.

(6) It is appropriate to amend Annex II to Directive 92/29/EEC in the light of the scientific and medical developments that have taken place since its adoption, particularly as regards the new medicines and medical equipment that have become available, and medicines or medical equipment which are not required to be carried on board any more. Moreover, in several instances, medical practice has shown that the wording of existing entries in Annex II to Directive 92/29/EEC needs to be updated or adapted to reflect current practices more closely.

([1]) OJ L 113, 30.4.1992, p. 19.
([2]) European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en
([3]) SWD(2017) 10 final
([4]) COM(2017) 12 final

(7) Vessels staying very close to shore or with no cabin accommodation belonging to category C should be given particular consideration as these vessels tend to be smaller and may lack the space for full medical supplies. Annex II to Directive 92/29/EEC should therefore allow Member States to consider, under exceptional circumstances, the use of alternatives (medicines or medical equipment) for objectively justified reasons. Given the specificities of category C vessels, there is no need to carry certain items on board and therefore the list of medicines and medical equipment of that category should be slightly shortened.

(8) Annex IV to Directive 92/29/EEC should be amended to take into account the amendment of Annex II, because Annex IV lays down a general framework for the inspection of the vessels' medical supplies and as such is closely related to Annex II and reproduces its contents for inspection purposes.

(9) Annexes II and IV to Directive 92/29/EEC should be amended to take into account international instruments, such as the International Medical Guide for Ships ([5]), as well as to maintain the existing levels of protection for persons carrying out an occupation on board a vessel, and to reflect scientific and medical developments in the area, requiring merely technical adjustments at the workplace.

(10) The Advisory Committee for Safety and Health at Work was consulted on the measures resulting from the adoption of the Commission's Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' that are required to keep the Union's occupational safety and health legislation effective and fit-for-purpose.

(11) In its 'Opinion on the Modernisation of Six OSH Directives to Ensure Healthier and Safer Work for All' ([6]), adopted on 6 December 2017, the Advisory Committee for Safety and Health at Work recommends that Annexes II and IV to Directive 92/29/EEC should be updated.

(12) In a subsequent 'Opinion on the Technical updates of annexes of the Directive Medical Treatment on board (92/29)' ([7]), adopted on 31 May 2018, the Advisory Committee for Safety and Health at Work recommends that Annexes II and IV to Directive 92/29/EEC should be updated to take into account the latest technological and medical developments in the field.

(13) The Commission was assisted by experts representing the Member States, who provided technical and scientific support.

(14) In accordance with the Joint Political Declaration on explanatory documents ([8]), adopted by the Member States and the Commission on 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(15) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 8 of Directive 92/29/EEC,

([5]) International medical guide for ships: including the ship's medicine chest. 3rd ed., World Health Organization, 2007 (ISBN 978 92 4 154720 8)
([6]) Advisory Committee for Safety and Health at Work Doc. 1718/2017
([7]) Advisory Committee for Safety and Health at Work Doc. 444/18
([8]) OJ C 369, 17.12.2011, p. 14.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and IV to Directive 92/29/EEC are replaced by the text in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

(1) Annex II to Directive 92/29/EEC is replaced by the following:

'ANNEX II

MEDICAL SUPPLIES (NON-EXHAUSTIVE LIST) (*)

(Article 1(d))

(*) *In light of Article 2(1)(a) Member States may, under exceptional circumstances, consider the use of alternative medicines or medical equipment for objectively justified reasons.*

I. **MEDICINES**

	Categories of vessels		
	A	B	C
1. **Cardiovascular**			
(a) Cardio-circulatory sympathomimetics	x	x	
(b) Anti-angina preparations	x	x	x
(c) Diuretics	x	x	
(d) Anti-haemorrhagics including uterotonics if there are women on board	x	x	
(e) Anti-hypertensive	x	x	
2. **Gastro-intestinal system**			
(a) Medicines for gastric and duodenal disorders			
— Medicine for treatment of stomach ulcer and gastritis	x	x	
— Anti-acid mucous dressings	x	x	
(b) Anti-emetics	x	x	
(c) Laxatives	x		
(d) Anti-diarrhoeals	x	x	x
(e) Haemorrhoid preparations	x	x	
3. **Analgesics and anti-spasmodics**			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	x	x	x
(b) Powerful analgesics	x	x	
(c) Spasmolytics	x	x	
4. **Nervous system**			
(a) Anxiolytics	x	x	
(b) Neuroleptics	x	x	
(c) Seasickness remedies	x	x	x
(d) Anti-epileptics	x	x	
5. **Anti-allergics and anti-anaphylactics**			
(a) Anti-histaminics	x	x	
(b) Glucocorticoids	x	x	

	Categories of vessels		
	A	B	C
6. **Respiratory system**			
(a) Bronchiospasm preparations	x	x	
(b) Anti-tussives	x	x	
(c) Medicines used for colds and sinusitis	x	x	
7. **Anti-infection**			
(a) Antibiotics (at least two classes)	x	x	
(b) Anti-parasitics	x	x	
(c) Anti-tetanus vaccines and immunoglobulins	x	x	
(d) Anti-malaria medicines, carriage shall be dependent upon operational area	x	x	
8. **Compounds promoting rehydration, caloric intake and plasma expansion**	x	x	
9. **Medicines for external use**			
(a) *Skin medicines*			
— Antiseptic solutions	x	x	x
— Antibiotic ointments	x	x	
— Anti-inflammatory and analgesic ointments	x	x	
— Anti-mycotic skin creams	x		
— Burn preparations	x	x	x
(b) *Eye medicines*			
— Antibiotic and anti-inflammatory	x	x	
— Anaesthetic drops	x	x	
— Saline solution for eyewash	x	x	x
— Hypotonic myotic drops	x	x	
(c) *Ear medicines*			
— Anaesthetic and anti-inflammatory solutions	x	x	
(d) *Medicines for oral and throat infections*			
— Antiseptic mouthwashes	x	x	
(e) *Local anaesthetics*			
— Local anaesthetics using freezing	x		
— Local anaesthetics given by subcutaneous injection	x	x	

II. **MEDICAL EQUIPMENT**

	Categories of vessels		
	A	B	C
1. **Resuscitation equipment**			
— Ambu bag (or equivalent); supplied with large, medium and small masks	x	x	
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container ([1])	x	x	
— Mechanical aspirator to clear upper respiratory passages	x	x	
2. **Dressing and suturing equipment**			
— Tourniquets	x	x	x
— Disposable suture stapler or suture kit with needles	x	x	
— Adhesive elastic bandage	x	x	x
— Gauze strips	x	x	
— Tubular gauze for finger bandages	x		
— Sterile gauze compresses	x	x	x
— Sterile sheet for burns victims	x	x	
— Triangular sling	x	x	
— Disposable gloves	x	x	x
— Adhesive dressings	x	x	x
— Sterile compression bandages	x	x	x
— Adhesive sutures or zinc oxide bandages	x	x	x
— Non-absorbable sutures with needles	x		
— Vaseline gauze	x	x	
3. **Instruments**			
— Disposable scalpels	x		
— Instrument box made of suitable material	x	x	
— Scissors	x	x	
— Dissecting forceps	x	x	
— Haemostatic clamps	x	x	
— Needle forceps	x		
— Disposable razors	x		
4. **Examination and monitoring equipment**			
— Disposable tongue depressors	x	x	
— Reactive strips for urine analysis	x		
— Temperature charts	x		
— Medical evacuation sheets	x	x	
— Stethoscope	x	x	
— Sphygmomanometer	x	x	

	Categories of vessels		
	A	B	C
— Medical thermometer	x	x	
— Hypothermic thermometer	x	x	
— Quick malaria test, carriage shall be dependent upon operational area	x	x	
5. **Equipment for injection, perfusion, puncture and catheterisation**			
— Bladder drainage equipment (suitable for men and women)	x		
— Intravenous infusion set	x	x	
— Disposable syringes and needles	x	x	
6. **General medical equipment**			
— Personal protective medical and nursing equipment	x	x	
— Bedpan	x		
— Hot-water bottle	x		
— Urine bottle	x		
— Ice bag	x		
7. **Immobilisation and setting equipment**			
— Set of splints of different sizes for the extremities	x	x	
— Collar for neck immobilisation	x	x	
8. **Disinfection, disinsectisation and prophylaxis**			
— Water-disinfection compound	x		
— Liquid insecticide	x		
— Powder insecticide	x		

([1]) Under the conditions of use prescribed by national laws and/or practices

III. **ANTIDOTES**

1. **Medicines**
— General
— Cardio-vascular
— Gastro-intestinal system
— Nervous system
— Respiratory system
— Anti-infective
— For external use
2. **Medical equipment**
— Necessary for the administration of oxygen (including maintenance requisites)

Note:

For the detailed implementation of Section III, Member States may refer to the IMO Medical First Aid Guide for use in accidents involving dangerous goods (MFAG) contained in the 1990 consolidated edition of the IMO International Maritime Dangerous Goods Code, as amended.

Any adaptation of Section III in implementation of Article 8 may take account, inter alia, of any updating of the MFAG.'

(2) Annex IV to Directive 92/29/EEC is replaced by the following:

'ANNEX IV

GENERAL FRAMEWORK FOR THE INSPECTION OF VESSELS' MEDICAL SUPPLIES

(Article 2(1)(c), Article 3(3))

SECTION A

CATEGORY A VESSELS

I. **Details of the vessel**

Name: .....

Flag: .....

Home port: .....

II. **Medical supplies**

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. **MEDICINE**			
1.1. **Cardiovascular**			
(a) Cardio-circulatory sympathomimetics	0	0	0
(b) Anti-angina preparations	0	0	0
(c) Diuretics	0	0	0
(d) Anti-haemorrhagics including uterotonics if there are women on board	0	0	0
(e) Anti-hypertensive	0	0	0
1.2. **Gastro-intestinal system**			
(a) Medicines for gastric and duodenal disorders	0	0	0
— Medicine for treatment of stomach ulcer and gastritis	0	0	0
— Anti-acid mucous dressings	0	0	0
(b) Anti-emetics	0	0	0
(c) Laxatives	0	0	0
(d) Anti-diarrhoeals	0	0	0
(e) Haemorrhoid preparations	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1.3. **Analgesics and anti-spasmodics**			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
(b) Powerful analgesics	0	0	0
(c) Spasmolytics	0	0	0
1.4. **Nervous system**			
(a) Anxiolytics	0	0	0
(b) Neuroleptics	0	0	0
(c) Seasickness remedies	0	0	0
(d) Anti-epileptics	0	0	0
1.5. **Anti-allergics and anti-anaphylactics**			
(a) Anti-histaminics	0	0	0
(b) Glucocorticoids	0	0	0
1.6. **Respiratory system**			
(a) Bronchiospasm preparations	0	0	0
(b) Anti-tussives	0	0	0
(c) Medicines used for colds and sinusitis	0	0	0
1.7. **Anti-infection**			
(a) Antibiotics (at least two classes)	0	0	0
(b) Anti-parasitics	0	0	0
(c) Anti-tetanus vaccines and immunoglobulins	0	0	0
(d) Anti-malaria medicines, carriage shall be dependent upon operational area	0	0	0
1.8. **Compounds promoting rehydration, caloric intake and plasma expansion**	0	0	0
1.9. **Medicines for external use**			
(a) *Skin medicines*	0	0	0
— Antiseptic solutions	0	0	0
— Antibiotic ointments	0	0	0
— Anti-inflammatory and analgesic ointments	0	0	0
— Anti-mycotic skin creams	0	0	0
— Burn preparations	0	0	0
(b) *Eye medicines*	0	0	0
— Antibiotic and anti-inflammatory	0	0	0
— Anaesthetic drops	0	0	0
— Saline solution for eyewash	0	0	0
— Hypotonic myotic drops	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
(c) *Ear medicines*	0	0	0
— Anaesthetic and anti-inflammatory solutions	0	0	0
(d) *Medicines for oral and throat infections*	0	0	0
— Antiseptic mouthwashes	0	0	0
(e) *Local anaesthetics*	0	0	0
— Local anaesthetics using freezing	0	0	0
— Local anaesthetics given by subcutaneous injection	0	0	0
2. **MEDICAL EQUIPMENT**			
2.1. **Resuscitation equipment**			
— Ambu bag (or equivalent); supplied with large, medium and small masks	0	0	0
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container ([1])	0	0	0
— Mechanical aspirator to clear upper respiratory passages	0	0	0
2.2. **Dressing and suturing equipment**			
— Tourniquets	0	0	0
— Disposable suture stapler or suture kit with needles	0	0	0
— Adhesive elastic bandage	0	0	0
— Gauze strips	0	0	0
— Tubular gauze for finger bandages	0	0	0
— Sterile gauze compresses	0	0	0
— Sterile sheet for burns victims	0	0	0
— Triangular sling	0	0	0
— Disposable gloves	0	0	0
— Adhesive dressings	0	0	0
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
— Non-absorbable sutures with needles	0	0	0
— Vaseline gauze	0	0	0
2.3. **Instruments**			
— Disposable scalpels	0	0	0
— Instrument box made of suitable material	0	0	0
— Scissors	0	0	0
— Dissecting forceps	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
— Haemostatic clamps	0	0	0
— Needle forceps	0	0	0
— Disposable razors	0	0	0
2.4. **Examination and monitoring equipment**	0	0	0
— Disposable tongue depressors	0	0	0
— Reactive strips for urine analysis	0	0	0
— Temperature charts	0	0	0
— Medical evacuation sheets	0	0	0
— Stethoscope	0	0	0
— Sphygmomanometer	0	0	0
— Medical thermometer	0	0	0
— Hypothermic thermometer	0	0	0
— Quick malaria test, carriage shall be dependent upon operational area	0	0	0
2.5. **Equipment for injection, perfusion, puncture and catheterisation**	0	0	0
— Bladder drainage equipment (suitable for men and women)	0	0	0
— Intravenous infusion set	0	0	0
— Disposable syringes and needles	0	0	0
2.6. **General medical equipment**	0	0	0
— Personal protective medical and nursing equipment	0	0	0
— Bedpan	0	0	0
— Hot-water bottle	0	0	0
— Urine bottle	0	0	0
— Ice bag	0	0	0
2.7. **Immobilisation and setting equipment**	0	0	0
— Set of splints of different sizes for the extremities	0	0	0
— Collar for neck immobilisation	0	0	0
2.8. **Disinfection, disinsectisation and prophylaxis**	0	0	0
— Water-disinfection compound	0	0	0
— Liquid insecticide	0	0	0
— Powder insecticide	0	0	0
3. **ANTIDOTES**			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0
3.4. Nervous system	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen (including maintenance requisites)	0	0	0

([1]) Under the conditions of use prescribed by national laws and/or practices.

Venue and date: .....

Captain's signature: .....

Authorisation by competent person or authority: .....

SECTION B

CATEGORY B VESSELS

I. **Details of the vessel**

Name: .....

Flag: .....

Home port: .....

II. **Medical supplies**

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. **MEDICINE**			
1.1. **Cardiovascular**			
(a) Cardio-circulatory sympathomimetics	0	0	0
(b) Anti-angina preparations	0	0	0
(c) Diuretics	0	0	0
(d) Anti-haemorrhagics including uterotonics if there are women on board	0	0	0
(e) Anti-hypertensive	0	0	0
1.2. **Gastro-intestinal system**			
(a) Medicines for gastric and duodenal disorders	0	0	0
— Medicine for treatment of stomach ulcer and gastritis	0	0	0
— Anti-acid mucous dressings	0	0	0
(b) Anti-emetics	0	0	0
(c) Anti-diarrhoeals	0	0	0
(d) Haemorrhoid preparations	0	0	0
1.3. **Analgesics and anti-spasmodics**			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
(b) Powerful analgesics	0	0	0
(c) Spasmolytics	0	0	0
1.4. **Nervous system**			
(a) Anxiolytics	0	0	0
(b) Neuroleptics	0	0	0
(c) Seasickness remedies	0	0	0
(d) Anti-epileptics	0	0	0
1.5. **Anti-allergics and anti-anaphylactics**			
(a) Anti-histaminics	0	0	0
(b) Glucocorticoids	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1.6. **Respiratory system**			
(a) Bronchiospasm preparations	0	0	0
(b) Anti-tussives	0	0	0
(c) Medicines used for colds and sinusitis	0	0	0
1.7. **Anti-infection**			
(a) Antibiotics (at least two classes)	0	0	0
(b) Anti-parasitics	0	0	0
(c) Anti-tetanus vaccines and immunoglobulins	0	0	0
(d) Anti-malaria medicines, carriage shall be dependent upon operational area	0	0	0
1.8. **Compounds promoting rehydration, caloric intake and plasma expansion**	0	0	0
1.9. **Medicines for external use**			
(a) *Skin medicines*	0	0	0
— Antiseptic solutions	0	0	0
— Antibiotic ointments	0	0	0
— Anti-inflammatory and analgesic ointments	0	0	0
— Burn preparations	0	0	0
(b) *Eye medicines*	0	0	0
— Antibiotic and anti-inflammatory	0	0	0
— Anaesthetic drops	0	0	0
— Saline solution for eyewash	0	0	0
— Hypotonic myotic drops	0	0	0
(c) *Ear medicines*	0	0	0
— Anaesthetic and anti-inflammatory solutions	0	0	0
(d) *Medicines for oral and throat infections*	0	0	0
— Antiseptic mouthwashes	0	0	0
(e) *Local anaesthetics*	0	0	0
— Local anaesthetics given by subcutaneous injection	0	0	0
2. **MEDICAL EQUIPMENT**			
2.1 **Resuscitation equipment**			
— Ambu bag (or equivalent); supplied with large, medium and small masks	0	0	0
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container [1]	0	0	0
— Mechanical aspirator to clear upper respiratory passages	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
2.2. **Dressing and suturing equipment**			
— Tourniquets	0	0	0
— Disposable suture stapler or suture kit with needles	0	0	0
— Adhesive elastic bandage	0	0	0
— Gauze strips	0	0	0
— Sterile gauze compresses	0	0	0
— Sterile sheet for burns victims	0	0	0
— Triangular sling	0	0	0
— Disposable gloves	0	0	0
— Adhesive dressings	0	0	0
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
— Vaseline gauze	0	0	0
2.3. **Instruments**			
— Instrument box made of suitable material	0	0	0
— Scissors	0	0	0
— Dissecting forceps	0	0	0
— Haemostatic clamps	0	0	0
2.4. Examination and monitoring equipment	0	0	0
— Disposable tongue depressors	0	0	0
— Medical evacuation sheets	0	0	0
— Stethoscope	0	0	0
— Sphygmomanometer	0	0	0
— Medical thermometer	0	0	0
— Hypothermic thermometer	0	0	0
— Quick malaria test, carriage shall be dependent upon operational area	0	0	0
2.5. Equipment for injection, perfusion, puncture and catheterisation	0	0	0
— Intravenous infusion set	0	0	0
— Disposable syringes and needles	0	0	0
2.6. General medical equipment	0	0	0
— Personal protective medical and nursing equipment	0	0	0
2.7. Immobilisation and setting equipment	0	0	0
— Set of splints of different sizes for the extremities	0	0	0
— Collar for neck immobilisation	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
3. **ANTIDOTES**			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0
3.4. Nervous system	0	0	0
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen (including maintenance requisites)	0	0	0

([1]) Under the conditions of use prescribed by national laws and/or practices.

Venue and date: .....

Captain's signature: .....

Authorisation by competent person or authority: .....

SECTION C

CATEGORY C VESSELS

I. **Details of the vessel**

Name: .....

Flag: .....

Home port: .....

II. **Medical supplies**

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. **MEDICINE**			
1.1. **Cardiovascular**			
(a) Anti-angina preparations	0	0	0
1.2. **Gastro-intestinal system**			
(a) Anti-diarrhoeals	0	0	0
1.3. **Analgesics and anti-spasmodics**			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
1.4. **Nervous system**			
(c) Seasickness remedies	0	0	0
1.5. **Medicines for external use**			
(a) *Skin medicines*	0	0	0
— Antiseptic solutions	0	0	0
— Burn preparations	0	0	0
(b) *Eye medicines*	0	0	0
— Saline solution for eyewash	0	0	0
2. **MEDICAL EQUIPMENT**			
2.1. **Dressing and suturing equipment**			
— Tourniquets	0	0	0
— Adhesive elastic bandage	0	0	0
— Sterile gauze compresses	0	0	0
— Disposable gloves	0	0	0
— Adhesive dressings	0	0	0
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
3. **ANTIDOTES**			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0
3.4. Nervous system	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen (including maintenance requisites)	0	0	0

Venue and date: .....

Captain's signature: .....

Authorisation by competent person or authority: .....'

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/1835

of 30 October 2019

excluding from European Union financing certain expenditure incurred by the Member States under the European Agricultural Guarantee Fund (EAGF) and under the European Agricultural Fund for Rural Development (EAFRD)

(notified under document C(2019) 7815)

(Only the Bulgarian, Croatian, Czech, Dutch, English, French, German, Greek, Hungarian, Italian, Lithuanian, Maltese, Portuguese, Romanian, Slovak, Spanish and Swedish texts are authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([1]), and in particular Article 52 thereof,

After consulting the Committee on the Agricultural Funds,

Whereas:

(1) In accordance with Article 52 of Regulation (EU) No 1306/2013 the Commission is to carry out the necessary verifications, communicate to the Member States the results of those verifications, take note of the comments of the Member States, initiate a bilateral discussion so that an agreement may be reached with the Member States in question, and formally communicate its conclusions to them.

(2) The Member States have had an opportunity to request the launch of a conciliation procedure. That opportunity has been used in some cases and the reports issued on the outcome have been examined by the Commission.

(3) In accordance with Regulation (EU) No 1306/2013, only agricultural expenditure which has been incurred in a way that has not infringed Union law may be financed.

(4) In the light of the verifications carried out, the outcome of the bilateral discussions and the conciliation procedures, part of the expenditure declared by the Member States does not fulfil this requirement and cannot, therefore, be financed under the EAGF and the EAFRD.

(5) The amounts that are not recognised as being chargeable to the EAGF and the EAFRD should be indicated. Those amounts do not relate to expenditure incurred more than 24 months before the Commission's written notification of the results of the verifications to the Member States.

(6) The amounts excluded from Union financing by the present Decision should also take into account any reductions or suspensions in accordance with Article 41 of Regulation (EU) No 1306/2013 due to the fact that such reductions or suspensions are of a provisional nature and without prejudice to decisions taken pursuant to Articles 51 or 52 of that Regulation.

(7) As regards the cases covered by this decision, the assessment of the amounts to be excluded on grounds of non-compliance with Union law was notified by the Commission to the Member States in a summary report on the subject ([2]).

(8) This Decision is without prejudice to any financial conclusions that the Commission may draw from the judgments of the Court of Justice of the European Union in cases pending on 15 September 2019,

([1]) OJ L 347, 20.12.2013, p.549
([2]) Ares(2019)6542527

HAS ADOPTED THIS DECISION:

Article 1

The amounts set out in the Annex and related to expenditure incurred by the Member States' accredited paying agencies and declared under the EAGF or the EAFRD shall be excluded from Union financing.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Federal Republic of Germany, Ireland, the Kingdom of Spain, the French Republic, the Republic of Croatia, the Italian Republic, the Republic of Cyprus, the Republic of Lithuania, the Grand Duchy of Luxembourg, Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Portuguese Republic, Romania, the Slovak Republic, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 30 October 2019.

For the Commission
Phil HOGAN
Member of the Commission

ANNEX

Decision: 61

Budget Item: 0 5 0 7 0 1 0 7

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
ES	Fruit and Vegetables - Operational Programmes	2009	Reimbursement following judgment in case T-237/17	FLAT RATE	10,00 %	EUR	3 922 888,80	204 258,51	1 880 130,29
	Fruit and Vegetables - Operational Programmes	2010	Reimbursement following judgment in case T-237/17	FLAT RATE	10,00 %	EUR	4 917 485,69	2 566 722,82	2 350 762,87
	Fruit and Vegetables - Operational Programmes	2011	Reimbursement following judgment in case T-237/17	FLAT RATE	10,00 %	EUR	440 969,18	220 484,59	220 484,59
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	1,59 %	EUR	122 921,79	0,00	122 921,79
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	3,58 %	EUR	8 144 125,58	0,00	8 144 125,58
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	3,80 %	EUR	1 383 647,93	0,00	1 383 647,93
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	4,46 %	EUR	3 642 817,36	0,00	3 642 817,36
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	4,99 %	EUR	375 612,88	0,00	375 612,88
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	5,86 %	EUR	9 260 920,72	0,00	9 260 920,72
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	6,40 %	EUR	677 367,04	0,00	677 367,04
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	6,52 %	EUR	1 126 563,99	0,00	1 126 563,99
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	7,68 %	EUR	773 889,45	0,00	773 889,45

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	8,60 %	EUR	608 889,90	0,00	608 889,90
	Decoupled Direct Aids	2011	Reimbursement following judgment in case T-459/16	FLAT RATE	10,04 %	EUR	15 628 447,21	0,00	15 628 447,21
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	1,53 %	EUR	107 658,06	0,00	107 658,06
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	3,52 %	EUR	1 461 366,24	0,00	1 461 366,24
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	3,61 %	EUR	8 152 425,60	0,00	8 152 425,60
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	4,40 %	EUR	324 045,51	0,00	324 045,51
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	4,41 %	EUR	3 250 342,68	0,00	3 250 342,68
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	5,47 %	EUR	8 971 740,91	0,00	8 971 740,91
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	6,42 %	EUR	1 133 969,53	0,00	1 133 969,53
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	7,67 %	EUR	758 779,44	0,00	758 779,44
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	8,71 %	EUR	634 659,58	0,00	634 659,58
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	8,84 %	EUR	817 979,54	0,00	817 979,54
	Decoupled Direct Aids	2012	Reimbursement following judgment in case T-459/16	FLAT RATE	10,06 %	EUR	16 284 452,86	0,00	16 284 452,86
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	1,52 %	EUR	233 815,98	0,00	233 815,98
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	2,73 %	EUR	1 889 533,78	0,00	1 889 533,78
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	3,47 %	EUR	286 966,22	0,00	286 966,22

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	3,60 %	EUR	8 922 409,09	0,00	8 922 409,09
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	4,34 %	EUR	3 595 030,51	0,00	3 595 030,51
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	5,23 %	EUR	9 337 109,09	0,00	9 337 109,09
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	5,67 %	EUR	1 253 352,06	0,00	1 253 352,06
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	8,11 %	EUR	735 385,02	0,00	735 385,02
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	8,35 %	EUR	976 720,07	0,00	976 720,07
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	8,47 %	EUR	791 381,36	0,00	791 381,36
	Decoupled Direct Aids	2013	Reimbursement following judgment in case T-459/16	FLAT RATE	10,09 %	EUR	16 273 380,81	0,00	16 273 380,81
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	1,78 %	EUR	213 024,96	0,00	213 024,96
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	2,43 %	EUR	1 257 733,69	0,00	1 257 733,69
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	3,58 %	EUR	8 900 539,54	0,00	8 900 539,54
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	3,67 %	EUR	163 452,06	0,00	163 452,06
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	5,22 %	EUR	13 137 895,99	0,00	13 137 895,99
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	5,62 %	EUR	1 224 032,81	0,00	1 224 032,81
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	8,21 %	EUR	1 097 274,61	0,00	1 097 274,61
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	8,22 %	EUR	747 321,72	0,00	747 321,72

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	8,53 %	EUR	1 000 460,40	0,00	1 000 460,40
	Decoupled Direct Aids	2014	Reimbursement following judgment in case T-459/16	FLAT RATE	10,09 %	EUR	16 483 871,52	0,00	16 483 871,52
					Total ES:	**EUR**	**181 444 658,76**	**4 829 965,92**	**176 614 692,84**

Currency	Amount	Deductions	Financial Impact
EUR	181 444 658,76	4 829 965,92	176 614 692,84

Budget Item: 6 7 0 1

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
BE	Clearance of Accounts - Financial Clearance	2017	administrative error (p.105 du CB report)	ONE OFF		EUR	- 497,41	0,00	- 497,41
	Clearance of Accounts - Financial Clearance	2017	over estimation on expenditure (prg. 5.3.4 of CB report)	ONE OFF		EUR	- 597,14	0,00	- 597,14
	School Fruit Scheme	2017	School Scheme for SPW (Service Public Wallonie)	ONE OFF		EUR	- 76 658,15	0,00	- 76 658,15
					Total BE:	**EUR**	**- 77 752,70**	**0,00**	**- 77 752,70**
BG	Cross-compliance	2016	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	-1 006 053,47	- 465,49	-1 005 587,98
	Cross-compliance	2017	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	- 1 943,57	0,00	- 1 943,57
	Cross-compliance	2018	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	- 86,08	0,00	- 86,08

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Cross-compliance	2015	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 13 495,90	0,00	- 13 495,90
	Cross-compliance	2016	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 1 392,60	- 5,43	- 1 387,17
	Cross-compliance	2017	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 1 108 875,35	0,00	-1 108 875,35
	Cross-compliance	2018	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 2 508,66	0,00	- 2 508,66
	Other Direct Aids	2018	Insufficient level of OTSC	ONE OFF		EUR	- 69 316,19	0,00	- 69 316,19
	Voluntary Coupled Support	2018	Insufficient level of OTSC	ONE OFF		EUR	- 143 052,20	0,00	- 143 052,20
	Fruit and Vegetables - Exceptional support measures	2015	Reimbursement due to double recovery of reductions FY 2015	ONE OFF		EUR	6 590,91	0,00	690,91
					Total BG:	**EUR**	**-2 340 133,11**	**- 470,92**	**-2 339 662,19**
CY	Voluntary Coupled Support	2017	Weak on-the-spot check - minimum control rate not reached - claim year 2016 - measure 1	ONE OFF		EUR	- 45 645,68	0,00	- 45 645,68
	Voluntary Coupled Support	2017	Weak on-the-spot check - minimum control rate not reached - claim year 2016 - measure 3	ONE OFF		EUR	- 11 476,64	0,00	- 11 476,64
					Total CY:	**EUR**	**- 57 122,32**	**0,00**	**- 57 122,32**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
CZ	School Fruit Scheme	2016	Deficiencies in key control 'Performance of on-the-spot checks of sufficient quality' FY2016 and FY2017	FLAT RATE	5,00 %	EUR	- 189 042,66	0,00	- 189 042,66
	School Fruit Scheme	2017	Deficiencies in key control 'Performance of on-the-spot checks of sufficient quality' FY2016 and FY2017	FLAT RATE	5,00 %	EUR	- 195 157,27	0,00	- 195 157,27
	School Fruit Scheme	2018	Deficiencies in key control 'Performance of on-the-spot checks of sufficient quality' FY2018	FLAT RATE	5,00 %	EUR	- 18 547,93	0,00	- 18 547,93
					Total CZ:	**EUR**	**- 402 747,86**	**0,00**	**- 402 747,86**
DE	Fruit and Vegetables - Operational programmes incl withdrawals	2016	Actions not implemented - OP 2015	ONE OFF		EUR	- 18 715,44	0,00	- 18 715,44
	Fruit and Vegetables - Operational programmes incl withdrawals	2017	Actions not implemented OP 2016	ONE OFF		EUR	- 114,70	0,00	- 114,70
	Fruit and Vegetables - Operational programmes incl withdrawals	2016	Carry over - ineligible amount FY 2016	ONE OFF		EUR	- 62 468,92	0,00	- 62 468,92
	Fruit and Vegetables - Operational programmes incl withdrawals	2017	Carry over - ineligible expenditure FY 2017	ONE OFF		EUR	- 2 593,24	0,00	- 2 593,24
	Irregularities	2017	compliance testing and substantive testing of Annexes II and III and known errors (annual sanctions)	ONE OFF		EUR	- 70 522,63	0,00	- 70 522,63

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Certification	2017	Differences in debts' reconciliation EAGF	ONE OFF		EUR	- 32 117,63	0,00	- 32 117,63
	Clearance of Accounts - Financial Clearance	2017	Financial errors found in substantive testing on EAGF (annex 1 of CB report)	ONE OFF		EUR	- 205,77	0,00	- 205,77
	Certification	2017	Individual errors in EAGF	ONE OFF		EUR	- 347 912,42	0,00	- 347 912,42
					Total DE:	**EUR**	**- 534 650,75**	**0,00**	**- 534 650,75**
ES	Wine - Investment	2015	Absence of checks on the soundness of estimates FY 2015	FLAT RATE	10,00 %	EUR	- 91 783,15	0,00	- 91 783,15
	Wine - Investment	2016	Absence of checks on the soundness of estimates FY 2016	FLAT RATE	10,00 %	EUR	- 143 195,41	0,00	- 143 195,41
	Wine - Investment	2017	Absence of checks on the soundness of estimates FY 2017	FLAT RATE	10,00 %	EUR	- 83 928,98	0,00	- 83 928,98
	Wine - Investment	2015	Actions paid not included in Support Applicatoin - FY 2015	ONE OFF		EUR	- 179 674,57	0,00	- 179 674,57
	Wine - Investment	2016	Actions paid not included in Support Applicatoin - FY 2016	ONE OFF		EUR	- 477 034,00	0,00	- 477 034,00
	Wine - Investment	2015	Deficiency control of replacement of barrels	FLAT RATE	5,00 %	EUR	- 20 659,11	0,00	- 20 659,11
	Wine - Investment	2016	Deficiency in control replacement barrels FY 2016	FLAT RATE	5,00 %	EUR	- 58 234,92	0,00	- 58 234,92
					Total ES:	**EUR**	**-1 054 510,14**	**0,00**	**-1 054 510,14**
FR	Irregularities	2015	Application de sanction en cas d'intentionnalité	ONE OFF		EUR	-1 915 954,75	- 353 235,44	-1 562 719,31
	Irregularities	2016	Application de sanction en cas d'intentionnalité	ONE OFF		EUR	-1 793 774,28	- 469 942,73	-1 323 831,55

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Irregularities	2017	Application de sanction en cas d'intentionnalité	ONE OFF		EUR	-1 435 446,92	0,00	-1 435 446,92
	Other Direct Aid - POSEI (2014+)	2016	Contrôles administratifs exhaustifs insuffisants FY2016	FLAT RATE	5,00 %	EUR	- 400 907,21	- 44 784,16	- 356 123,05
	Other Direct Aid - POSEI (2014+)	2017	Contrôles administratifs exhaustifs insuffisants FY2017	FLAT RATE	5,00 %	EUR	- 448 715,16	0,00	- 448 715,16
	Other Direct Aid - POSEI (2014+)	2018	Contrôles administratifs exhaustifs insuffisants FY2018	FLAT RATE	5,00 %	EUR	- 453 373,17	0,00	- 453 373,17
	Wine - Promotion on third country markets	2015	Weakness in key controls on administrative checks and on OTSC. Absence of risk analysis.	FLAT RATE	7,00 %	EUR	- 177 746,45	0,00	- 177 746,45
	Wine - Promotion on third country markets	2016	Weakness in key controls on administrative checks and on OTSC. Absence of risk analysis.	FLAT RATE	7,00 %	EUR	- 205 303,65	- 54 653,76	- 150 649,89
	Wine - Promotion on third country markets	2017	Weakness in key controls on administrative checks and on OTSC. Absence of risk analysis.	FLAT RATE	7,00 %	EUR	- 32 754,65	0,00	- 32 754,65
					Total FR:	**EUR**	**-6 863 976,24**	**- 922 616,09**	**-5 941 360,15**
GB	Entitlements	2016	BPS calculation not finalised/notified - impact on BPS 2015	ONE OFF		EUR	- 72 690,20	- 416,38	- 72 273,82
	Entitlements	2017	BPS calculation not finalised/notified - impact on BPS 2016	ONE OFF		EUR	- 125 141,46	- 746,55	- 124 394,91
	Decoupled Direct Aids	2016	BPS calculation not finalised/notified - impact on greening 2015	ONE OFF		EUR	- 34 726,50	- 334,36	- 34 392,14

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2017	BPS calculation not finalised/notified - impact on greening 2016	ONE OFF		EUR	- 53 070,85	- 507,58	- 52 563,27
	Decoupled Direct Aids	2016	BPS calculation not finalised/notified - impact on YF 2015	ONE OFF		EUR	- 621,92	- 3,56	- 618,36
	Decoupled Direct Aids	2017	BPS calculation not finalised/notified - impact on YF 2016	ONE OFF		EUR	- 105,86	- 0,63	- 105,23
	Entitlements	2016	Checks of the active farmer status - impact on BPS 2015	ONE OFF		EUR	- 30 199,79	- 172,99	- 30 026,80
	Entitlements	2017	Checks of the active farmer status - impact on BPS 2016	ONE OFF		EUR	- 110 341,24	- 658,26	- 109 682,98
	Entitlements	2018	Checks of the active farmer status - impact on BPS 2017	FLAT RATE	2,00 %	EUR	- 53 909,19	0,00	- 53 909,19
	Decoupled Direct Aids	2016	Checks of the active farmer status - impact on greening 2015	ONE OFF		EUR	- 13 142,45	- 126,54	- 13 015,91
	Decoupled Direct Aids	2017	Checks of the active farmer status - impact on greening 2016	ONE OFF		EUR	- 46 208,88	- 441,95	- 45 766,93
	Decoupled Direct Aids	2018	Checks of the active farmer status - impact on greening 2017	FLAT RATE	2,00 %	EUR	- 22 855,89	0,00	- 22 855,89
	Decoupled Direct Aids	2016	Checks of the active farmer status - impact on YF 2015	ONE OFF		EUR	- 107,06	- 0,61	- 106,45

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2017	Checks of the active farmer status - impact on YF 2016	ONE OFF		EUR	- 294,97	- 1,76	- 293,21
	Decoupled Direct Aids	2018	Checks of the active farmer status - impact on YF 2017	FLAT RATE	2,00 %	EUR	- 44,17	0,00	- 44,17
	Entitlements	2016	Checks on the establishment of PE - impact on BPS 2015	ONE OFF		EUR	- 23 659,93	- 135,53	- 23 524,40
	Entitlements	2017	Checks on the establishment of PE - impact on BPS 2016	ONE OFF		EUR	- 24 133,52	- 143,97	- 23 989,55
	Entitlements	2018	Checks on the establishment of PE - impact on BPS 2017	ONE OFF		EUR	- 24 851,63	0,00	- 24 851,63
	Decoupled Direct Aids	2016	Checks on the establishment of PE - impact on greening 2015	ONE OFF		EUR	- 10 490,85	- 101,01	- 10 389,84
	Decoupled Direct Aids	2017	Checks on the establishment of PE - impact on greening 2016	ONE OFF		EUR	- 10 700,16	- 102,34	- 10 597,82
	Decoupled Direct Aids	2018	Checks on the establishment of PE - impact on greening 2017	ONE OFF		EUR	- 10 697,48	0,00	- 10 697,48
	Entitlements	2017	Weakness in the definition of Active Farmer- connected companies (BPS)	ONE OFF		EUR	-1 028 190,68	0,00	-1 028 190,68
	Decoupled Direct Aids	2017	Weakness in the definition of Active Farmer- connected companies (Greening)	ONE OFF		EUR	- 560 949,25	0,00	- 560 949,25

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Voluntary Coupled Support	2017	Weakness in the definition of Active Farmer- connected companies (VCS01)	ONE OFF		EUR	- 40 185,21	0,00	- 40 185,21
	Voluntary Coupled Support	2017	Weakness in the definition of Active Farmer- connected companies (VCS02)	ONE OFF		EUR	- 8 468,96	0,00	- 8 468,96
	Voluntary Coupled Support	2017	Weakness in the definition of Active Farmer- connected companies (VCS03)	ONE OFF		EUR	- 96 566,25	0,00	- 96 566,25
	Decoupled Direct Aids	2017	Weakness in the definition of Active Farmer- connected companies (YFS)	ONE OFF		EUR	- 3 447,83	0,00	- 3 447,83
					Total GB:	**EUR**	**-2 405 802,18**	**- 3 894,02**	**-240 908,16**
HR	Decoupled Direct Aids	2017	Incorrect calculation of administrative penalties	ONE OFF		EUR	- 84 324,37	0,00	- 84 324,37
	Decoupled Direct Aids	2016	Minimum control rate for on-the-spot checks not reached	ONE OFF		EUR	- 35 671,36	0,00	- 35 671,36
	Decoupled Direct Aids	2017	Minimum control rate for on-the-spot checks not reached	ONE OFF		EUR	- 35 671,36	0,00	- 35 671,36
	Decoupled Direct Aids	2018	Minimum control rate for on-the-spot checks not reached	ONE OFF		EUR	- 35 671,36	0,00	- 35 671,36
	Decoupled Direct Aids	2016	Weak check of the recovery of payment entitlements	ONE OFF		EUR	- 325,70	0,00	- 325,70
	Decoupled Direct Aids	2017	Weak check of the recovery of payment entitlements	ONE OFF		EUR	- 580,06	0,00	- 580,06
	Decoupled Direct Aids	2016	Weak check of the status of the farmer (National Reserve)	ONE OFF		EUR	- 8 016,98	0,00	- 8 016,98

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2017	Weak check of the status of the farmer (National Reserve)	ONE OFF		EUR	- 7 212,34	0,00	- 7 212,34
	Decoupled Direct Aids	2016	Weak check of the status of the farmer (YFS)	ONE OFF		EUR	- 18 828,55	0,00	- 18 828,55
	Decoupled Direct Aids	2017	Weak check of the status of the farmer (YFS)	ONE OFF		EUR	- 25 056,29	0,00	- 25 056,29
	Decoupled Direct Aids	2016	Weak check of the value of payment entitlements	ONE OFF		EUR	- 37 401,73	0,00	- 37 401,73
	Decoupled Direct Aids	2017	Weak check of the value of payment entitlements	ONE OFF		EUR	- 103 179,76	0,00	- 103 179,76
	Decoupled Direct Aids	2017	Weak check on landscape features	ONE OFF		EUR	- 11 057,33	0,00	- 11 057,33
	Decoupled Direct Aids	2018	Weak check on landscape features	ONE OFF		EUR	- 4 390,01	0,00	- 4 390,01
	Decoupled Direct Aids	2018	Weak check on organic farmers	ONE OFF		EUR	- 3 480,59	0,00	- 3 480,59
	Decoupled Direct Aids	2016	Weak check on permanent grassland	ONE OFF		EUR	- 1 445,37	0,00	- 13 445,37
	Decoupled Direct Aids	2017	Weak check on permanent grassland	ONE OFF		EUR	- 5 470,77	0,00	- 5 470,77
	Decoupled Direct Aids	2018	Weak check on permanent grassland	ONE OFF		EUR	- 4 819,93	0,00	- 4 819,93
	Decoupled Direct Aids	2016	Weak check on retroactive recovery	ONE OFF		EUR	- 485 129,84	0,00	- 485 129,84
	Decoupled Direct Aids	2017	Weak check on retroactive recovery	ONE OFF		EUR	- 277 225,31	0,00	- 277 225,31
	Decoupled Direct Aids	2018	Weak check on retroactive recovery	ONE OFF		EUR	- 16 508,26	0,00	- 16 508,26
					Total HR:	**EUR**	**-1 213 467,27**	**0,00**	**-1 213 467,27**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
HU	Decoupled Direct Aids	2016	OTSC level insufficient	ONE OFF		EUR	- 484 117,64	0,00	- 484 117,64
	Decoupled Direct Aids	2016	OTSC quality EFA incorrectly identified	ONE OFF		EUR	- 11 871,24	0,00	- 11 871,24
	Decoupled Direct Aids	2017	OTSC quality EFA incorrectly identified	ONE OFF		EUR	- 2 572,84	0,00	- 2 572,84
					Total HU:	**EUR**	**- 498 561,72**	**0,00**	**- 498 561,72**
IE	Decoupled Direct Aids	2016	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	-1 132 326,70	0,00	-1 132 326,70
	Decoupled Direct Aids	2017	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	-1 089 743,91	0,00	-1 089 743,91
	Decoupled Direct Aids	2018	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	- 633 104,48	0,00	- 633 104,48
					Total IE:	**EUR**	**-2 855 175,09**	**0,00**	**-2 855 175,09**
IT	Decoupled Direct Aids	2016	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	-68 685 227,76	- 166 676,14	-68 518 551,62
	Voluntary Coupled Support Area Based	2016	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	-3 690 568,93	- 262,10	-3 690 306,83
	Decoupled Direct Aids	2017	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	-65 482 175,39	- 5 116,81	-65 477 058,61
	Reimbursement of direct aids in relation to financial discipline	2017	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	- 754 110,44	- 1,21	- 754 109,23
	Voluntary Coupled Support	2017	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	-3 811 472,84	- 0,27	-3 811 472,58
	Decoupled Direct Aids	2018	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	- 830 757,67	- 127,68	- 830 629,95

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Reimbursement of direct aids in relation to financial discipline	2018	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	- 730 282,20	0,00	- 730 282,20
	Voluntary Coupled Support	2018	Comprehensive correction for all findings	FLAT RATE	2,00 %	EUR	- 111 868,12	0,00	- 111 868,12
	Cross-compliance	2016	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 208 203,54	0,00	- 208 203,54
	Cross-compliance	2017	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 4 103,38	0,00	- 4 103,38
	Cross-compliance	2018	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 3 627,62	0,00	- 3 627,62
	Cross-compliance	2017	Deficient I&R checks under SMR 7 - CY 2016	FLAT RATE	2,00 %	EUR	- 315 751,97	0,00	- 315 751,97
	Cross-compliance	2018	Deficient I&R checks under SMR 7 - CY 2016	FLAT RATE	2,00 %	EUR	- 10 223,00	0,00	- 10 223,00
	Certification	2017	Known errors in the EAGF	ONE OFF		EUR	- 4 834,89	0,00	- 4 834,89
	Fruit and Vegetables - Operational programmes incl withdrawals	2014	OP 2013 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	-1 015 887,56	0,00	-1 015 887,56

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Fruit and Vegetables - Operational programmes incl withdrawals	2015	OP 2013 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 4 241,09	0,00	- 4 241,09
	Fruit and Vegetables - Operational programmes incl withdrawals	2016	OP 2013 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 1 110,78	0,00	- 1 110,78
	Fruit and Vegetables - Operational programmes incl withdrawals	2014	OP 2014 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 170 533,71	0,00	- 170 533,71
	Fruit and Vegetables - Operational programmes incl withdrawals	2015	OP 2014 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	-2 522 983,06	0,00	-2 522 983,06
	Fruit and Vegetables - Operational programmes incl withdrawals	2016	OP 2014 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 18 839,14	0,00	- 18 839,14
	Fruit and Vegetables - Operational programmes incl withdrawals	2017	OP 2014 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	3 889,40	0,00	3 889,40

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Fruit and Vegetables - Operational programmes incl withdrawals	2015	OP 2015 -FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 933 283,90	0,00	- 933 283,90
	Fruit and Vegetables - Operational programmes incl withdrawals	2016	OP 2015 -FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	-2 963 312,69	0,00	-2 963 312,69
	Fruit and Vegetables - Operational programmes incl withdrawals	2017	OP 2015 -FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 3 941,19	0,00	- 3 941,19
	Fruit and Vegetables - Operational programmes incl withdrawals	2016	OP 2016 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	- 649 642,58	0,00	- 649 642,58
	Fruit and Vegetables - Operational programmes incl withdrawals	2017	OP 2016 - FV/2016/002/IT; shortcomings in F&V sector under the scheme of the Operational Programmes and recognition of Producer Organisations	FLAT RATE	5,00 %	EUR	-2 770 183,74	0,00	-2 770 183,74
					Total IT:	**EUR**	**-155 693 277,79**	**- 172 184,21**	**-155 521 093,58**
LU	Decoupled Direct Aids	2016	Weak check on landscape features - CY2015 - BPS	ONE OFF		EUR	- 4 732,24	- 11,14	- 4 721,10

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2016	Weak check on landscape features - CY2015 - greening	ONE OFF		EUR	- 3 798,16	- 8,94	- 3 789,22
	Decoupled Direct Aids	2017	Weak check on landscape features - CY2016 - BPS	ONE OFF		EUR	- 4 732,24	0,00	- 4 732,24
	Decoupled Direct Aids	2017	Weak check on landscape features - CY2016 - greening	ONE OFF		EUR	- 2 604,22	0,00	- 2 604,22
	Decoupled Direct Aids	2018	Weak check on landscape features - CY2017 -BPS	ONE OFF		EUR	- 4 732,25	0,00	- 4 732,25
	Decoupled Direct Aids	2018	Weak check on landscape features - CY2017 - greening	ONE OFF		EUR	- 19 678,14	0,00	- 19 678,14
	Decoupled Direct Aids	2016	Weak check on permanent grass-land - CY2015 - BPS	ONE OFF		EUR	- 13 828,00	- 32,57	- 13 795,43
	Decoupled Direct Aids	2016	Weak check on permanent grass-land - CY2015 - greening	ONE OFF		EUR	- 9 378,34	- 22,09	- 9 356,25
	Decoupled Direct Aids	2017	Weaknesses in the on-the-spot checks - CY2016 - BPS	ONE OFF		EUR	- 11 228,50	0,00	- 11 228,50
	Decoupled Direct Aids	2017	Weaknesses in the on-the-spot checks - CY2016 - greening	ONE OFF		EUR	- 5 175,15	0,00	- 5 175,15
	Decoupled Direct Aids	2018	Weaknesses in the on-the-spot checks - CY2017 -BPS	ONE OFF		EUR	- 9 785,03	0,00	- 9 785,03
	Decoupled Direct Aids	2018	Weaknesses in the on-the-spot checks - CY2017 - greening	ONE OFF		EUR	- 4 021,65	0,00	- 4 021,65
					Total LU:	**EUR**	**- 93 693,92**	**- 74,74**	**- 93 619,18**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
MT	Voluntary Coupled Support	2016	VCS 1.4 - CY 2015	ONE OFF		EUR	- 33 498,88	- 712,48	- 32 786,40
	Voluntary Coupled Support	2017	VCS 1.4 - CY 2015	ONE OFF		EUR	- 384,46	- 47,09	- 337,37
	Voluntary Coupled Support	2017	VCS 1.4 - CY 2016	ONE OFF		EUR	- 25 238,90	- 902,82	- 24 336,08
	Voluntary Coupled Support	2018	VCS 1.4 - CY 2017	ONE OFF		EUR	- 2 306,34	- 824,30	- 1 482,04
	Voluntary Coupled Support	2016	VCS 1.5-1.6 - CY 2015	FLAT RATE	3,00 %	EUR	- 57 676,21	- 88,01	- 57 588,20
	Voluntary Coupled Support	2017	VCS 1.5-1.6 - CY 2016	FLAT RATE	3,00 %	EUR	- 60 919,52	- 185,76	- 60 733,76
	Voluntary Coupled Support	2018	VCS 1.5-1.6 - CY 2017	FLAT RATE	3,00 %	EUR	- 61 345,33	- 41,35	- 61 303,98
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 7 but not SMR 8 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 3 035,82	0,00	- 3 035,82
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to the requirements of SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 2 797,27	0,00	- 2 797,27
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to the requirements of SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 2 853,82	- 71,68	- 2 782,14

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 7 and SMR 8 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 966,76	0,00	- 966,76
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to combinations of SMRs - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 1 104,65	0,00	- 1 104,65
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to combinations of SMRs - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 1 186,87	0,00	- 1 186,87
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 8 only - No evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 430,66	0,00	- 430,66
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 8 and not subject to SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 423,66	- 0,91	- 422,75
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 8 and not subject to SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 412,07	- 0,12	- 411,95
					Total MT:	**EUR**	**- 254 581,22**	**- 2 874,52**	**- 251 706,70**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
NL	Entitlements	2016	Deficiency regarding active farmer status - impact on BPS	ONE OFF		EUR	-2 627 743,09	0,00	-2 627 743,09
	Entitlements	2017	Deficiency regarding active farmer status - impact on BPS	ONE OFF		EUR	- 113 182,27	0,00	- 113 182,27
	Decoupled Direct Aids	2016	Deficiency regarding active farmer status - impact on Greening	ONE OFF		EUR	-1 154 421,24	0,00	-1 154 421,24
	Decoupled Direct Aids	2017	Deficiency regarding active farmer status - impact on Greening	ONE OFF		EUR	- 46 449,89	0,00	- 46 449,89
	Cross Compliance - Recoveries	2016	Deficiency regarding active farmer status - impact on Recoveries	ONE OFF		EUR	559,36	0,00	559,36
	Irregularities	2016	Deficiency regarding active farmer status - impact on Recoveries	ONE OFF		EUR	9 603,85	0,00	9 603,85
	Voluntary Coupled Support	2016	Deficiency regarding active farmer status - impact on VCS	ONE OFF		EUR	- 66 023,74	0,00	- 66 023,74
	Decoupled Direct Aids	2016	Deficiency regarding active farmer status - impact on YF	ONE OFF		EUR	- 11 566,93	0,00	- 11 566,93
	Decoupled Direct Aids	2017	Insufficent control rate	ONE OFF		EUR	- 39 998,52	0,00	- 39 998,52
	Decoupled Direct Aids	2018	LPIS and other weaknesses	ONE OFF		EUR	- 166 919,54	0,00	- 166 919,54
	Temporary and exceptional support measures	2016	Recovery of undue payments R. 2015/1853 (Article 1)	ONE OFF		EUR	-2 515 000,00	0,00	-2 515 000,00

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2017	Weaknesses in retroactive recoveries	ONE OFF		EUR	- 1 888,98	0,00	- 1 888,98
	Decoupled Direct Aids	2016	Weaknesses in the LPIS	ONE OFF		EUR	- 10 405,19	0,00	- 10 405,19
	Decoupled Direct Aids	2017	Weaknesses in the LPIS	ONE OFF		EUR	- 15 624,74	0,00	- 15 624,74
	Decoupled Direct Aids	2016	Weaknesses in the LPIS	ONE OFF		EUR	- 5 202,60	0,00	- 5 202,60
	Decoupled Direct Aids	2016	Weaknesses in the OTSC - check of maintenance	ONE OFF		EUR	- 28 396,88	0,00	- 28 396,88
	Decoupled Direct Aids	2017	Weaknesses in the OTSC - check of maintenance	ONE OFF		EUR	- 50 082,79	0,00	- 50 082,79
	Decoupled Direct Aids	2016	Weaknesses in the OTSC - remote sensing	ONE OFF		EUR	- 32 382,33	0,00	- 32 382,33
	Decoupled Direct Aids	2017	Weaknesses in the OTSC - remote sensing	ONE OFF		EUR	- 62 115,67	0,00	- 62 115,67
	Voluntary Coupled Support	2018	Weaknesses in the set-up and control of Bovine premia	ONE OFF		EUR	- 242 859,95	0,00	- 242 859,95
	Voluntary Coupled Support	2016	Weaknesses in the set-up and control of Bovine premia	ONE OFF		EUR	- 292 314,10	0,00	- 292 314,10
	Voluntary Coupled Support	2017	Weaknesses in the set-up and control of Bovine premia	ONE OFF		EUR	- 203 767,61	0,00	- 203 767,61
	Voluntary Coupled Support	2018	Weaknesses in the set-up and control of Ovine premia	ONE OFF		EUR	- 311 190,35	0,00	- 311 190,35
	Voluntary Coupled Support	2016	Weaknesses in the set-up and control of Ovine premia	ONE OFF		EUR	- 245 664,73	0,00	- 245 664,73
	Voluntary Coupled Support	2017	Weaknesses in the set-up and control of Ovine premia	ONE OFF		EUR	- 216 663,18	0,00	- 216 663,18

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2018	Weaknesses in VCS animals - effect on allocation of entitlements on BPS, Greening and young farmer scheme payments	ONE OFF		EUR	- 732 338,89	0,00	- 732 338,89
	Decoupled Direct Aids	2016	Weaknesses in VCS animals - effect on allocation of entitlements on BPS payments	ONE OFF		EUR	- 167 677,35	0,00	- 167 677,35
	Decoupled Direct Aids	2017	Weaknesses in VCS animals - effect on allocation of entitlements on BPS payments	ONE OFF		EUR	- 335 906,85	0,00	- 335 906,85
	Decoupled Direct Aids	2016	Weaknesses in VCS animals - effect on allocation of entitlements on greening payments	ONE OFF		EUR	- 72 621,06	0,00	- 72 621,06
	Decoupled Direct Aids	2017	Weaknesses in VCS animals - effect on allocation of entitlements on greening payments	ONE OFF		EUR	- 145 212,53	0,00	- 145 212,53
	Decoupled Direct Aids	2016	Weaknesses in VCS animals - effect on allocation of entitlements on young farmer scheme payments	ONE OFF		EUR	- 24 208,33	0,00	- 24 208,33

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Decoupled Direct Aids	2017	Weaknesses in VCS animals - effect on allocation of entitlements on young farmer scheme payments	ONE OFF		EUR	- 23 805,29	0,00	- 23 805,29
					Total NL:	**EUR**	**-9 951 471,41**	**0,00**	**-9 951 471,41**
RO	Certification	2016	Known errors in the EAGF	ONE OFF		EUR	- 76,27	0,00	- 76,27
	Certification	2016	MLE in the EAGF	ESTIMATED BY AMOUNT		EUR	-17 323 228,52	- 440,82	-17 322 787,70
					Total RO:	**EUR**	**-17 323 304,79**	**- 440,82**	**-17 322 863,97**
SE	Voluntary Coupled Support	2017	Weakness in the key control concerning the checks on the correctness of the aid calculation including the application of sanctions VCS CY2016	FLAT RATE	3,00 %	EUR	-2 618 729,82	- 5 697,92	-2 613 031,90
	Voluntary Coupled Support	2018	Weakness in the key control concerning the checks on the correctness of the aid calculation including the application of sanctions VCS CY2017	FLAT RATE	3,00 %	EUR	-2 610 686,25	0,00	-2 610 686,25
	Voluntary Coupled Support	2016	Weakness in the key control in respect of administrative checks to establish the eligibility of the aid-correctness of the final payment CY2015 for VCS	ONE OFF		EUR	- 862 615,07	0,00	- 862 615,07

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Entitlements	2017	Weakness in the key control in respect of the administrative checks to establish access to the aid claimed regarding active farmer status CY2016	ESTIMATED BY PERCENTAGE	0,58 %	EUR	- 96 196,72	- 3 374,63	- 92 822,09
	Greening Payment	2017	Weakness in the key control in respect of the administrative checks to establish access to the aid claimed regarding active farmer status CY2016	ESTIMATED BY PERCENTAGE	0,58 %	EUR	- 51 533,13	- 47 356,10	- 4 177,03
	Voluntary Coupled Support	2017	Weakness in the key control in respect of the administrative checks to establish access to the aid claimed regarding active farmer status CY2016	ESTIMATED BY PERCENTAGE	0,58 %	EUR	- 29 660,36	0,00	- 29 660,36
	Young farmers scheme	2017	Weakness in the key control in respect of the administrative checks to establish access to the aid claimed regarding active farmer status CY2016	ESTIMATED BY PERCENTAGE	0,58 %	EUR	- 2 826,93	0,00	- 2 826,93
	Voluntary Coupled Support	2016	Weakness in the the key control concerning the checks on the correctness of the aid calculation including the application of sanctions VCS CY 2015	FLAT RATE	3,00 %	EUR	-2 560 986,85	- 25 878,45	-2 535 108,40

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Voluntary Coupled Support	2017	Weakness in the the key control in respect of administrative checks to establish the eligibility of the aid-correctness of the final payment CY2016 for VCS	ONE OFF		EUR	- 160 270,35	0,00	- 160 270,35
					Total SE:	**EUR**	**-8 993 505,48**	**- 82 307,10**	**-8 911 198,38**

Currency	Amount	Deductions	Financial Impact
EUR	-210 613 733,99	-1 184 862,42	-209 428 871,57

Budget Item: 6711

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
BE	Clearance of Accounts - Financial Clearance	2017	Substantial error on sampling (Annex 15 of CB report)	ONE OFF		EUR	- 3 869,02	0,00	- 3 869,02
	Clearance of Accounts - Financial Clearance	2017	Substantial error on sampling (annex 14 of CB report)	ONE OFF		EUR	- 205,57	0,00	- 205,57
					Total BE:	**EUR**	**- 4 074,59**	**0,00**	**- 4 074,59**
BG	Cross-compliance	2016	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	- 223 326,63	- 8 009,67	- 215 316,96
	Cross-compliance	2017	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	- 834,40	0,00	- 834,40

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Cross-compliance	2018	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2015	FLAT RATE	5,00 %	EUR	- 293,61	0,00	- 293,61
	Cross-compliance	2017	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 184 118,40	- 688,70	- 183 429,70
	Cross-compliance	2018	Deficient on-the-spot checks of animal-related SMRs - Deficient reporting - CY 2016	FLAT RATE	5,00 %	EUR	- 8 204,10	0,00	- 8 204,10
					Total BG:	**EUR**	**- 416 777,14**	**- 8 698,37**	**- 408 078,77**
CZ	Rural Development EAFRD measures subject to IACS	2016	M10: double financing	ONE OFF		EUR	- 7 674,67	0,00	- 7 674,67
	Rural Development EAFRD measures subject to IACS	2017	M10: double financing	ONE OFF		EUR	- 7 484,02	0,00	- 7 484,02
	Rural Development EAFRD measures subject to IACS	2017	M14: advance notification of on-the-spot checks - FY2017	FLAT RATE	5,00 %	EUR	- 14 191,54	0,00	- 14 191,54
	Rural Development EAFRD measures subject to IACS	2018	M14: advance notification of on-the-spot checks - FY2018 and FY2019	FLAT RATE	5,00 %	EUR	- 15 511,62	0,00	- 15 511,62
	Rural Development EAFRD measures subject to IACS	2019	M14: advance notification of on-the-spot checks - FY2018 and FY2019	FLAT RATE	5,00 %	EUR	- 5 405,86	0,00	- 5 405,86
					Total CZ:	**EUR**	**- 50 267,71**	**0,00**	**- 50 267,71**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
DE	Certification	2017	Differences in debts' reconciliation EAFRD	ONE OFF		EUR	- 9 497,41	0,00	- 9 497,41
	Rural Development EAFRD forestry measures	2016	Double-financing between M8 (first afforestation) and EFA greening - FY 2016.	ONE OFF		EUR	- 10 543,25	0,00	- 10 543,25
	Rural Development EAFRD forestry measures	2017	Double-financing between M8 (first afforestation) and EFA greening - FY 2017.	ONE OFF		EUR	- 8 997,06	0,00	- 8 997,06
	Rural Development EAFRD forestry measures	2018	Double-financing between M8 (first afforestation) and EFA greening - FY 2018.	ONE OFF		EUR	- 8 919,87	0,00	- 8 919,87
	Clearance of Accounts - Financial Clearance	2017	Financial errors found in substantive testing on EAFRD (annexes 11, 7a, 7b) of CB report	ONE OFF		EUR	- 35 267,33	0,00	- 35 267,33
	Certification	2017	Individual errors in EAFRD	ONE OFF		EUR	- 7 618,01	0,00	- 7 618,01
					Total DE:	**EUR**	**- 80 842,93**	**0,00**	**- 80 842,93**
ES	Rural Development EAFRD investment - private beneficiaries	2018	M121: 5 % flat rate correction (transitional expenditure on M04 in FY2018)	FLAT RATE	5,00 %	EUR	- 2 447,56	0,00	- 2 447,56
	Rural Development EAFRD Axis 1+3 - Investment orientated measures (2007-2013)	2013	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FY: 2013)	FLAT RATE	5,00 %	EUR	- 24 078,53	0,00	- 24 078,53

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD Investment - private beneficiaries	2014	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FY: 2014)	FLAT RATE	5,00 %	EUR	- 29 716,69	0,00	- 29 716,69
	Rural Development EAFRD investment - private beneficiaries	2016	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FY: 2016)	FLAT RATE	5,00 %	EUR	- 576 669,13	0,00	- 576 669,13
	Rural Development EAFRD Measures with flat-rate support	2016	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction. FYs 2016, 2017 [transitional expenditure on M06]	FLAT RATE	5,00 %	EUR	- 23 343,35	0,00	- 23 343,35
	Rural Development EAFRD Measures with flat-rate support	2017	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction. FYs 2016, 2017 [transitional expenditure on M06]	FLAT RATE	5,00 %	EUR	- 3 889,09	0,00	- 3 889,09
	Rural Development EAFRD investment - private beneficiaries	2015	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FYs: 2015-2016-2017, incl. transitional expenditure on M04) [for FY 2016 and 2017: overlap with exp. on M4.1]	FLAT RATE	5,00 %	EUR	- 35 782,98	0,00	- 35 782,98

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2016	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FYs: 2015-2016-2017, incl. transitional expenditure on M04) [for FY 2016 and 2017: overlap with exp. on M4.1]	FLAT RATE	5,00 %	EUR	- 58 528,57	0,00	- 58 528,57
	Rural Development EAFRD investment - private beneficiaries	2017	M121: Weakness in KC (Verification of eligibility - 5 %) and lack of Ancillary Control (Audit trail - 2 %) => 5 % flat rate correction (FYs: 2015-2016-2017, incl. transitional expenditure on M04) [for FY 2016 and 2017: overlap with exp. on M4.1]	FLAT RATE	5,00 %	EUR	- 50 965,72	0,00	- 50 965,72
	Rural Development EAFRD Axis 1+3 - Investment orientated measures (2007-2013)	2013	M123: Lack of Ancillary Control (Audit trail) => 2 % flat rate correction (FY: 2013)	FLAT RATE	2,00 %	EUR	- 24 354,54	0,00	- 24 354,54
	Rural Development EAFRD Investment - private beneficiaries	2014	M123: Lack of Ancillary Control (Audit trail) => 2 % flat rate correction (FY: 2014)	FLAT RATE	2,00 %	EUR	- 6 109,94	0,00	- 6 109,94
	Rural Development EAFRD investment - private beneficiaries	2015	M123: Lack of Ancillary Control (Audit trail) => 2 % flat rate correction (FYs: 2015-2016-2017)	FLAT RATE	2,00 %	EUR	- 267 943,18	0,00	- 267 943,18

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2016	M123: Lack of Ancillary Control (Audit trail) => 2 % flat rate correction (FYs: 2015-2016-2017)	FLAT RATE	2,00 %	EUR	- 315 906,15	0,00	- 315 906,15
					Total ES:	**EUR**	**-1 419 735,43**	**0,00**	**-1 419 735,43**
FR	Rural Development EAFRD Axis 1+3 - Investment orientated measures (2007-2013)	2012	Absence of the key control 'In-situ visits carried out for all investment operations to verify the realisation of the investment'	FLAT RATE	10,00 %	EUR	- 5 560,80	0,00	- 5 560,80
	Rural Development EAFRD Axis 1+3 - Investment orientated measures (2007-2013)	2013	Absence of the key control 'In-situ visits carried out for all investment operations to verify the realisation of the investment'	FLAT RATE	10,00 %	EUR	- 6 579,04	0,00	- 6 579,04
	Rural Development EAFRD Investment - public beneficiaries	2014	Absence of the key control 'In-situ visits carried out for all investment operations to verify the realisation of the investment'	FLAT RATE	10,00 %	EUR	- 4 875,00	- 2 437,50	- 2 437,50
	Rural Development EAFRD Measures with flat-rate support	2015	Absence of the key control 'In-situ visits carried out for all investment operations to verify the realisation of the investment'	FLAT RATE	10,00 %	EUR	- 28 776,35	- 28 776,35	0,00
	Rural Development EAFRD investment - public beneficiaries	2015	Deficiencies in the execution of the key control 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 3 506,13	- 3 506,13	0,00
	Rural Development EAFRD Investment - public beneficiaries	2014	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 73 581,42	0,00	- 73 581,42

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2015	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 162 273,81	- 161 526,67	- 747,14
	Rural Development EAFRD investment - public beneficiaries	2015	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 797 732,62	- 797 732,62	0,00
	Rural Development EAFRD Measures with flat-rate support	2015	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 265 184,89	- 265 184,89	0,00
	Rural Development EAFRD investment - private beneficiaries	2016	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 147 822,70	- 86 087,35	- 61 735,35
	Rural Development EAFRD investment - public beneficiaries	2016	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 560 112,80	- 363 185,54	- 196 927,26

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD Measures with flat-rate support	2016	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 110 309,10	- 71 526,07	- 38 783,03
	Rural Development EAFRD investment - private beneficiaries	2017	deficiency in the execution of the key controls 'Verification that public procurement procedures are in compliance with national and Union regulations' and 'Appropriate evaluation of the reasonableness of costs'	FLAT RATE	5,00 %	EUR	- 35 929,52	- 24 437,81	- 11 491,71
	Rural Development EAFRD Measures with flat-rate support	2016	OTSC not performed before the final payment - Follow up of RD3/2014/012/FR	FLAT RATE	2,00 %	EUR	- 7 141,25	0,00	- 7 141,25
	Rural Development EAFRD Measures with flat-rate support	2017	OTSC not performed before the final payment - Follow up of RD3/2014/012/FR	FLAT RATE	2,00 %	EUR	- 86 868,35	0,00	- 86 868,35
	Rural Development EAFRD Measures with flat-rate support	2018	OTSC not performed before the final payment - Follow up of RD3/2014/012/FR	FLAT RATE	2,00 %	EUR	- 329,60	0,00	- 329,60
	Rural Development EAFRD investment - private beneficiaries	2016	Reasonableness of the costs not assessed with the required quality	FLAT RATE	2,66 %	EUR	- 458 109,26	- 457 977,66	- 131,60
	Rural Development EAFRD investment - private beneficiaries	2017	Reasonableness of the costs not assessed with the required quality	FLAT RATE	2,66 %	EUR	- 253 541,50	0,00	- 253 541,50

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2016	Reasonableness of the costs not assessed with the required quality	FLAT RATE	4,14 %	EUR	- 913 484,71	- 820 627,41	- 92 857,30
	Rural Development EAFRD investment - private beneficiaries	2017	Reasonableness of the costs not assessed with the required quality	FLAT RATE	4,14 %	EUR	- 129 621,33	- 64 754,26	- 64 867,07
					Total FR:	**EUR**	**-4 051 340,18**	**-3 147 760,26**	**- 903 579,92**
GB	Rural Development EAFRD measures subject to IACS	2018	Checks of the active farmer status - impact on RD 2017	FLAT RATE	2,00 %	EUR	- 1 313,52	0,00	- 1 313,52
	Rural Development EAFRD measures subject to IACS	2017	Weakness in the definition of Active Farmer- connected companies (Natural constraints)	ONE OFF		EUR	- 81 774,79	0,00	- 81 774,79
					Total GB:	**EUR**	**- 83 088,31**	**0,00**	**- 83 088,31**
HU	Rural Development EAFRD measures subject to IACS	2017	No application of reductions related with late submission of payment claims (M14 of RDP 2014-2020) - FY2017	FLAT RATE	5,00 %	EUR	-1 080 678,64	0,00	-1 080 678,64
	Rural Development EAFRD measures subject to IACS	2016	No verification of all animals during the on-the-spot-checks (Measure 215 of RDP 2007-2013); No application of reductions related with late submission of payment claims (Measure 215 of RDP 2007-2013; M14 of RDP 2014-2020) - FY2016	FLAT RATE	5,00 %	EUR	-1 011 685,76	0,00	-1 011 685,76

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD Axis 2 (2007-2013, area related measures)	2014	Sanction system in the last year of RD programme – Warning letter (Measure 214 of RDP 2007-2013) - CY 2013	FLAT RATE	10,00 %	EUR	- 20 339,71	0,00	- 20 339,71
					Total HU:	**EUR**	**-2 112 704,11**	**0,00**	**-2 112 704,11**
IE	Rural Development EAFRD measures subject to IACS	2016	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	- 483 545,11	0,00	- 483 545,11
	Rural Development EAFRD measures subject to IACS	2017	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	- 466 516,59	0,00	- 466 516,59
	Rural Development EAFRD measures subject to IACS	2018	Weaknesses LPIS	ESTIMATED BY AMOUNT		EUR	- 284 061,57	0,00	- 284 061,57
					Total IE:	**EUR**	**-1 234 123,27**	**0,00**	**-1 234 123,27**
IT	Cross-compliance	2016	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 7 296,99	- 66,24	- 7 230,75
	Cross-compliance	2017	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 2 923,66	0,00	- 2 923,66
	Cross-compliance	2018	Deficient I&R checks under SMR 7 - CY 2015	FLAT RATE	2,00 %	EUR	- 99,12	0,00	- 99,12

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Cross-compliance	2017	Deficient I&R checks under SMR 7 - CY 2016	FLAT RATE	2,00 %	EUR	- 27 283,36	0,00	- 27 283,36
	Cross-compliance	2018	Deficient I&R checks under SMR 7 - CY 2016	FLAT RATE	2,00 %	EUR	- 2 117,20	0,00	- 2 117,20
	Certification	2017	Errors in the EAFRD	ONE OFF		EUR	- 29 136,27	- 319,58	- 28 816,69
	Certification	2017	Known error (EAFRD)	ONE OFF		EUR	- 121 884,94	0,00	- 121 884,94
	Rural Development EAFRD Investment - public beneficiaries	2014	Public Procurement Procedures not properly checked (artificial splitting)	ONE OFF		EUR	- 431 400,00	0,00	- 431 400,00
	Rural Development EAFRD investment - private beneficiaries	2015	Public Procurement Procedures not properly checked (artificial splitting)	ONE OFF		EUR	- 330 045,02	0,00	- 330 045,02
	Rural Development EAFRD investment - private beneficiaries	2016	Public Procurement Procedures not properly checked (artificial splitting)	ONE OFF		EUR	- 15 123,95	0,00	- 15 123,95

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD Investment - public beneficiaries	2014	Public Procurement Procedures not properly checked (Awarding decision not properly justified)	ONE OFF		EUR	- 44 449,58	0,00	- 44 449,58
	Rural Development EAFRD investment - public beneficiaries	2015	Public Procurement Procedures not properly checked (Awarding decision not properly justified)	ONE OFF		EUR	- 28 584,53	0,00	- 28 584,53
	Rural Development EAFRD investment - public beneficiaries	2016	Public Procurement Procedures not properly checked (Awarding decision not properly justified)	ONE OFF		EUR	- 7 895,28	0,00	- 7 895,28
					Total IT:	**EUR**	**-1 048 239,90**	**- 385,82**	**-1 047 854,08**
LT	Rural Development EAFRD investment - private beneficiaries	2016	M121 + M123- Scope of on-the-spot checks and checks on reasonableness of costs	FLAT RATE	5,00 %	EUR	-1 109 209,77	0,00	-1 109 209,77
	Rural Development EAFRD Measures with flat-rate support	2015	M311 - Ineligible car costs (-5 % flat-rate correction from enquiry RD1/2014/834/LT)	ONE OFF		EUR	- 25 892,39	- 1 294,62	- 24 597,77
	Rural Development EAFRD Measures with flat-rate support	2016	M311 - Reasonableness of costs	FLAT RATE	5,00 %	EUR	- 7 070,44	0,00	- 7 070,44
	Rural Development EAFRD Measures with flat-rate support	2016	M312 - Scope of on-the-spot checks and checks on reasonableness of costs	FLAT RATE	5,00 %	EUR	- 297 843,38	0,00	- 297 843,38
					Total LT:	**EUR**	**-1 440 015,98**	**- 1 294,62**	**-1 438 721,36**

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
LU	Rural Development EAFRD measures subject to IACS	2016	EAFRD M10 and M11: Insufficient quantity of on-the-spot checks	ONE OFF		EUR	- 25 037,52	0,00	- 25 037,52
	Rural Development EAFRD measures subject to IACS	2017	EAFRD M10 and M11: Insufficient quantity of on-the-spot checks	ONE OFF		EUR	- 4 245,01	0,00	- 4 245,01
	Rural Development EAFRD measures subject to IACS	2016	M10 and M11: Absence of on-the-spot checks	FLAT RATE	5,00 %	EUR	- 27 749,53	0,00	- 27 749,53
	Rural Development EAFRD measures subject to IACS	2017	M10 and M11: Absence of on-the-spot checks	FLAT RATE	5,00 %	EUR	- 55 330,54	0,00	- 55 330,54
	Rural Development EAFRD measures subject to IACS	2018	M10 and M11: Absence of on-the-spot checks	FLAT RATE	5,00 %	EUR	- 61 198,87	0,00	- 61 198,87
	Rural Development EAFRD measures subject to IACS	2016	M11: payments executed before the completion of the administrative checks	ONE OFF		EUR	- 962,05	0,00	- 962,05
	Rural Development EAFRD measures subject to IACS	2017	M11: payments executed before the completion of the administrative checks	ONE OFF		EUR	- 263,51	0,00	- 263,51
	Rural Development EAFRD investment - public beneficiaries	2016	M20: weak checks on the eligibility of the costs	ONE OFF		EUR	- 24 360,56	0,00	- 24 360,56

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - public beneficiaries	2017	M20: weak checks on the eligibility of the costs	ONE OFF		EUR	- 38 435,81	0,00	- 38 435,81
	Rural Development EAFRD Measures with flat-rate support	2017	M6.1: weak checks on the eligibility of the project (Business Plans)	ONE OFF		EUR	- 47 340,00	0,00	- 47 340,00
	Rural Development EAFRD Measures with flat-rate support	2018	M6.1: weak checks on the eligibility of the project (Business Plans)	ONE OFF		EUR	- 11 835,00	0,00	- 11 835,00
					Total LU:	**EUR**	**- 296 758,40**	**0,00**	**- 296 758,40**
MT	Rural Development EAFRD investment - private beneficiaries	2015	Appropriate evaluation of the reasonableness of costs	FLAT RATE	5,00 %	EUR	- 639,69	- 199,58	- 440,11
	Rural Development EAFRD Leader	2015	Appropriate evaluation of the reasonableness of costs	FLAT RATE	5,00 %	EUR	- 264,48	- 82,52	- 181,96
	Rural Development EAFRD investment - private beneficiaries	2016	Appropriate evaluation of the reasonableness of costs	FLAT RATE	5,00 %	EUR	- 30 407,39	0,00	- 30 407,39
	Rural Development EAFRD Leader	2016	Appropriate evaluation of the reasonableness of costs	FLAT RATE	5,00 %	EUR	- 253,80	0,00	- 253,80
	Rural Development EAFRD Measures with flat-rate support	2016	Appropriate evaluation of the reasonableness of costs	FLAT RATE	5,00 %	EUR	- 4 212,63	0,00	- 4 212,63

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2015	Performance of OTSC of sufficient quality	ONE OFF		EUR	- 64 128,03	- 1 000,40	- 63 127,63
	Rural Development EAFRD investment - private beneficiaries	2016	Performance of OTSC of sufficient quality	ONE OFF		EUR	- 41 890,44	0,00	- 41 890,44
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 7 but not SMR 8 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 144,27	0,00	- 144,27
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to the requirements of SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 79,81	0,00	- 79,81
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to the requirements of SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision	FLAT RATE	2,00 %	EUR	- 88,00	0,00	- 88,00
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 7 and SMR 8 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 84,04	0,00	- 84,04

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to combinations of SMRs - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 75,05	0,00	- 75,05
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to combinations of SMRs - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 73,91	0,00	- 73,91
	Cross-compliance	2016	CY 2015 - Beneficiaries subject to the requirements of SMR 8 only - No evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 400,38	0,00	- 400,38
	Cross-compliance	2017	CY 2016 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 8 and not subject to SMR7 - Deficient on-the-spot checks of animal-related SMRs and/or no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 465,51	0,00	- 465,51
	Cross-compliance	2018	CY 2017 - Beneficiaries subject to the requirements of SMR 6 and/or SMR 8 and not subject to SMR 7 - Deficient on-the-spot checks of animal-related SMRs and no evidence of adequate supervision procedures	FLAT RATE	2,00 %	EUR	- 445,90	0,00	- 445,90
					Total MT:	**EUR**	**- 143 653,33**	**- 1 282,50**	**- 142 370,83**
NL	Rural Development EAFRD Risk management	2016	Deficiency regarding active farmer status - impact on RD	ONE OFF		EUR	- 19 981,45	0,00	- 19 981,45
	Rural Development EAFRD measures subject to IACS	2018	LPIS and other weaknesses	ONE OFF		EUR	- 29 502,31	0,00	- 29 502,31

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD measures subject to IACS	2017	Weaknesses in the LPIS (EAFRD)	ONE OFF		EUR	- 805 547,41	0,00	- 805 547,41
					Total NL:	**EUR**	**- 855 031,17**	**0,00**	**- 855 031,17**
PT	Rural Development EAFRD forestry measures	2016	Double-financing between M8 (first afforestation) and EFA greening - FY 2016.	ONE OFF		EUR	- 45 335,01	- 166,16	- 45 168,85
	Rural Development EAFRD forestry measures	2017	Double-financing between M8 (first afforestation) and EFA greening - FY 2017.	ONE OFF		EUR	- 62 829,11	0,00	- 62 829,11
	Rural Development EAFRD forestry measures	2018	Double-financing between M8 (first afforestation) and EFA greening - FY 2018 + FY 2019	ONE OFF		EUR	- 64 068,90	0,00	- 64 068,90
	Rural Development EAFRD forestry measures	2019	Double-financing between M8 (first afforestation) and EFA greening - FY 2018 + FY 2019	ONE OFF		EUR	- 2 485,97	0,00	- 2 485,97
					Total PT:	**EUR**	**- 174 718,99**	**- 166,16**	**- 174 552,83**
RO	Certification	2017	Individual errors in EAFRD.	ONE OFF		EUR	- 54 870,22	0,00	- 54 870,22
					Total RO:	**EUR**	**- 54 870,22**	**0,00**	**- 54 870,22**
SE	Rural Development EAFRD investment - private beneficiaries	2015	1 KC - Selection and appraisal of projects applications	FLAT RATE	5,00 %	EUR	- 45 164,84	- 45 164,84	0,00

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2016	1 KC - Selection and appraisal of projects applications	FLAT RATE	5,00 %	EUR	- 3 966,68	0,00	- 3 966,68
	Rural Development EAFRD investment - private beneficiaries	2017	KC Appropriate checks to ensure that investment/project/application fulfil all eligibility criteria as laid down in the EU legislation and the eligibility criteria as laid down in the RDP of the Member State or region (M04.4)	ONE OFF		EUR	- 15 197,09	0,00	- 15 197,09
	Rural Development EAFRD investment - private beneficiaries	2018	KC Appropriate checks to ensure that investment/project/application fulfil all eligibility criteria as laid down in the EU legislation and the eligibility criteria as laid down in the RDP of the Member State or region (M04.4)	ONE OFF		EUR	- 21 238,15	0,00	- 21 238,15
	Rural Development EAFRD investment - private beneficiaries	2015	Selection and appraisal of projects/ applications (M121)	FLAT RATE	5,00 %	EUR	- 9 197,44	- 9 197,44	0,00
	Rural Development EAFRD investment - private beneficiaries	2016	Selection and appraisal of projects/ applications (M121)	FLAT RATE	5,00 %	EUR	- 300,26	- 300,26	0,00
	Rural Development EAFRD investment - private beneficiaries	2016	Transitional expenditure (M121)	FLAT RATE	5,00 %	EUR	- 185,67	0,00	- 185,67

Member State	Measure	FY	Reason	Type	Correction %	Currency	Amount	Deductions	Financial Impact
	Rural Development EAFRD investment - private beneficiaries	2016	Transitional expenditure (M216)	FLAT RATE	5,00 %	EUR	- 949,82	0,00	- 949,82
	Rural Development EAFRD investment - private beneficiaries	2016	weakness in reasonableness of costs to be covered by public procurement procedures (M216)	FLAT RATE	5,00 %	EUR	- 3 685,07	0,00	- 3 685,07
	Rural Development EAFRD measures subject to IACS	2017	Weakness in the key control in respect of the administrative checks to establish access to the aid claimed regarding active farmer status CY2016	ESTIMATED BY PERCENTAGE	0,58 %	EUR	- 1 824,63	0,00	- 17 824,63
					Total SE:	**EUR**	**- 117 709,65**	**- 54 662,54**	**- 63 047,11**
SK	Rural Development EAFRD forestry measures	2016	M8.3 and M8.4: deficiency in key control 'Selection and appraisal of projects' - CY2015 and 2016 - FY2016 and 2017	FLAT RATE	5,00 %	EUR	- 214 806,09	- 168 268,94	- 46 537,15
	Rural Development EAFRD forestry measures	2017	M8.3 and M8.4: deficiency in key control 'Selection and appraisal of projects' - CY2015 and 2016 - FY2016 and 2017	FLAT RATE	5,00 %	EUR	-1 326 332,65	0,00	-1 326 332,65
					Total SK:	**EUR**	**-1 541 138,74**	**- 168 268,94**	**-1 372 869,80**

Currency	Amount	Deductions	Financial Impact
EUR	-15 125 090,05	-3 382 519,21	-11 742 570,84

III

(Other acts)

EUROPEAN ECONOMIC AREA

DECISION OF THE EEA JOINT COMMITTEE No 78/2019
of 29 March 2019
amending Annex IX (Financial services) to the EEA Agreement 2019/1836

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 ([1]), as corrected by OJ L 270, 15.10.2015, p. 4, OJ L 187, 12.7.2016, p. 30 and OJ L 278, 27.10.2017, p. 54, is to be incorporated into the EEA Agreement.

(2) Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 amending Regulation (EU) No 600/2014 on markets in financial instruments, Regulation (EU) No 596/2014 on market abuse and Regulation (EU) No 909/2014 on improving securities settlement in the European Union and on central securities depositories ([2]) is to be incorporated into the EEA Agreement.

(3) Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU ([3]), as corrected by OJ L 188, 13.7.2016, p. 28, OJ L 273, 8.10.2016, p. 35 and OJ L 64, 10.3.2017, p. 116, is to be incorporated into the EEA Agreement.

(4) Directive (EU) 2016/1034 of the European Parliament and of the Council of 23 June 2016 amending Directive 2014/65/EU on markets in financial instruments ([4]) is to be incorporated into the EEA Agreement.

(5) Directive 2014/65/EU repeals Directive 2004/39/EC of the European Parliament and of the Council ([5]), which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.

(6) Regulation (EU) No 600/2014 specifies cases in which the European Banking Authority (EBA) and European Securities and Markets Authority (ESMA) may temporarily prohibit or restrict certain financial activities, and lays down conditions thereto, in accordance with Article 9(5) of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ([6]) and of Regulation (EU) No 1095/2010 of the European Parliament and of the Council ([7]), respectively. For the purposes of the EEA Agreement, these powers are to be exercised by the EFTA Surveillance Authority as regards the EFTA States, in accordance with points 31g and 31i of Annex IX to the EEA Agreement. To ensure integration of the expertise of EBA and ESMA in the process and consistency between the two pillars of the EEA, such decisions of the EFTA Surveillance Authority will be adopted on the basis of drafts prepared by EBA or ESMA, as the case may be. This will preserve key advantages of supervision by a single authority.

([1]) OJ L 173, 12.6.2014, p. 84.
([2]) OJ L 175, 30.6.2016, p. 1.
([3]) OJ L 173, 12.6.2014, p. 349.
([4]) OJ L 175, 30.6.2016, p. 8.
([5]) OJ L 145, 30.4.2004, p. 1.
([6]) OJ L 331, 15.12.2010, p. 12.
([7]) OJ L 331, 15.12.2010, p. 84.

(7) The Contracting Parties share the understanding that this Decision implements the agreement that was reflected in the conclusions ([8]) of the EU and EEA EFTA Ministers of Finance and Economy of 14 October 2014 regarding the incorporation of the EU ESAs Regulations into the EEA Agreement.

(8) Annex IX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex IX to the EEA Agreement shall be amended as follows:

1. The following is added in point 13b (Directive 2002/92/EC of the European Parliament and of the Council):

', as amended by:

— **32014 L 0065**: Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 (OJ L 173, 12.6.2014, p. 349), as corrected by OJ L 188, 13.7.2016, p. 28, OJ L 273, 8.10.2016, p. 35 and OJ L 64, 10.3.2017, p. 116.'

2. The text of point 31ba (Directive 2004/39/EC of the European Parliament and of the Council) is replaced by the following:

'**32014 L 0065**: Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349), as corrected by OJ L 188, 13.7.2016, p. 28, OJ L 273, 8.10.2016, p. 35 and OJ L 64, 10.3.2017, p. 116, as amended by:

— **32016 L 1034**: Directive (EU) 2016/1034 of the European Parliament and of the Council of 23 June 2016 (OJ L 175, 30.6.2016, p. 8).

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

(a) Notwithstanding the provisions of Protocol 1 to this Agreement, and unless otherwise provided for in this Agreement, the terms "Member State(s)" and "competent authorities" shall be understood to include, in addition to their meaning in the Directive, the EFTA States and their competent authorities, respectively.

(b) References to members of the ESCB shall be understood to include, in addition to their meaning in the Directive, the national central banks of the EFTA States.

(c) References to other acts in the Directive shall be considered relevant to the extent and in the form that those acts are incorporated into the Agreement.

(d) In Article 3(2), as regards the EFTA States, the words "2 July 2014" shall read "the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019" and the words "3 July 2019" shall read "five years thereafter".

(e) In Article 16(11), as regards the EFTA States, the words "2 July 2014" shall read "the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019".

(f) In Article 41(2), the word "Union" shall be replaced by the word "EEA".

(g) In Article 57:

(i) in the second subparagraph of paragraph 5, the words "it shall take action" shall be replaced by the words "ESMA or, as the case may be, the EFTA Surveillance Authority shall take action";

(ii) in paragraph 6, the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA".

(h) In points (f) and (g) of Article 70(6), as regards the EFTA States, the words "2 July 2014" shall read "the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019".

([8]) Council Conclusions on the EU and EEA EFTA Ministers of Finance and Economy, 14178/1/14 REV 1.

(i) In Article 79:

(i) in the second subparagraph of paragraph 1, the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA";

(ii) in the fifth subparagraph of paragraph 1, the words ", the EFTA Surveillance Authority" shall be inserted after the words "the Commission, ESMA".

(j) In Articles 81(5), 82(2) and 87(1), the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA".

(k) In Article 86, the words "ESMA, which" shall be replaced by the words "ESMA. ESMA or, as the case may be, the EFTA Surveillance Authority".

(l) In Article 95(1), as regards the EFTA States, the words "3 January 2018" shall read "the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019".'

3. The text of point 31baa (deleted) is replaced by the following:

'**32014 R 0600**: Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 (OJ L 173, 12.6.2014, p. 84), as corrected by OJ L 270, 15.10.2015, p. 4, OJ L 187, 12.7.2016, p. 30 and OJ L 278, 27.10.2017, p. 54, as amended by:

— **32016 R 1033**: Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 (OJ L 175, 30.6.2016, p. 1).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) Notwithstanding the provisions of Protocol 1 to this Agreement, and unless otherwise provided for in this Agreement, the terms "Member State(s)" and "competent authorities" shall be understood to include, in addition to their meaning in the Regulation, the EFTA States and their competent authorities, respectively.

(b) References to members of the ESCB shall be understood to include, in addition to their meaning in the Regulation, the national central banks of the EFTA States.

(c) Unless otherwise provided for in this Agreement, the European Banking Authority (EBA) or the European Securities and Markets Authority (ESMA), as the case may be, and the EFTA Surveillance Authority shall cooperate, exchange information and consult each other for the purposes of the Regulation, in particular prior to taking any action.

(d) References to other acts in the Regulation shall be considered relevant to the extent and in the form that those acts are incorporated into the Agreement.

(e) References to the powers of ESMA under Article 19 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council in the Regulation shall be understood as referring, in the cases provided for in and in accordance with point 31i of this Annex, to the powers of the EFTA Surveillance Authority as regards the EFTA States.

(f) In point (e) of Article 1(1):

(i) as regards the EFTA States, the words "competent authorities, ESMA and EBA" shall read "competent authorities and the EFTA Surveillance Authority";

(ii) the words "or, as regards the EFTA States, the EFTA Surveillance Authority" shall be inserted after the words "powers of ESMA".

(g) In Article 4:

(i) in paragraph 4, the words "and to the EFTA Surveillance Authority" shall be inserted after the words "the Commission";

(ii) in paragraph 7, the words "or, as regards waivers granted by competent authorities of the EFTA States, before the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019" shall be inserted after the words "3 January 2018".

(h) In Articles 7(1), 9(2), 11(1) and 19(1), the words "and to the EFTA Surveillance Authority" shall be inserted after the words "the Commission".

(i) In Article 36(5):

(i) in the first and second sentences, as regards the EFTA States, the word "ESMA" shall read "the EFTA Surveillance Authority";

(ii) the words "and shall include in the list all notifications received by the EFTA Surveillance Authority" shall be inserted after the words "ESMA shall publish a list of all notifications that it receives".

(j) In Article 37(2):

(i) as regards the EFTA States, the words "3 January 2018" shall read "the date of entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019";

(ii) the words "Article 101 and 102 TFEU" shall be replaced by the words "Articles 53 and 54 of the EEA Agreement".

(k) In Article 40:

(i) as regards the EFTA States, in paragraphs 1 to 4, 6 and 7, the word "ESMA" shall read "the EFTA Surveillance Authority";

(ii) as regards the EFTA States, in paragraph 2, the words "Union law" shall read "the EEA Agreement";

(iii) in paragraph 3, the words "after consulting the public bodies" shall be replaced by the words "after consultation by ESMA of the public bodies";

(iv) in paragraph 3, the words "without issuing the opinion" shall be replaced by the words "without ESMA issuing the opinion";

(v) in paragraph 5, the words "any decision to take any action" shall be replaced by the words "each of its decisions to take action";

(vi) in paragraph 5, the words ". The EFTA Surveillance Authority shall publish on its website notice of each of its own decisions to take any action under this Article. A reference to the publication of the notice by the EFTA Surveillance Authority shall be posted on ESMA's website" shall be inserted after the words "this Article".

(l) In Article 41:

(i) as regards the EFTA States, in paragraphs 1 to 4, 6 and 7, the word "EBA" shall read "the EFTA Surveillance Authority";

(ii) as regards the EFTA States, in paragraph 2, the words "Union law" shall read "the EEA Agreement";

(iii) in paragraph 3, the words "without issuing the opinion" shall be replaced by the words "without EBA issuing the opinion";

(iv) in paragraph 5, the words "any decision to take any action" shall be replaced by the words "each of its decisions to take action";

(v) in paragraph 5, the words ". The EFTA Surveillance Authority shall publish on its website notice of each of its own decisions to take any action under this Article. A reference to the publication of the notice by the EFTA Surveillance Authority shall be posted on EBA's website" shall be inserted after the words "this Article".

(m) In Article 45:

(i) in the paragraph 1, the words "or, as regards the EFTA States, the EFTA Surveillance Authority" shall be inserted after the word "ESMA";

(ii) in paragraphs 2, 4, 5, 8 and 9 and in the first subparagraph of paragraph 3, the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA";

(iii) in the second and third subparagraphs of paragraph 3, the words "or, as the case may be, preparing drafts for the EFTA Surveillance Authority," shall be inserted after the words "before taking any measure";

(iv) in paragraph 6, the words "any decision" shall read "each of its decisions";

(v) in paragraph 6, the words ". The EFTA Surveillance Authority shall publish on its website notice of each of its own decisions to impose or renew any measure referred to in paragraph 1(c). A reference to the publication of the notice by the EFTA Surveillance Authority shall be posted on ESMA's website" shall be inserted after the words "paragraph 1(c)";

(vi) in paragraph 7, the words "on the ESMA website or, as regards measures taken by the EFTA Surveillance Authority, when the notice is published on the website of the EFTA Surveillance Authority," shall be inserted after the words "when the notice is published".'

4. The following indent is added in point 31bc (Regulation (EU) No 648/2012 of the European Parliament and of the Council):

— '**32014 R 0600**: Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 (OJ L 173, 12.6.2014, p. 84), as corrected by OJ L 270, 15.10.2015, p. 4, OJ L 187, 12.7.2016, p. 30 and OJ L 278, 27.10.2017, p. 54.'

Article 2

The texts of Regulations (EU) No 600/2014, as corrected by OJ L 270, 15.10.2015, p. 4, OJ L 187, 12.7.2016, p. 30 and OJ L 278, 27.10.2017, p. 54, and (EU) 2016/1033 and Directives 2014/65/EU, as corrected by OJ L 188, 13.7.2016, p. 28, OJ L 273, 8.10.2016, p. 35 and OJ L 64, 10.3.2017, p. 116, and (EU) 2016/1034 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on the day following the last notification under Article 103(1) of the EEA Agreement [9].

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 29 March 2019.

For the EEA Joint Committee
The President
Claude MAERTEN

[9] Constitutional requirements indicated.

ANNEX

JOINT DECLARATION BY THE CONTRACTING PARTIES

to Decision of the EEA Joint Committee No 78/2019 of 29 March 2019 incorporating Directive 2014/65/EU into the EEA Agreement

The Contracting Parties share the understanding that the incorporation into the EEA Agreement of Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU is without prejudice to national rules of general application concerning the screening for security or public order of foreign direct investment.

DECISION OF THE EEA JOINT COMMITTEE NO 85/2019

of 29 March 2019

amending Annex IX (Financial services) to the EEA Agreement 2019/1837

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ("the EEA Agreement"), and in particular Article 98 thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2016/2020 of 26 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on criteria for determining whether derivatives subject to the clearing obligation should be subject to the trading obligation ([1]) is to be incorporated into the EEA Agreement.

(2) Commission Delegated Regulation (EU) 2016/2021 of 2 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on access in respect of benchmarks ([2]) is to be incorporated into the EEA Agreement.

(3) Commission Delegated Regulation (EU) 2016/2022 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards concerning the information for registration of third-country firms and the format of information to be provided to the clients ([3]) is to be incorporated into the EEA Agreement.

(4) Commission Delegated Regulation (EU) 2017/565 of 25 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive ([4]) is to be incorporated into the EEA Agreement.

(5) Commission Delegated Regulation (EU) 2017/566 of 18 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards for the ratio of unexecuted orders to transactions in order to prevent disorderly trading conditions ([5]) is to be incorporated into the EEA Agreement.

(6) Commission Delegated Regulation (EU) 2017/567 of 18 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to definitions, transparency, portfolio compression and supervisory measures on product intervention and positions ([6]) is to be incorporated into the EEA Agreement.

(7) Commission Delegated Regulation (EU) 2017/568 of 24 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the admission of financial instruments to trading on regulated markets ([7]) is to be incorporated into the EEA Agreement.

(8) Commission Delegated Regulation (EU) 2017/569 of 24 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the suspension and removal of financial instruments from trading ([8]) is to be incorporated into the EEA Agreement.

([1]) OJ L 313, 19.11.2016, p. 2.
([2]) OJ L 313, 19.11.2016, p. 6.
([3]) OJ L 313, 19.11.2016, p. 11.
([4]) OJ L 87, 31.3.2017, p. 1.
([5]) OJ L 87, 31.3.2017, p. 84.
([6]) OJ L 87, 31.3.2017, p. 90.
([7]) OJ L 87, 31.3.2017, p. 117.
([8]) OJ L 87, 31.3.2017, p. 122.

(9) Commission Delegated Regulation (EU) 2017/570 of 26 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards for the determination of a material market in terms of liquidity in relation to notifications of a temporary halt in trading ([9]) is to be incorporated into the EEA Agreement.

(10) Commission Delegated Regulation (EU) 2017/571 of 2 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the authorisation, organisational requirements and the publication of transactions for data reporting services providers ([10]) is to be incorporated into the EEA Agreement.

(11) Commission Delegated Regulation (EU) 2017/572 of 2 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on the specification of the offering of pre-and post-trade data and the level of disaggregation of data ([11]) is to be incorporated into the EEA Agreement.

(12) Commission Delegated Regulation (EU) 2017/573 of 6 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on requirements to ensure fair and non-discriminatory co-location services and fee structures ([12]) is to be incorporated into the EEA Agreement.

(13) Commission Delegated Regulation (EU) 2017/574 of 7 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the level of accuracy of business clocks ([13]) is to be incorporated into the EEA Agreement.

(14) Commission Delegated Regulation (EU) 2017/575 of 8 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards concerning the data to be published by execution venues on the quality of execution of transactions ([14]) is to be incorporated into the EEA Agreement.

(15) Commission Delegated Regulation (EU) 2017/576 of 8 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the annual publication by investment firms of information on the identity of execution venues and on the quality of execution ([15]) is to be incorporated into the EEA Agreement.

(16) Commission Delegated Regulation (EU) 2017/577 of 13 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the volume cap mechanism and the provision of information for the purposes of transparency and other calculations ([16]) is to be incorporated into the EEA Agreement.

(17) Commission Delegated Regulation (EU) 2017/578 of 13 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards specifying the requirements on market making agreements and schemes ([17]) is to be incorporated into the EEA Agreement.

(18) Commission Delegated Regulation (EU) 2017/579 of 13 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the direct, substantial and foreseeable effect of derivative contracts within the Union and the prevention of the evasion of rules and obligations ([18]) is to be incorporated into the EEA Agreement.

(19) Commission Delegated Regulation (EU) 2017/580 of 24 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the maintenance of relevant data relating to orders in financial instruments ([19]) is to be incorporated into the EEA Agreement.

([9]) OJ L 87, 31.3.2017, p. 124.
([10]) OJ L 87, 31.3.2017, p. 126.
([11]) OJ L 87, 31.3.2017, p. 142.
([12]) OJ L 87, 31.3.2017, p. 145.
([13]) OJ L 87, 31.3.2017, p. 148.
([14]) OJ L 87, 31.3.2017, p. 152.
([15]) OJ L 87, 31.3.2017, p. 166.
([16]) OJ L 87, 31.3.2017, p. 174.
([17]) OJ L 87, 31.3.2017, p. 183.
([18]) OJ L 87, 31.3.2017, p. 189.
([19]) OJ L 87, 31.3.2017, p. 193.

(20) Commission Delegated Regulation (EU) 2017/581 of 24 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on clearing access in respect of trading venues and central counterparties ([20]) is to be incorporated into the EEA Agreement.

(21) Commission Delegated Regulation (EU) 2017/582 of 29 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards specifying the obligation to clear derivatives traded on regulated markets and timing of acceptance for clearing ([21]) is to be incorporated into the EEA Agreement.

(22) Commission Delegated Regulation (EU) 2017/583 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of bonds, structured finance products, emission allowances and derivatives ([22]) is to be incorporated into the EEA Agreement.

(23) Commission Delegated Regulation (EU) 2017/584 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying organisational requirements of trading venues ([23]) is to be incorporated into the EEA Agreement.

(24) Commission Delegated Regulation (EU) 2017/585 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the data standards and formats for financial instrument reference data and technical measures in relation to arrangements to be made by the European Securities and Markets Authority and competent authorities ([24]) is to be incorporated into the EEA Agreement.

(25) Commission Delegated Regulation (EU) 2017/586 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the exchange of information between competent authorities when cooperating in supervisory activities, on-the-spot verifications and investigations ([25]) is to be incorporated into the EEA Agreement.

(26) Commission Delegated Regulation (EU) 2017/587 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of shares, depositary receipts, exchange-traded funds, certificates and other similar financial instruments and on transaction execution obligations in respect of certain shares on a trading venue or by a systematic internaliser ([26]) is to be incorporated into the EEA Agreement.

(27) Commission Delegated Regulation (EU) 2017/588 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the tick size regime for shares, depositary receipts and exchange-traded funds ([27]) is to be incorporated into the EEA Agreement.

(28) Commission Delegated Regulation (EU) 2017/589 of 19 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the organisational requirements of investment firms engaged in algorithmic trading ([28]) is to be incorporated into the EEA Agreement.

(29) Commission Delegated Regulation (EU) 2017/590 of 28 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the reporting of transactions to competent authorities ([29]) is to be incorporated into the EEA Agreement.

(30) Commission Delegated Regulation (EU) 2017/591 of 1 December 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the application of position limits to commodity derivatives ([30]) is to be incorporated into the EEA Agreement.

([20]) OJ L 87, 31.3.2017, p. 212.
([21]) OJ L 87, 31.3.2017, p. 224.
([22]) OJ L 87, 31.3.2017, p. 229.
([23]) OJ L 87, 31.3.2017, p. 350.
([24]) OJ L 87, 31.3.2017, p. 368.
([25]) OJ L 87, 31.3.2017, p. 382.
([26]) OJ L 87, 31.3.2017, p. 387.
([27]) OJ L 87, 31.3.2017, p. 411.
([28]) OJ L 87, 31.3.2017, p. 417.
([29]) OJ L 87, 31.3.2017, p. 449.
([30]) OJ L 87, 31.3.2017, p. 479.

(31) Commission Delegated Regulation (EU) 2017/592 of 1 December 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the criteria to establish when an activity is considered to be ancillary to the main business ([31]) is to be incorporated into the EEA Agreement.

(32) Commission Delegated Regulation (EU) 2017/1018 of 29 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards specifying information to be notified by investment firms, market operators and credit institutions ([32]), as corrected by OJ L 292, 10.11.2017, p. 119, is to be incorporated into the EEA Agreement.

(33) Commission Delegated Regulation (EU) 2017/1799 of 12 June 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council as regards the exemption of certain third countries central banks in their performance of monetary, foreign exchange and financial stability policies from pre- and post-trade transparency requirements ([33]) is to be incorporated into the EEA Agreement.

(34) Commission Delegated Regulation (EU) 2017/1943 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on information and requirements for the authorisation of investment firms ([34]) is to be incorporated into the EEA Agreement.

(35) Commission Delegated Regulation (EU) 2017/1946 of 11 July 2017 supplementing Directives 2004/39/EC and 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for an exhaustive list of information to be included by proposed acquirers in the notification of a proposed acquisition of a qualifying holding in an investment firm ([35]) is to be incorporated into the EEA Agreement.

(36) Commission Delegated Regulation (EU) 2017/2154 of 22 September 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on indirect clearing arrangements ([36]) is to be incorporated into the EEA Agreement.

(37) Commission Delegated Regulation (EU) 2017/2194 of 14 August 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to package orders ([37]) is to be incorporated into the EEA Agreement.

(38) Commission Delegated Regulation (EU) 2017/2417 of 17 November 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the trading obligation for certain derivatives ([38]) is to be incorporated into the EEA Agreement.

(39) Commission Delegated Regulation (EU) 2018/63 of 26 September 2017 amending Delegated Regulation (EU) 2017/571 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the authorisation, organisational requirements and the publication of transactions for data reporting services providers ([39]) is to be incorporated into the EEA Agreement.

(40) Commission Implementing Regulation (EU) 2016/824 of 25 May 2016 laying down implementing technical standards with regard to the content and format of the description of the functioning of multilateral trading facilities and organised trading facilities and the notification to the European Securities and Markets Authority according to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments ([40]) is to be incorporated into the EEA Agreement.

(41) Commission Implementing Regulation (EU) 2017/953 of 6 June 2017 laying down implementing technical standards with regard to the format and the timing of position reports by investment firms and market operators of trading venues pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments ([41]) is to be incorporated into the EEA Agreement.

([31]) OJ L 87, 31.3.2017, p. 492.
([32]) OJ L 155, 17.6.2017, p. 1.
([33]) OJ L 259, 7.10.2017, p. 11.
([34]) OJ L 276, 26.10.2017, p. 4.
([35]) OJ L 276, 26.10.2017, p. 32.
([36]) OJ L 304, 21.11.2017, p. 6.
([37]) OJ L 312, 28.11.2017, p. 1.
([38]) OJ L 343, 22.12.2017, p. 48.
([39]) OJ L 12, 17.1.2018, p. 2.
([40]) OJ L 137, 26.5.2016, p. 10.
([41]) OJ L 144, 7.6.2017, p. 12.

(42) Commission Implementing Regulation (EU) 2017/980 of 7 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for cooperation in supervisory activities, for on-site verifications, and investigations and exchange of information between competent authorities in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([42]) is to be incorporated into the EEA Agreement.

(43) Commission Implementing Regulation (EU) 2017/981 of 7 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the consultation of other competent authorities prior to granting an authorisation in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([43]) is to be incorporated into the EEA Agreement.

(44) Commission Implementing Regulation (EU) 2017/988 of 6 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for cooperation arrangements in respect of a trading venue whose operations are of substantial importance in a host Member State ([44]) is to be incorporated into the EEA Agreement.

(45) Commission Implementing Regulation (EU) 2017/1005 of 15 June 2017 laying down implementing technical standards with regard to the format and timing of the communications and the publication of the suspension and removal of financial instruments pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments ([45]) is to be incorporated into the EEA Agreement.

(46) Commission Implementing Regulation (EU) 2017/1093 of 20 June 2017 laying down implementing technical standards with regard to the format of position reports by investment firms and market operators ([46]) is to be incorporated into the EEA Agreement.

(47) Commission Implementing Regulation (EU) 2017/1110 of 22 June 2017 laying down implementing technical standards with regard to the standard forms, templates and procedures for the authorisation of data reporting services providers and related notifications pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments ([47]) is to be incorporated into the EEA Agreement.

(48) Commission Implementing Regulation (EU) 2017/1111 of 22 June 2017 laying down implementing technical standards with regard to procedures and forms for submitting information on sanctions and measures in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([48]) is to be incorporated into the EEA Agreement.

(49) Commission Implementing Regulation (EU) 2017/1944 of 13 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the consultation process between relevant competent authorities in relation to the notification of a proposed acquisition of a qualifying holding in an investment firm in accordance with Directives 2004/39/EC and 2014/65/EU of the European Parliament and of the Council ([49]) is to be incorporated into the EEA Agreement.

(50) Commission Implementing Regulation (EU) 2017/1945 of 19 June 2017 laying down implementing technical standards with regard to notifications by and to applicant and authorised investment firms according to Directive 2014/65/EU of the European Parliament and of the Council ([50]) is to be incorporated into the EEA Agreement.

(51) Commission Implementing Regulation (EU) 2017/2382 of 14 December 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the transmission of information in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([51]), as corrected by OJ L 33, 7.2.2018, p. 5, is to be incorporated into the EEA Agreement.

([42]) OJ L 148, 10.6.2017, p. 3.
([43]) OJ L 148, 10.6.2017, p. 16.
([44]) OJ L 149, 13.6.2017, p. 3.
([45]) OJ L 153, 16.6.2017, p. 1.
([46]) OJ L 158, 21.6.2017, p. 16.
([47]) OJ L 162, 23.6.2017, p. 3.
([48]) OJ L 162, 23.6.2017, p. 14.
([49]) OJ L 276, 26.10.2017, p. 12.
([50]) OJ L 276, 26.10.2017, p. 22.
([51]) OJ L 340, 20.12.2017, p. 6.

(52) Commission Delegated Directive (EU) 2017/593 of 7 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to safeguarding of financial instruments and funds belonging to clients, product governance obligations and the rules applicable to the provision or reception of fees, commissions or any monetary or non-monetary benefits ([52]) is to be incorporated into the EEA Agreement.

(53) Commission Implementing Decision (EU) 2017/2238 of 5 December 2017 on the equivalence of the legal and supervisory framework applicable to designated contract markets and swap execution facilities in the United States of America in accordance with Regulation (EU) No 600/2014 of the European Parliament and of the Council ([53]) is to be incorporated into the EEA Agreement.

(54) Commission Implementing Decision (EU) 2017/2318 of 13 December 2017 on the equivalence of the legal and supervisory framework in Australia applicable to financial markets in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([54]) is to be incorporated into the EEA Agreement.

(55) Commission Implementing Decision (EU) 2017/2319 of 13 December 2017 on the equivalence of the legal and supervisory framework applicable to recognised exchange companies in Hong Kong Special Administrative Region in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([55]) is to be incorporated into the EEA Agreement.

(56) Commission Implementing Decision (EU) 2017/2320 of 13 December 2017 on the equivalence of the legal and supervisory framework of the United States of America for national securities exchanges and alternative trading systems in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([56]) is to be incorporated into the EEA Agreement.

(57) Commission Implementing Decision (EU) 2017/2441 of 21 December 2017 on the equivalence of the legal and supervisory framework applicable to stock exchanges in Switzerland in accordance with Directive 2014/65/EU of the European Parliament and of the Council ([57]) is to be incorporated into the EEA Agreement.

(58) Annex IX to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following is added after point 31baa (Regulation (EU) No 600/2014 of the European Parliament and of the Council) of Annex IX to the EEA Agreement:

'31bad. **32016 R 0824:** Commission Implementing Regulation (EU) 2016/824 of 25 May 2016 laying down implementing technical standards with regard to the content and format of the description of the functioning of multilateral trading facilities and organised trading facilities and the notification to the European Securities and Markets Authority according to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments (OJ L 137, 26.5.2016, p. 10).

31bae. **32016 R 2020:** Commission Delegated Regulation (EU) 2016/2020 of 26 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on criteria for determining whether derivatives subject to the clearing obligation should be subject to the trading obligation (OJ L 313, 19.11.2016, p. 2).

31baf. **32016 R 2021:** Commission Delegated Regulation (EU) 2016/2021 of 2 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on access in respect of benchmarks (OJ L 313, 19.11.2016, p. 6).

([52]) OJ L 87, 31.3.2017, p. 500.
([53]) OJ L 320, 6.12.2017, p. 11.
([54]) OJ L 331, 14.12.2017, p. 81.
([55]) OJ L 331, 14.12.2017, p. 87.
([56]) OJ L 331, 14.12.2017, p. 94.
([57]) OJ L 344, 23.12.2017, p. 52.

31bag. **32016 R 2022:** Commission Delegated Regulation (EU) 2016/2022 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards concerning the information for registration of third-country firms and the format of information to be provided to the clients (OJ L 313, 19.11.2016, p. 11).

31bah. **32017 R 0565:** Commission Delegated Regulation (EU) 2017/565 of 25 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive (OJ L 87, 31.3.2017, p. 1).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) References to other acts in the Regulation shall be considered relevant to the extent and in the form that those acts are incorporated into the Agreement.

(b) In paragraph 3 of Article 10, the words ", Icelandic króna" shall be inserted after the word "Polish złoty"

(c) In paragraphs 5 and 6 of Article 50, the words "Union legislation" shall be replaced by the words "provisions of the EEA Agreement".

31bai. **32017 R 0566:** Commission Delegated Regulation (EU) 2017/566 of 18 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards for the ratio of unexecuted orders to transactions in order to prevent disorderly trading conditions (OJ L 87, 31.3.2017, p. 84).

31baj. **32017 R 0567:** Commission Delegated Regulation (EU) 2017/567 of 18 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to definitions, transparency, portfolio compression and supervisory measures on product intervention and positions (OJ L 87, 31.3.2017, p. 90).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) References to other acts in the Regulation shall be considered relevant to the extent and in the form that those acts are incorporated into the Agreement.

(b) In Articles 19 and 22 the words "or as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA".

(c) In Article 20, the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "EBA".

31bak. **32017 R 0568:** Commission Delegated Regulation (EU) 2017/568 of 24 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the admission of financial instruments to trading on regulated markets (OJ L 87, 31.3.2017, p. 117).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

In Article 7, the words "Union law" shall be replaced by "the EEA Agreement".

31bal. **32017 R 0569:** Commission Delegated Regulation (EU) 2017/569 of 24 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the suspension and removal of financial instruments from trading (OJ L 87, 31.3.2017, p. 122).

31bam. **32017 R 0570:** Commission Delegated Regulation (EU) 2017/570 of 26 May 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards for the determination of a material market in terms of liquidity in relation to notifications of a temporary halt in trading (OJ L 87, 31.3.2017, p. 124).

31ban. **32017 R 0571:** Commission Delegated Regulation (EU) 2017/571 of 2 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the authorisation, organisational requirements and the publication of transactions for data reporting services providers (OJ L 87, 31.3.2017, p. 126), as amended by:

32018 R 0063: Commission Delegated Regulation (EU) 2018/63 of 26 September 2017 (OJ L 12, 17.1.2018, p. 2).

31bao. **32017 R 0572:** Commission Delegated Regulation (EU) 2017/572 of 2 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on the specification of the offering of pre-and post-trade data and the level of disaggregation of data (OJ L 87, 31.3.2017, p. 142).

31bap. **32017 R 0573:** Commission Delegated Regulation (EU) 2017/573 of 6 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on requirements to ensure fair and non-discriminatory co-location services and fee structures (OJ L 87, 31.3.2017, p. 145).

31baq. **32017 R 0574:** Commission Delegated Regulation (EU) 2017/574 of 7 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the level of accuracy of business clocks (OJ L 87, 31.3.2017, p. 148).

31bar. **32017 R 0575:** Commission Delegated Regulation (EU) 2017/575 of 8 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards concerning the data to be published by execution venues on the quality of execution of transactions (OJ L 87, 31.3.2017, p. 152).

31bas. **32017 R 0576:** Commission Delegated Regulation (EU) 2017/576 of 8 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the annual publication by investment firms of information on the identity of execution venues and on the quality of execution (OJ L 87, 31.3.2017, p. 166).

31bat. **32017 R 0577:** Commission Delegated Regulation (EU) 2017/577 of 13 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the volume cap mechanism and the provision of information for the purposes of transparency and other calculations (OJ L 87, 31.3.2017, p. 174).

31bau. **32017 R 0578:** Commission Delegated Regulation (EU) 2017/578 of 13 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards specifying the requirements on market making agreements and schemes (OJ L 87, 31.3.2017, p. 183).

31bav. **32017 R 0579:** Commission Delegated Regulation (EU) 2017/579 of 13 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the direct, substantial and foreseeable effect of derivative contracts within the Union and the prevention of the evasion of rules and obligations (OJ L 87, 31.3.2017, p. 189).

31baw. **32017 R 0580:** Commission Delegated Regulation (EU) 2017/580 of 24 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the maintenance of relevant data relating to orders in financial instruments (OJ L 87, 31.3.2017, p. 193).

31bax. **32017 R 0581:** Commission Delegated Regulation (EU) 2017/581 of 24 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on clearing access in respect of trading venues and central counterparties (OJ L 87, 31.3.2017, p. 212).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) In Articles 16, 17, 18 and 20(1), as regards the EFTA States, the word "ESMA" shall read "the EFTA Surveillance Authority".

(b) In Article 20(2) the words "or, as the case may be, the EFTA Surveillance Authority" shall be inserted after the word "ESMA".

(c) In Article 20(3) the words "or, as regards the EFTA states, the EFTA Surveillance Authority on the basis of a draft prepared by ESMA" shall be inserted after the word "ESMA".

31bay. **32017 R 0582:** Commission Delegated Regulation (EU) 2017/582 of 29 June 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards specifying the obligation to clear derivatives traded on regulated markets and timing of acceptance for clearing (OJ L 87, 31.3.2017, p. 224).

31baz. **32017 R 0583:** Commission Delegated Regulation (EU) 2017/583 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of bonds, structured finance products, emission allowances and derivatives (OJ L 87, 31.3.2017, p. 229).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

References to members of the ESCB shall be understood to include, in addition to their meaning in the Regulation, the national central banks of the EFTA States.

31baza. **32017 R 0584:** Commission Delegated Regulation (EU) 2017/584 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying organisational requirements of trading venues (OJ L 87, 31.3.2017, p. 350).

31bazb. **32017 R 0585:** Commission Delegated Regulation (EU) 2017/585 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the data standards and formats for financial instrument reference data and technical measures in relation to arrangements to be made by the European Securities and Markets Authority and competent authorities (OJ L 87, 31.3.2017, p. 368).

31bazc. **32017 R 0586:** Commission Delegated Regulation (EU) 2017/586 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the exchange of information between competent authorities when cooperating in supervisory activities, on-the-spot verifications and investigations (OJ L 87, 31.3.2017, p. 382).

31bazd. **32017 R 0587:** Commission Delegated Regulation (EU) 2017/587 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of shares, depositary receipts, exchange-traded funds, certificates and other similar financial instruments and on transaction execution obligations in respect of certain shares on a trading venue or by a systematic internaliser (OJ L 87, 31.3.2017, p. 387).

31baze. **32017 R 0588:** Commission Delegated Regulation (EU) 2017/588 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the tick size regime for shares, depositary receipts and exchange-traded funds (OJ L 87, 31.3.2017, p. 411).

31bazf. **32017 R 0589:** Commission Delegated Regulation (EU) 2017/589 of 19 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the organisational requirements of investment firms engaged in algorithmic trading (OJ L 87, 31.3.2017, p. 417).

31bazg. **32017 R 0590:** Commission Delegated Regulation (EU) 2017/590 of 28 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the reporting of transactions to competent authorities (OJ L 87, 31.3.2017, p. 449).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) References to members of the ESCB shall be understood to include, in addition to their meaning in the Regulation, the national central banks of the EFTA States.

(b) In Annex II, the entry for Liechtenstein shall be replaced by the following:

LI	Liechtenstein	CONCAT		

31bazh. **32017 R 0591:** Commission Delegated Regulation (EU) 2017/591 of 1 December 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the application of position limits to commodity derivatives (OJ L 87, 31.3.2017, p. 479).

31bazi. **32017 R 0592:** Commission Delegated Regulation (EU) 2017/592 of 1 December 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for the criteria to establish when an activity is considered to be ancillary to the main business (OJ L 87, 31.3.2017, p. 492).

31bazj. **32017 L 0593:** Commission Delegated Directive (EU) 2017/593 of 7 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to safeguarding of financial instruments and funds belonging to clients, product governance obligations and the rules applicable to the provision or reception of fees, commissions or any monetary or non-monetary benefits (OJ L 87, 31.3.2017, p. 500).

31bazk. **32017 R 0953:** Commission Implementing Regulation (EU) 2017/953 of 6 June 2017 laying down implementing technical standards with regard to the format and the timing of position reports by investment firms and market operators of trading venues pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments (OJ L 144, 7.6.2017, p. 12).

31bazl. **32017 R 0980:** Commission Implementing Regulation (EU) 2017/980 of 7 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for cooperation in supervisory activities, for on-site verifications, and investigations and exchange of information between competent authorities in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 148, 10.6.2017, p. 3).

31bazm. **32017 R 0981:** Commission Implementing Regulation (EU) 2017/981 of 7 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the consultation of other competent authorities prior to granting an authorisation in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 148, 10.6.2017, p. 16).

31bazn. **32017 R 0988:** Commission Implementing Regulation (EU) 2017/988 of 6 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for cooperation arrangements in respect of a trading venue whose operations are of substantial importance in a host Member State (OJ L 149, 13.6.2017, p. 3).

31bazo. **32017 R 1005:** Commission Implementing Regulation (EU) 2017/1005 of 15 June 2017 laying down implementing technical standards with regard to the format and timing of the communications and the publication of the suspension and removal of financial instruments pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments (OJ L 153, 16.6.2017, p. 1).

31bazp. **32017 R 1018:** Commission Delegated Regulation (EU) 2017/1018 of 29 June 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards specifying information to be notified by investment firms, market operators and credit institutions (OJ L 155, 17.6.2017, p. 1), as corrected by OJ L 292, 10.11.2017, p. 119.

31bazq. **32017 R 1093:** Commission Implementing Regulation (EU) 2017/1093 of 20 June 2017 laying down implementing technical standards with regard to the format of position reports by investment firms and market operators (OJ L 158, 21.6.2017, p. 16).

31bazr. **32017 R 1110:** Commission Implementing Regulation (EU) 2017/1110 of 22 June 2017 laying down implementing technical standards with regard to the standard forms, templates and procedures for the authorisation of data reporting services providers and related notifications pursuant to Directive 2014/65/EU of the European Parliament and of the Council on markets in financial instruments (OJ L 162, 23.6.2017, p. 3).

31bazs. **32017 R 1111:** Commission Implementing Regulation (EU) 2017/1111 of 22 June 2017 laying down implementing technical standards with regard to procedures and forms for submitting information on sanctions and measures in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 162, 23.6.2017, p. 14).

31bazt. **32017 R 1799:** Commission Delegated Regulation (EU) 2017/1799 of 12 June 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council as regards the exemption of certain third countries central banks in their performance of monetary, foreign exchange and financial stability policies from pre- and post-trade transparency requirements (OJ L 259, 7.10.2017, p. 11).

31bazu. **32017 R 1943:** Commission Delegated Regulation (EU) 2017/1943 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on information and requirements for the authorisation of investment firms (OJ L 276, 26.10.2017, p. 4).

31bazv. **32017 R 1944:** Commission Implementing Regulation (EU) 2017/1944 of 13 June 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the consultation process between relevant competent authorities in relation to the notification of a proposed acquisition of a qualifying holding in an investment firm in accordance with Directives 2004/39/EC and 2014/65/EU of the European Parliament and of the Council (OJ L 276, 26.10.2017, p. 12).

31bazw. **32017 R 1945:** Commission Implementing Regulation (EU) 2017/1945 of 19 June 2017 laying down implementing technical standards with regard to notifications by and to applicant and authorised investment firms according to Directive 2014/65/EU of the European Parliament and of the Council (OJ L 276, 26.10.2017, p. 22).

31bazx. **32017 R 1946:** Commission Delegated Regulation (EU) 2017/1946 of 11 July 2017 supplementing Directives 2004/39/EC and 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards for an exhaustive list of information to be included by proposed acquirers in the notification of a proposed acquisition of a qualifying holding in an investment firm (OJ L 276, 26.10.2017, p. 32).

31bazy. **32017 R 2154:** Commission Delegated Regulation (EU) 2017/2154 of 22 September 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to regulatory technical standards on indirect clearing arrangements (OJ L 304, 21.11.2017, p. 6).

31bazz. **32017 R 2194:** Commission Delegated Regulation (EU) 2017/2194 of 14 August 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to package orders (OJ L 312, 28.11.2017, p. 1).

31bazza. **32017 D 2238:** Commission Implementing Decision (EU) 2017/2238 of 5 December 2017 on the equivalence of the legal and supervisory framework applicable to designated contract markets and swap execution facilities in the United States of America in accordance with Regulation (EU) No 600/2014 of the European Parliament and of the Council (OJ L 320, 6.12.2017, p. 11).

31bazzb. **32017 D 2318:** Commission Implementing Decision (EU) 2017/2318 of 13 December 2017 on the equivalence of the legal and supervisory framework in Australia applicable to financial markets in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 331, 14.12.2017, p. 81).

31bazzc. **32017 D 2319:** Commission Implementing Decision (EU) 2017/2319 of 13 December 2017 on the equivalence of the legal and supervisory framework applicable to recognised exchange companies in Hong Kong Special Administrative Region in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 331, 14.12.2017, p. 87).

31bazzd. **32017 D 2320:** Commission Implementing Decision (EU) 2017/2320 of 13 December 2017 on the equivalence of the legal and supervisory framework of the United States of America for national securities exchanges and alternative trading systems in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 331, 14.12.2017, p. 94).

31bazze. **32017 R 2382:** Commission Implementing Regulation (EU) 2017/2382 of 14 December 2017 laying down implementing technical standards with regard to standard forms, templates and procedures for the transmission of information in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 340, 20.12.2017, p. 6), as corrected by OJ L 33, 7.2.2018, p. 5.

31bazzf. **32017 R 2417:** Commission Delegated Regulation (EU) 2017/2417 of 17 November 2017 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on the trading obligation for certain derivatives (OJ L 343, 22.12.2017, p. 48).

31bazzg. **32017 D 2441:** Commission Implementing Decision (EU) 2017/2441 of 21 December 2017 on the equivalence of the legal and supervisory framework applicable to stock exchanges in Switzerland in accordance with Directive 2014/65/EU of the European Parliament and of the Council (OJ L 344, 23.12.2017, p. 52).'

Article 2

The texts of Delegation Regulations (EU) 2016/2020, (EU) 2016/2021, (EU) 2016/2022, (EU) 2017/565, (EU) 2017/566, (EU) 2017/567, (EU) 2017/568, (EU) 2017/569, (EU) 2017/570, (EU) 2017/571, (EU) 2017/572, (EU) 2017/573, (EU) 2017/574, (EU) 2017/575, (EU) 2017/576, (EU) 2017/577, (EU) 2017/578, (EU) 2017/579, (EU) 2017/580, (EU) 2017/581, (EU) 2017/582, (EU) 2017/583, (EU) 2017/584, (EU) 2017/585, (EU) 2017/586, (EU) 2017/587, (EU) 2017/588, (EU) 2017/589, (EU) 2017/590, (EU) 2017/591, (EU) 2017/592, (EU) 2017/1018, (EU) 2017/1799, (EU) 2017/1943, (EU) 2017/1946, (EU) 2017/2154, (EU) 2017/2194, (EU) 2017/2417 and (EU) 2018/63, Implementing Regulations (EU) 2016/824, (EU) 2017/953, (EU) 2017/980, (EU) 2017/981, (EU) 2017/988, (EU) 2017/1005, (EU) 2017/1093, (EU) 2017/1110, (EU) 2017/1111, (EU) 2017/1944, (EU) 2017/1945 and (EU) 2017/2382, Delegated Directive (EU) 2017/593 and Implementing Decisions (EU) 2017/2238, (EU) 2017/2318, (EU) 2017/2319, (EU) 2017/2320 and (EU) 2017/2441 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 30 March 2019, or on the day of the entry into force of Decision of the EEA Joint Committee No 78/2019 of 29 March 2019 ([58]), whichever is the later, provided that all the notifications under Article 103 (1) of the EEA Agreement have been made (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 29 March 2019.

For the EEA Joint Committee
The President
Claude MAERTEN

([58]) See page 142 of this Official Journal.
(*) No constitutional requirements indicated.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN