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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) No 518/2014

of 5 March 2014

amending Commission Delegated Regulations (EU) No 1059/2010, (EU) No 1060/2010, (EU) No 1061/2010, (EU) No 1062/2010, (EU) No 626/2011, (EU) No 392/2012, (EU) No 874/2012, (EU) No 665/2013, (EU) No 811/2013 and (EU) No 812/2013 with regard to labelling of energy-related products on the internet

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products ([1]), and in particular Articles 7 and 10 thereof,

Whereas:

(1) Directive 2010/30/EU requires the Commission to lay down details relating to the labelling of energy-related products by means of delegated acts which contain measures that ensure that potential end-users are provided with the information specified on the label and in the product fiche in case of distance selling, including mail order, by catalogue, telemarketing or through the internet.

(2) Currently, it is specified that in the case of distance selling the information on the label is to be presented in a specific order. However, there is currently no requirement to display the label itself or the product fiche. Therefore, the ability of end-users to make better informed decisions about their purchases is affected in the case of distance selling because they are neither guided by the colour scale of the label, nor are they informed as to which energy labelling class is the best for the product group or provided with the additional information which is contained in the fiche.

(3) Distance selling through the internet is increasingly becoming a significant share of the sales of energy-related products. When selling through the internet, it is possible to display the label and the fiche without involving an additional administrative burden. Therefore, dealers should display the label and fiche when selling through the internet.

(4) For the label and fiche to be displayed on the internet, suppliers should for each model of an energy-related product provide dealers with an electronic version of the label and the fiche, e.g. through making them available on a website where they can be downloaded by dealers.

(5) In order to implement the requirements of this Regulation as part of normal business cycles, suppliers should be obliged to make the label and fiche available electronically only for new models, including upgrades of existing models, which in practical terms means those with a new model identifier. For existing models supply of an electronic label and fiche should be on a voluntary basis.

([1]) OJ L 153, 18.6.2010, p. 1.

(6) Since displaying the label and the fiche next to the product may require more screen space, it should be allowed to have them displayed using a nested display.

(7) Commission Delegated Regulations (EU) No 1059/2010 ([1]), (EU) No 1060/2010 ([2]), (EU) No 1061/2010 ([3]), (EU) No 1062/2010 ([4]), (EU) No 626/2011 ([5]), (EU) No 392/2012 ([6]), (EU) No 874/2012 ([7]), (EU) No 665/2013 ([8]), (EU) No 811/2013 ([9]), and (EU) No 812/2013 ([10]) should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) No 1059/2010

Delegated Regulation (EU) No 1059/2010 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex I is made available to dealers for each household dishwasher model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household dishwasher models;';

(b) the following point (g) is added:

'(g) an electronic product fiche as set out in Annex II is made available to dealers for each household dishwasher model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household dishwasher models.';

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

'(b) household dishwashers offered for sale, hire or hire- purchase where the end-user cannot be expected to see the household dishwasher displayed, are marketed with the information provided by suppliers in accordance with Annex IV. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(f) and 3(g) the provisions of Annex VIII shall apply instead;';

(3) a new Annex VIII is added in accordance with Annex I to this Regulation.

([1]) Commission Delegated Regulations (EU) No 1059/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household dishwashers (OJ L 314, 30.11.2010, p. 1).

([2]) Commission Delegated Regulation (EU) No 1060/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household refrigerating appliances (OJ L 314, 30.11.2010, p. 17).

([3]) Commission Delegated Regulation (EU) No 1061/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household washing machines (OJ L 314, 30.11.2010, p. 47).

([4]) Commission Delegated Regulation (EU) No 1062/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of televisions (OJ L 314, 30.11.2010, p. 64).

([5]) Commission Delegated Regulation (EU) No 626/2011 of 4 May 2011 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of air conditioners (OJ L 178, 6.7.2011, p. 1).

([6]) Commission Delegated Regulation (EU) No 392/2012 of 1 March 2012 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household tumble driers (OJ L 123, 9.5.2012, p. 1).

([7]) Commission Delegated Regulation (EU) No 874/2012 of 12 July 2012 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of electrical lamps and luminaires (OJ L 258, 26.9.2012, p. 1).

([8]) Commission Delegated Regulation (EU) No 665/2013 of 3 May 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of vacuum cleaners (OJ L 192, 13.7.2013, p. 1).

([9]) Commission Delegated Regulation (EU) No 811/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device (OJ L 239, 6.9.2013, p. 1).

([10]) Commission Delegated Regulation (EU) No 812/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of water heaters, hot water storage tanks and packages of water heater and solar device (OJ L 239, 6.9.2013, p. 83).

Article 2

Amendments to Delegated Regulation (EU) No 1060/2010

Delegated Regulation (EU) No 1060/2010 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex II is made available to dealers for each household refrigerating appliance model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household refrigerating appliance models;';

(b) the following point (g) is added:

'(g) an electronic product fiche as set out in Annex III is made available to dealers for each household refrigerating appliance model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household refrigerating appliance models.';

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

'(b) household refrigerating appliances offered for sale, hire or hire purchase where the end-user cannot be expected to see the product displayed, are marketed with the information to be provided by the suppliers in accordance with Annex V. Where the offer for is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(f) and 3(g) the provisions of Annex X shall apply instead;';

(3) a new Annex X is added in accordance with Annex II to this Regulation.

Article 3

Amendments to Delegated Regulation (EU) No 1061/2010

Delegated Regulation (EU) No 1061/2010 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex I is made available to dealers for each household washing machine model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household washing machine models;';

(b) the following point (g) is added:

'(g) an electronic product fiche as set out in Annex II is made available to dealers for each household washing machine model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household washing machine models.';

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

'(b) household washing machines offered for sale, hire or hire-purchase where the end-user cannot be expected to see the product displayed are marketed with the information to be provided by suppliers in accordance with Annex IV. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(f) and 3(g) the provisions of Annex VIII shall apply instead;';

(3) a new Annex VIII is added in accordance with Annex III to this Regulation.

Article 4

Amendments to Delegated Regulation (EU) No 1062/2010

Delegated Regulation (EU) No 1062/2010 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex V is made available to dealers for each television model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other television models;';

(b) in paragraph 1, the following point (g) is added:

'(g) an electronic product fiche as set out in Annex III is made available to dealers for each television model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other television models.';

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

'(b) televisions offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the television displayed, are marketed with the information to be provided by the suppliers in accordance with Annex VI. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(1)(f) and 3(1)(g) the provisions in Annex IX shall apply instead;';

(3) a new Annex IX is added in accordance with Annex IV to this Regulation.

Article 5

Amendments to Delegated Regulation (EU) No 626/2011

Delegated Regulation (EU) No 626/2011 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (h) is added:

'(h) an electronic label in the format and containing the information set out in Annex III is made available to dealers for each air conditioner model placed on the market from 1 January 2015 with a new model identifier, respecting energy efficiency classes set out in Annex II. It may also be made available to dealers for other air conditioner models;';

(b) in paragraph 1, the following point (i) is added:

'(i) an electronic product fiche as set out in Annex IV is made available to dealers for each air conditioner model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other air conditioner models.';

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

'(b) air conditioners offered for sale, hire or hire purchase where the end-user cannot be expected to see the product displayed, are marketed with the information provided by suppliers in accordance with Annexes IV and VI. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(1)(h) and 3(1)(i) the provisions of Annex IX shall apply instead;';

(3) a new Annex IX is added in accordance with Annex V to this Regulation.

Article 6

Amendments to Delegated Regulation (EU) No 392/2012

Delegated Regulation (EU) No 392/2012 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex I is made available to dealers for each household tumble drier model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household tumble drier models;';

(b) the following point (g) is added:

'(g) an electronic product fiche as set out in Annex II is made available to dealers for each household tumble drier model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other household tumble drier models.';

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

'(b) household tumble driers offered for sale, hire or hire-purchase where the end-user cannot be expected to see the product displayed, as specified in Article 7 of Directive 2010/30/EU, are marketed with the information provided by suppliers in accordance with Annex IV to this Regulation. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(f) and 3(g) the provisions of Annex VIII shall apply instead;';

(3) a new Annex VIII is added in accordance with Annex VI to this Regulation.

Article 7

Amendments to Delegated Regulation (EU) No 874/2012

Delegated Regulation (EU) No 874/2012 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in point 1 of Annex I is made available to dealers for each lamp model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other lamp models.';

(b) in paragraph 2, the following point (e) is added:

'(e) an electronic label in the format and containing information set out in point 2 of Annex I is made available to dealers for each luminaire model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other luminaire models.';

(2) Article 4 is amended as follows:

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

'(a) each model offered for sale, hire or hire-purchase where the final owner cannot be expected to see the product displayed is marketed with the information to be provided by suppliers in accordance with Annex IV. Where the offer is made through the internet and an electronic label has been made available in accordance with Article 3(1)(f) the provisions in Annex VIII shall apply instead;';

(b) in paragraph 2, the following point (d) is added:

'(d) each model offered for sale, hire or hire-purchase through the internet and for which an electronic label has been made available in accordance with Article 3(2)(e) is accompanied by the label in accordance with Annex VIII.';

(3) a new Annex VIII is added in accordance with Annex VII to this Regulation.

Article 8

Amendments to Delegated Regulation (EU) No 665/2013

Delegated Regulation (EU) No 665/2013 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in Annex II is made available to dealers for each vacuum cleaner model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other vacuum cleaner models;';

(b) in paragraph 1, the following point (g) is added:

'(g) an electronic product fiche as set out in Annex III is made available to dealers for each vacuum cleaner model placed on the market from 1 January 2015 with a new model identifier. It may also be made available to dealers for other vacuum cleaner models.';

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

'(b) vacuum cleaners offered for sale, hire or hire-purchase where the end-user cannot be expected to see the product displayed, as specified in Article 7 of Directive 2010/30/EU, are marketed with the information provided by suppliers in accordance with Annex V to this Regulation. Where the offer is made through the internet and an electronic label and an electronic product fiche have been made available in accordance with Article 3(1)(f) and 3(1)(g) the provisions in Annex VIII shall apply instead;';

(3) a new Annex VIII is added in accordance with Annex VIII to this Regulation.

Article 9

Amendments to Delegated Regulation (EU) No 811/2013

Delegated Regulation (EU) No 811/2013 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (f) is added in the first subparagraph:

'(f) an electronic label in the format and containing the information set out in point 1.1 of Annex III is made available to dealers for each space heater model conforming to the seasonal space heating energy efficiency classes set out in point 1 of Annex II;';

(b) in paragraph 1, the following point (g) is added in the first subparagraph:

'(g) an electronic product fiche as set out in point 1 of Annex IV is made available to dealers for each space heater model, whereby for heat pump space heaters models, the electronic product fiche is made available to dealers at least for the heat generator.';

(c) in paragraph 1, the following subparagraph is added:

'From 26 September 2019 an electronic label in the format and containing the information set out in point 1.2 of Annex III shall be made available to dealers for each space heater model conforming to the seasonal space heating energy efficiency classes set out in point 1 of Annex II.';

(d) in paragraph 2, the following point (f) is added in the first subparagraph:

'(f) an electronic label in the format and containing the information set out in point 2.1 of Annex III is made available to dealers for each combination heater model conforming to the seasonal space heating energy efficiency classes and water heating energy efficiency classes set out in points 1 and 2 of Annex II;';

(e) in paragraph 2, the following point (g) is added in the first subparagraph:

'(g) an electronic product fiche as set out in point 2 of Annex IV is made available to dealers for each combination heater model, whereby for heat pump combination heaters models, the electronic product fiche is made available to dealers at least for the heat generator.';

(f) in paragraph 2, the following subparagraph is added:

'From 26 September 2019 an electronic label in the format and containing the information set out in point 2.2 of Annex III shall be made available to dealers for each combination heater model conforming to the seasonal space heating energy efficiency classes and water heating energy efficiency classes set out in points 1 and 2 of Annex II.';

(g) in paragraph 3, the following point (c) is added:

'(c) an electronic product fiche, as set out in point 3 of Annex IV, is made available to dealers for each temperature control model.';

(h) in paragraph 4, the following point (c) is added:

'(c) an electronic product fiche, as set out in point 4 of Annex IV, is made available to dealers for each solar device model.';

(i) in paragraph 5, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in point 3 of Annex III is made available to dealers for each model comprising a package of space heater, temperature control and solar device conforming to the seasonal space heating energy efficiency classes set out in point 1 of Annex II;';

(j) in paragraph 5, the following point (g) is added:

'(g) an electronic product fiche as set out in point 5 of Annex IV is made available to dealers for each model comprising a package of space heater, temperature control and solar device.';

(k) in paragraph 6, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in point 4 of Annex III is made available to dealers for each model comprising a package of combination heater, temperature control and solar device conforming to the seasonal space heating energy efficiency classes and water heating energy efficiency classes set out in points 1 and 2 of Annex II;';

(l) in paragraph 6, the following point (g) is added:

'(g) an electronic product fiche as set out in point 6 of Annex IV is made available to dealers for each model comprising a package of combination heater, temperature control and solar device.';

(2) Article 4 is amended as follows:

(a) in paragraph 1, point (b) is replaced by the following:

'(b) space heaters offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the space heater displayed, are marketed with the information provided by the suppliers in accordance with point 1 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex IX shall apply;';

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

'(b) combination heaters offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the combination heater displayed, are marketed with the information provided by the suppliers in accordance with point 2 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex IX shall apply;';

(c) in paragraph 3, point (b) is replaced by the following:

'(b) packages of space heater, temperature control and solar device offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the package of space heater, temperature control and solar device displayed, are marketed with the information provided in accordance with point 3 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex IX shall apply;';

(d) in paragraph 4, point (b) is replaced by the following:

'(b) packages of combination heater, temperature control and solar device offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the package of combination heater, temperature control and solar device displayed, are marketed with the information provided in accordance with point 4 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex IX shall apply;';

(3) Annex VI is amended in accordance with Annex IX to this Regulation;

(4) a new Annex IX is added in accordance with Annex IX to this Regulation.

Article 10

Amendments to Delegated Regulation (EU) No 812/2013

Delegated Regulation (EU) No 812/2013 is amended as follows:

(1) Article 3 is amended as follows:

(a) in paragraph 1, the following point (f) is added in the first subparagraph:

'(f) an electronic label in the format and containing the information set out in point 1.1 of Annex III is made available to dealers for each water heater model conforming to the water heating energy efficiency classes set out in point 1 of Annex II;';

(b) in paragraph 1, the following point (g) is added in the first subparagraph:

'(g) an electronic product fiche as set out in point 1 of Annex IV is made available to dealers for each water heater model, whereby for heat pump water heaters models, the electronic product fiche is made available to dealers at least for the heat generator.';

(c) in paragraph 1, the following subparagraph is added:

'From 26 September 2017 an electronic label in the format and containing the information set out in point 1.2 of Annex III shall be made available to dealers for each water heater model conforming to the water heating energy efficiency classes set out in point 1 of Annex II.';

(d) in paragraph 2, the following point (f) is added in the first subparagraph:

'(f) an electronic label in the format and containing the information set out in point 2.1 of Annex III is made available to dealers for each hot water storage tank model in accordance with the energy efficiency classes set out in point 2 of Annex II;';

(e) in paragraph 2, the following point (g) is added in the first subparagraph:

'(g) an electronic product fiche as set out in point 2 of Annex IV is made available to dealers for each hot water storage tank model.';

(f) in paragraph 2, the following subparagraph is added:

'From 26 September 2017 an electronic label in the format and containing the information set out in point 2.2 of Annex III shall be made available to dealers for each hot water storage tank model, in accordance with the energy efficiency classes set out in point 2 of Annex II.';

(g) in paragraph 3, the following point (c) is added:

'(c) an electronic product fiche, as set out in point 3 of Annex IV, is made available to dealers for each solar device model.';

(h) in paragraph 4, the following point (f) is added:

'(f) an electronic label in the format and containing the information set out in point 3 of Annex III is made available to dealers for each model comprising a package of water heater and solar device, in accordance with the water heating energy efficiency classes set out in point 1 of Annex II;';

(i) in paragraph 4, the following point (g) is added:

'(g) an electronic product fiche as set out in point 4 of Annex IV is made available to dealers for each model comprising a package of water heater and solar device.';

(2) Article 4 is amended as follows:

(a) in paragraph 1, point (b) is replaced by the following:

'(b) water heaters offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the water heater displayed, are marketed with the information provided by the suppliers in accordance with point 1 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex X shall apply;';

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

'(b) hot water storage tanks offered for sale, hire or hire-purchase, where the end user cannot be expected to see the hot water storage tank displayed, are marketed with the information provided by the suppliers in accordance with point 2 of Annex VI; except where the offer is made through the internet in which case the provisions in Annex X shall apply;';

(c) in paragraph 3, point (b) is replaced by the following:

'(b) packages of water heater and solar device offered for sale, hire or hire purchase, where the end-user cannot be expected to see the package of water heater and solar device displayed, are marketed with the information provided in accordance with point 3 of Annex VI, except where the offer is made through the internet, in which case the provisions in Annex X shall apply;';

(3) Annex VI is amended in accordance with Annex X to this Regulation;

(4) A new Annex X is added in accordance with Annex X to this Regulation.

Article 11

Entry into force

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, 5 March 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Amendments to the Annexes to Delegated Regulation (EU) No 1059/2010

The following Annex VIII is added:

'ANNEX VIII

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screenf" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(f) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 2 of Annex I. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX II

Amendments to the Annexes to Delegated Regulation (EU) No 1060/2010

The following Annex X is added:

'ANNEX X

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smart-phone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(f) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 3 of Annex II. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX III

Amendments to the Annexes to Delegated Regulation (EU) No 1061/2010

The following Annex VIII is added:

'ANNEX VIII

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(f) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 2 of Annex I. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX IV

Amendments to the Annexes to Delegated Regulation (EU) No 1062/2010

The following Annex IX is added:

'ANNEX IX

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smart-phone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(1)(f) shall be shown on the display mechanism in proximity to the price of the product in accordance with the timetable set out in Article 3(3). The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 5 of Annex V. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(1)(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX V

Amendments to the Annexes to Delegated Regulation (EU) No 626/2011

The following Annex IX is added:

'ANNEX IX

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(1)(h) shall be shown on the display mechanism in proximity to the price of the product in accordance with the timetable set out in Article 3(4) to 3(6). The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in Annex III. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(1)(i) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX VI

Amendments to the Annexes to Delegated Regulation (EU) No 392/2012

The following Annex VIII is added:

'ANNEX VIII

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smart-phone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(f) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 4 of Annex I. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX VII

Amendments to the Annexes to Delegated Regulation (EU) No 874/2012

The following Annex VIII is added:

'ANNEX VIII

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 4 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

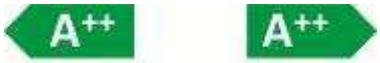
(2) The appropriate label made available by suppliers in accordance with Article 3(1)(f) or Article 3(2)(e) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in Annex I. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:



(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.'

ANNEX VIII

Amendments to the Annexes to Delegated Regulation (EU) No 665/2013

The following Annex VII is added:

'ANNEX VII

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3(1)(f) shall be shown on the display mechanism in proximity to the price of the product in accordance with the timetable set out in Article 3(2). The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in point 3 of Annex II. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

(b) indicate on the arrow the energy efficiency class of the product in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3(1)(g) shall be shown on the display mechanism in proximity to the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX IX

Amendments to the Annexes to Delegated Regulation (EU) No 811/2013

(a) In Annex VI the title is replaced by the following:

'Information to be provided in the cases where end-users cannot be expected to see the product displayed, except on the internet'

(b) The following Annex IX is added:

'ANNEX IX

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smartphone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3 or in the case of a package where appropriate duly filled in based on the label and fiches provided by suppliers in accordance with Article 3, shall be shown on the display mechanism in proximity to the price of the product or package in accordance with the timetable set out in Article 3. If both a product and a package are shown, but with a price indicated only for the package, only the package label shall be displayed. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in Annex III. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product or package on the label;

(b) indicate on the arrow the energy efficiency class of the product or package in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product or package;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product or package in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3 shall be shown on the display mechanism in proximity to the price of the product or package. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

ANNEX X

Amendments to the Annexes to Delegated Regulation (EU) No 812/2013

(a) In Annex VI the title is replaced by the following:

'Information to be provided in the cases where end-users cannot be expected to see the product displayed, except on the internet'

(b) The following Annex X is added:

'ANNEX X

Information to be provided in the case of sale, hire or hire-purchase through the internet

(1) For the purpose of points 2 to 5 of this Annex the following definitions shall apply:

(a) "display mechanism" means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

(b) "nested display" means visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

(c) "tactile screen" means a screen responding to touch, such as that of a tablet computer, slate computer or a smart-phone;

(d) "alternative text" means text provided as an alternative to a graphic allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

(2) The appropriate label made available by suppliers in accordance with Article 3 or in the case of a package where appropriate duly filled in based on the label and fiches provided by suppliers in accordance with Article 3, shall be shown on the display mechanism in proximity to the price of the product or package in accordance with the time-table set out in Article 3. If both a product and a package are shown, but with a price indicated only for the package, only the package label shall be displayed. The size shall be such that the label is clearly visible and legible and shall be proportionate to the size specified in Annex III. The label may be displayed using a nested display, in which case the image used for accessing the label shall comply with the specifications laid down in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

(3) The image used for accessing the label in the case of nested display shall:

(a) be an arrow in the colour corresponding to the energy efficiency class of the product or package on the label;

(b) indicate on the arrow the energy efficiency class of the product or package in white in a font size equivalent to that of the price; and

(c) have one of the following two formats:

(4) In the case of nested display, the sequence of display of the label shall be as follows:

(a) the image referred to in point 3 of this Annex shall be shown on the display mechanism in proximity to the price of the product or package;

(b) the image shall link to the label;

(c) the label shall be displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

(d) the label shall be displayed by pop up, new tab, new page or inset screen display;

(e) for magnification of the label on tactile screens, the device conventions for tactile magnification shall apply;

(f) the label shall cease to be displayed by means of a close option or other standard closing mechanism;

(g) the alternative text for the graphic, to be displayed on failure to display the label, shall be the energy efficiency class of the product or package in a font size equivalent to that of the price.

(5) The appropriate product fiche made available by suppliers in accordance with Article 3 shall be shown on the display mechanism in proximity to the price of the product or package. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing the fiche shall clearly and legibly indicate "Product fiche". If nested display is used, the product fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.'

COMMISSION REGULATION (EU) No 519/2014

of 16 May 2014

amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([1]), in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 ([2]) provides for maximum limits for certain mycotoxins in certain foodstuffs.

(2) Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are heterogeneously distributed in a lot. It is therefore necessary to set out criteria which the sampling methods should fulfil.

(3) Commission Regulation (EC) No 401/2006 ([3]) establishes the criteria for the sampling for the control of the levels of mycotoxins.

(4) It is necessary to amend the rules concerning the sampling of spices in order to take into account the differences in particle size which leads to the heterogeneous distribution of mycotoxin contamination in spices. Furthermore it is appropriate to establish rules for the sampling of large lots in order to ensure a uniform enforcement approach across the Union. It is also appropriate to clarify which method of sampling has to be applied for the sampling of apple juice.

(5) The performance criteria for T-2 and HT-2 toxin need to be updated in order to take into account scientific and technological progress. Performance criteria for citrinin need to be established given the maximum level established for citrinin in food supplements based on rice fermented with the red yeast *Monascus purpureus*.

(6) For the analysis of mycotoxins, screening methodologies are used more and more. It is appropriate to establish criteria with which the screening methods have to comply with for use for regulatory purposes.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 401/2006 is amended as follows:

(1) Annex I is amended as follows:

(a) In part B, footnote (1) is replaced by the following:

'(1) The sampling of such lots shall be performed in accordance with the rules set out in part L. Guidance for sampling large lots shall be provided in a guidance document available on the following website: http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-sampling-final.pdf

([1]) OJ L 165, 30.4.2004, p. 1.
([2]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).
([3]) Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

The application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in part L.

For the sampling of lots for *Fusarium*-toxins, the application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in part B;'

(b) In part B.2, Table 1 is replaced by the following table:

'Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample Weight (kg)
Cereals and cereal products	> 300 and < 1 500	3 sublots	100	10
	≥ 50 and ≤ 300	100 tonnes	100	10
	< 50	—	3-100 (*)	1-10

(*) Depending on the lot weight — see Table 2.'

(c) In part B.3, the following sentence is added at the end of the first indent:

'For lots > 500 tonnes, the number of incremental samples is provided for in part L.2 of Annex I.'

(d) In part D.2 the following sentence is added after the first sentence:

'This method of sampling is of also of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices with a relatively large particle size (particle size comparable with peanuts or larger e.g. nutmeg).';

(e) In part E, the first sentence is replaced by the following:

'This method of sampling is of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices except in cases of spices with a relatively large particle size (heterogeneous distribution of mycotoxin contamination).';

(f) In part I, the heading and the first sentence are replaced by the following:

'I. METHOD OF SAMPLING FOR SOLID APPLE PRODUCTS

This method of sampling is of application for the official control of the maximum levels established for patulin in solid apple products, including solid apple products for infants and young children.'

(g) In part I.1, second paragraph, the following sentences are deleted:

'In case of liquid products the lot shall be thoroughly mixed insofar as possible by either manual or mechanical means immediately prior to sampling. In this case, a homogenous distribution of patulin can be assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.'

(h) New Parts L and M as set out in Annex I to this Regulation, are added.

(2) In Annex II, points 4.2 'General requirements', 4.3 'Specific requirements' and 4.4 'Estimation of measurement uncertainty, recovery calculation and reporting of results' are replaced by the text set out in Annex II to this Regulation.

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 July 2014.

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

Done at Brussels, 16 May 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

'L. METHOD OF SAMPLING FOR VERY LARGE LOTS OR LOTS STORED OR TRANSPORTED IN A WAY WHEREBY SAMPLING THROUGHOUT THE LOT IS NOT FEASIBLE

L.1. **General principles**

In case the way of transport or storage of a lot does not enable to take incremental samples throughout the whole lot, sampling of such lots should preferably be done when the lot is in flow (dynamic sampling).

In the case of large warehouses destined to store food, operators should be encouraged to install equipment in the warehouse enabling (automatic) sampling across the whole stored lot.

When the sampling procedures as provided for in this part L are applied, the food business operator or his representative should be informed of the sampling procedure. If the sampling procedure is questioned by the food business operator or his representative, the food business operator or his representative shall enable the competent authority to sample throughout the whole lot at his/her own cost.

Sampling of a part of the lot is allowed, on the condition that the quantity of the sampled part is at least 10 % of the lot to be sampled. If a part of a lot of food of the same class or description has been sampled and identified as not satisfying Union requirements, it shall be presumed that the entire lot is also affected, unless further detailed assessment shows no evidence that the rest of the lot is unsatisfactory.

The relevant provisions, such as weight of the incremental sample, provided for in the other parts of this Annex are applicable for the sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible.

L.2. **Number of incremental samples to be taken in the case of very large lots**

In the case of large sampled portions (sampled portions > 500 tonnes), the number of incremental samples to be taken = 100 incremental samples + √tonnes. However in case the lot is less than 1 500 tonnes and can be subdivided into sublots in accordance with the table 1 of part B and on the condition that the sublots can be separated physically, the number of incremental samples as provided for in part B have to be taken.

L.3. **Large lots transported by ship**

L.3.1. *Dynamic sampling of large lots transported by ship*

The sampling of large lots in ships is preferably carried out while the product is in flow (dynamic sampling).

The sampling is to be done per hold (entity that can physically be separated). Holds are however emptied partly one after the other so that the initial physical separation no longer exists after transfer into storage facilities. Sampling can therefore be performed based on initial physical separation or based on the separation after transfer into the storage facilities.

The unloading of a ship can last for several days. Normally, sampling has to be performed at regular intervals during the whole duration of unloading. It is however not always feasible or appropriate for an official inspector to be present for sampling during the whole operation of unloading. Therefore sampling of part of the lot is allowed to be undertaken (sampled portion). The number of incremental samples is determined by taking into account the size of the sampled portion.

Even if the official sample is taken automatically, the presence of an inspector is necessary. However if the automatic sampling is done with pre-set parameters which cannot be changed during the sampling and the incremental samples are collected in a sealed receptacle, preventing any possible fraud, then the presence of an inspector is only required at the beginning of the sampling, every time the receptacle of the samples needs to be changed and at the end of the sampling.

L.3.2. *Sampling of lots transported by ship by static sampling*

In cases where the sampling is done in a static way the same procedure as foreseen for storage facilities (silos) accessible from above has to be applied (see point L.5.1).

The sampling has to be performed on the accessible part (from above) of the lot/hold. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.4. **Sampling of large lots stored in warehouses**

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.5. **Sampling of storage facilities (silos)**

L.5.1. *Sampling of silos (easily) accessible from above*

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.5.2. *Sampling of silos not accessible from above (closed silos)*

L.5.2.1. Silos not accessible from above (closed silos) with individual sizes > 100 tonnes

Food stored in such silos cannot be sampled in a static way. Therefore when the food in the silo has to be sampled and there is no possibility to move the consignment, the agreement has to be made with the operator that he or she has to inform the inspector about when the silo will be unloaded, partially or completely, in order to enable sampling when the food is in flow.

L.5.2.2. Silos not accessible from above (closed silos) with individual sizes < 100 tonnes

Contrary to the provision in part point L.1 (sampled part at least 10 %), the sampling procedure involves the release into a receptacle of a quantity of 50 to 100 kg and taking the sample from it. The size of the aggregate sample corresponds to the whole lot and the number of incremental samples relate to the quantity of the food from the silo released into the receptacle for sampling.

L.6. **Sampling of loose food in large closed containers**

Such lots can often only be sampled when unloaded. In certain cases it is not possible to unload at the point of import or control and therefore the sampling should take place when such containers are unloaded. The operator has to inform the inspector about the place and time of unloading the containers.

M. METHOD OF SAMPLING OF FOOD SUPPLEMENTS BASED ON RICE FERMENTED WITH RED YEAST *MONASCUS PURPUREUS*

This method of sampling is applicable to the official control of the maximum level established for citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus*.

Sampling procedure and sample size

The sampling procedure is on the supposition that the food supplements based on rice fermented with red yeast *Monascus purpureus* are marketed in retail packages containing usually 30 to 120 capsules per retail package.

Lot size (number of retail packages)	Number of retail packages to be taken for sample	Sample size
1-50	1	All capsules
51-250	2	All capsules
251-1 000	4	From each retail package taken for sample, half of the capsules
> 1 000	4 + 1 retail package per 1 000 retail packages with a maximum of 25 retail packages	≤ 10 retail packages: from each retail package, half of the capsules > 10 retail packages: from each retail package, an equal number of capsules is taken to result in a sample with the equivalent of the content of retail 5 packages'

ANNEX II

'4.2. **General requirements**

Confirmatory methods of analysis used for food control purposes shall comply with the provisions of items 1 and 2 of Annex III to Regulation (EC) No 882/2004.

4.3. **Specific requirements**

4.3.1. *Specific requirements for confirmatory methods*

4.3.1.1. Performance criteria

It is recommended that fully validated confirmatory methods (i.e. methods validated by collaborative trials for relevant matrices) are used where appropriate and available. Other suitable validated confirmatory methods (e.g. methods validated in-house on relevant matrices belonging to the commodity group of interest) may also be used provided they fulfil the performance criteria set out in the following tables.

Where possible, the validation of in-house validated methods shall include a certified reference material.

(a) Performance criteria for aflatoxins

Criterion	Concentration Range	Recommended Value	Maximum permitted Value
Blanks	All	Negligible	—
Recovery — Aflatoxin M1	0,01-0,05 mg/kg	60 to 120 %	
	> 0,05 mg/kg	70 to 110 %	
Recovery-Aflatoxins B_1, B_2, G_1, G_2	< 1,0 mg/kg	50 to 120 %	
	1-10 mg/kg	70 to 110 %	
	> 10 mg/kg	80 to 110 %	
Reproducibility RSD_R	All	As derived from Horwitz Equation (*)(**)	2 × value derived from Horwitz Equation (*)(**)
Repeatability RSD_r may be calculated as 0,66 times Reproducibility RSD_R at the concentration of interest.			

Note:

— Values to apply to both B_1 and sum of $B_1 + B_2 + G_1 + G_2$

— If sum of individual aflatoxins $B_1 + B_2 + G_1 + G_2$ are to be reported, then response of each to the analytical system must be either known or equivalent.

(b) Performance criteria for ochratoxin A

Level µg/kg	Ochratoxin A		
	RSD_r %	RSD_R %	Recovery %
< 1	≤ 40	≤ 60	50 to 120
≥ 1	≤ 20	≤ 30	70 to 110

(c) Performance criteria for patulin

Level µg/kg	Patulin		
	RSD_r %	RSD_R %	Recovery %
< 20	≤ 30	≤ 40	50 to 120
20-50	≤ 20	≤ 30	70 to 105
> 50	≤ 15	≤ 25	75 to 105

(d) Performance criteria for deoxynivalenol

Level µg/kg	Deoxynivalenol		
	RSD_r %	RSD_R %	Recovery %
> 100-≤ 500	≤ 20	≤ 40	60 to 110
> 500	≤ 20	≤ 40	70 to 120

(e) Performance criteria for zearalenone

Level µg/kg	Zearalenone		
	RSD_r %	RSD_R %	Recovery %
≤ 50	≤ 40	≤ 50	60 to 120
> 50	≤ 25	≤ 40	70 to 120

(f) Performance criteria for Fumonisin B_1 and B_2 individually

Level µg/kg	Fumonisin B_1 and B_2 individually		
	RSD_r %	RSD_R %	Recovery %
≤ 500	≤ 30	≤ 60	60 to 120
> 500	≤ 20	≤ 30	70 to 110

(g) Performance criteria for T-2 and HT-2 toxin individually

Level µg/kg	T-2 and HT-2 toxin individually		
	RSD_r %	RSD_R %	Recovery %
15-250	≤ 30	≤ 50	60 to 130
> 250	≤ 25	≤ 40	60 to 130

(h) Performance criteria for citrinin

Level µg/kg	Citrinin			
	RSD_r %	Recommended RSD_R %	Maximum allowed RSD_R %	Recovery %
All	0,66 × RSD_R	As derived from Horwitz Equation (*)(**)	2 × value derived from Horwitz Equation (*)(**)	70 to 120

(i) Notes to the performance criteria for the mycotoxins:

— The detection limits of the methods used are not stated as the precision values given at the concentrations of interest.

— The precision values are calculated from the Horwitz equation, in particular the original Horwitz equation (for concentrations $1{,}2 \times 10^{-7} \leq C \leq 0{,}138$) (*) and the modified Horwitz equation (for concentrations $C < 1{,}2 \times 10^{-7}$) (**).

(*) Horwitz equation for concentrations $1{,}2 \times 10^{-7} \leq C \leq 0{,}138$:

$RSD_R = 2^{(1-0.5\log C)}$

(ref: *W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,1980, 63, 1344)*

(**) Modified Horwitz equation (*) for concentrations $C < 1{,}2 \times 10^{-7}$:

$RSD_R = 22\ \%$

(ref: *M. Thompson, Analyst, 2000, 125, p. 385-386)*

Where:

— RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [(sR/) × 100]

— C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 mg/kg)

This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

4.3.1.2. "Fitness-for-purpose" approach

For in-house validated methods, as an alternative, a "fitness-for-purpose" approach (***) may be used to assess their suitability for official control. Methods suitable for official control must produce results with a standard measurement uncertainty (u) less than the maximum standard measurement uncertainty calculated using the formula below:

$$Uf = \sqrt{(\mathrm{LOD}/2)^2 + (\alpha \times C)^2}$$

where:

— *Uf* is the maximum standard measurement uncertainty (µg/kg)

— LOD is the limit of detection of the method (µg/kg)

— α is a constant, numeric factor to be used depending on the value of C. The values to be used are set out in Table hereafter.

— C is the concentration of interest (µg/kg)

If the analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method shall be considered being equally suitable to one which meets the performance criteria given in point 4.3.1.1.

Table

Numeric values to be used for α as constant in formula set out in this point, depending on the concentration of interest

C (µg/kg)	α
≤ 50	0,2
51-500	0,18
501-1 000	0,15
1 001-10 000	0,12
> 10 000	0,1

(***) Ref: *M. Thompson and R. Wood, Accred. Qual. Assur., 2006, 10, p. 471-478.*

4.3.2. *Specific requirements for semi-quantitative screening methods*

4.3.2.1. Scope

The scope applies to bioanalytical methods based on immuno-recognition or receptor binding (such as ELISA, dip-sticks, lateral flow devices, immuno-sensors) and physicochemical methods based on chromatography or direct detection by mass spectrometry (e.g. ambient MS). Other methods (e.g. thin layer chromatography) are not excluded provided the signals generated relate directly to the mycotoxins of interest and allow that the principle described hereunder is applicable.

The specific requirements apply to methods of which the result of the measurement is a numerical value, for example a (relative) response from a dip-stick reader, a signal from LC-MS, etc., and that normal statistics apply.

The requirements do not apply to methods that do not give numerical values (e.g. only a line that is present or absent), which require different validation approaches. Specific requirements for these methods are provided in point 4.3.3.

This document describes procedures for the validation of screening methods by means of an inter-laboratory validation, the verification of the performance of a method validated by means of an inter-laboratory exercise and the single-laboratory validation of a screening method.

4.3.2.2. Terminology

Screening target concentration (STC): the concentration of interest for detection of the mycotoxin in a sample. When the aim is to test compliance with regulatory limits, the STC is equal to the applicable maximum level. For other purposes or in case no maximum level has been established, the STC is predefined by the laboratory.

Screening method: means method used for selection of those samples with levels of mycotoxins that exceed the screening target concentration (STC), with a given certainty. For the purpose of mycotoxin screening, a certainty of 95 % is considered fit-for-purpose. The result of the screening analysis is either "negative" or "suspect". Screening methods shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks to consumers. These methods shall be based on bio-analytical, LC-MS or HPLC methods. Results from samples exceeding the cut-off value shall be verified by a full re-analysis from the original sample by a confirmatory method.

"Negative sample" means the mycotoxin content in the sample is < STC with a certainty of 95 % (i.e. there is a 5 % chance that samples will be incorrectly reported as negative).

"False negative sample" means the mycotoxin content in the sample is > STC but it has been identified as negative.

"Suspect sample" (screen positive) means the sample exceeds the cut-off level (see below) and may contain the mycotoxin at a level higher than the STC. Any suspect result triggers a confirmatory analysis for unambiguous identification and quantification of the mycotoxin.

"False suspect sample" is a negative sample that has been identified as suspect.

"Confirmatory methods" means methods that provide full or complementary information enabling the mycotoxin to be identified and quantified unequivocally at the level of interest.

Cut-off level: the response, signal, or concentration, obtained with the screening method, above which the sample is classified as "suspect". The cut-off is determined during the validation and takes the variability of the measurement into account.

Negative control (blank matrix) sample: a sample known to be free ([1]) of the mycotoxin to be screened for, e.g. by previous determination using a confirmatory method of sufficient sensitivity. If no blank samples can be obtained, then material with the lowest obtainable level might be used as long as the level allows the conclusion that the screening method is fit for purpose.

Positive control sample: sample containing the mycotoxin at the screening target concentration, e.g. a certified reference material, a material of known content (e.g. test material of proficiency tests) or otherwise sufficiently characterised by a confirmatory method. In the absence of any of the above, a blend of samples with different levels of contamination or a spiked sample prepared within laboratory and sufficiently characterised can be used, provided it can be proven that the contamination level has been verified.

4.3.2.3. Validation procedure

The aim of the validation is to demonstrate the fitness of purpose of the screening method. This is done by determination of the cut-off value and determination of the false negative and false suspect rate. In these two parameters performance characteristics such as sensitivity, selectivity, and precision are embedded.

Screening methods can be validated by inter-laboratory or by single laboratory validation. If inter-laboratory validation data is already available for a certain mycotoxin/matrix/STC combination, a verification of method performance is sufficient in a laboratory implementing the method.

4.3.2.3.1. Initial validation by single laboratory validation

Mycotoxins:

The validation shall be performed for every individual mycotoxin in the scope. In case of bio-analytical methods that give a combined response for a certain mycotoxin group (e.g. aflatoxins B_1, B_2, G_1 & G_2; fumonisins B_1 & B_2), applicability must be demonstrated and limitations of the test mentioned in the scope of the method. Undesired cross-reactivity (e.g. DON-3-glycoside, 3- or 15-acetyl-DON for immuno-based methods for DON) is not considered to increase the false negative rate of the target mycotoxins, but may increase the false suspect rate. This unwanted increasing will be diminished by confirmatory analysis for unambiguous identification and quantification of the mycotoxins.

Matrices:

An initial validation should be performed for each commodity, or, when the method is known to be applicable to multiple commodities, for each commodity group. In the latter case, one representative and relevant commodity is selected from that group (see table A).

Sample set:

The minimum number of different samples required for validation is 20 homogeneous negative control samples and 20 homogeneous positive control samples that contain the mycotoxin at the STC, analysed under intermediate precision (RSD_{Ri}) conditions spread over 5 different days. Optionally, additional sets of 20 samples containing the mycotoxin at other levels can be added to the validation set to gain insight to what extent the method can distinguish between different mycotoxin concentrations.

Concentration:

For each STC to be used in routine application, a validation has to be performed.

4.3.2.3.2. Initial validation through collaborative trials

Validation through collaborative trials shall be done in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) which requires inclusion of valid data from at least eight different laboratories. Other than that, the only difference compared to single laboratory validations is that the ≥ 20 samples per commodity/level can be evenly divided over the participating laboratories, with a minimum of two samples per laboratory.

([1]) Samples are considered free of analyte if the amount present in the sample does not exceed more than 1/5th of the STC. If the level can be quantified with a confirmatory method, the level must be taken into consideration for the validation assessment.

4.3.2.4. Determination of cut-off level and rate of false suspected results of blank samples

The (relative) responses for the negative control and positive control samples are taken as basis for the calculation of the required parameters.

Screening methods with a response proportional with the mycotoxin concentration

For screening methods with a response proportional with the mycotoxin concentration the following applies:

$$Cut\text{-}off = R_{STC} - t\text{-}value_{0,05} * SD_{STC}$$

R_{STC} = mean response of the positive control samples (at STC)

t-value: one tailed t-value for a rate of false negative results of 5 % (see table B)

SD_{STC} = standard deviationScreening methods with a response inversely proportional with the mycotoxin concentration

Similarly, for screening methods with a response inversely proportional with the mycotoxin concentration, the cut-off is determined as:

$$Cut\text{-}off = R_{STC} + t\text{-}value_{0,05} * SD_{STC}$$

By using this specific t-value for establishing the cut-off value, the rate of false negative results is by default set at 5 %.

Fitness for purpose assessment

Results from the negative control samples are used to estimate the corresponding rate of false suspect results. The t-value is calculated corresponding to the event that a result of a negative control sample is above the cut off value, thus erroneously classified as suspect.

t-value = (cut off − $mean_{blank}$)/$SD_{blank}$for screening methods with a response proportional with the mycotoxin concentration

or

t-value = ($mean_{blank}$ − cut off)/$SD_{blank}$for screening methods with a response inversely proportional with the mycotoxin concentration

From the obtained t-value, based on the degrees of freedom calculated from the number of experiments, the probability of false suspect samples for a one tailed distribution can either be calculated (e.g.. spread sheet function "TDIST") or taken from a table for t-distribution.

The corresponding value of the one tailed t-distribution specifies the rate of false suspect results.

This concept is described in detail with an example in Analytical and Bioanalytical Chemistry DOI 10.1007/s00216 -013-6922-1.

4.3.2.5. Extension of the scope of the method

4.3.2.5.1. Extension of scope to other mycotoxins:

When new mycotoxins are added to the scope of an existing screening method, a full validation is required to demonstrate the suitability of the method.

4.3.2.5.2. Extension to other commodities:

If the screening method is known or expected to be applicable to other commodities, the validity to these other commodities shall be verified. As long as the new commodity belongs to a commodity group (see Table A) for which an initial validation has already been performed, a limited additional validation is sufficient. For this, a minimum of 10 homogeneous negative control and 10 homogeneous positive control (at STC) samples shall be analysed under intermediate precision conditions. The positive control samples shall all be above the cut-off value. In case this criterion is not met, a full validation is required.

4.3.2.6. Verification of methods already validated through collaborative trials

For screening methods that have already been successfully validated through a collaborative laboratory trial, the method performance shall be verified. For this a minimum of 6 negative control and 6 positive control (at STC) samples shall be analysed. The positive control samples shall all be above the cut-off value. In case this criterion is not met, the laboratory has to perform a root-cause analysis to identify why it cannot meet the specification as obtained in the collaborative trial. Only after taking corrective action it shall re-verify the method performance in its laboratory. In case the laboratory is not capable to verify the results from the collaborative trial, it will need to establish its own cut-off in a complete single laboratory validation.

4.3.2.7. Continuous method verification/on-going method validation

After initial validation, additional validation data are acquired by including at least two positive control samples in each batch of samples screened. One positive control sample is a known sample (e.g. one used during initial validation), the other is a different commodity from the same commodity group (in case only one commodity is analysed, a different sample of that commodity is used instead). Inclusion of a negative control sample is optional. The results obtained for the two positive control samples are added to the existing validation set.

At least once a year the cut-off value is re-established and the validity of the method is re-assessed. The continuous method verification serves several purposes:

— quality control for the batch of samples screened

— providing information on robustness of the method at conditions in the laboratory that applies the method

— justification of applicability of the method to different commodities

— allowing to adjust cut-off values in case of gradual drifts over time.

4.3.2.8. Validation report

The validation report shall contain:

— A statement on the STC

— A statement on the obtained cut-off.

Note: The cut-off must have the same number of significant figures as the STC. Numerical values used to calculate the cut-off need at least one more significant figure than the STC.

— A statement on calculated false suspected rate

— A statement on how the false suspected rate was generated.

Note: The statement on the calculated false suspected rate indicates if the method is fit-for-purpose as it indicates the number of blank (or low level contamination) samples that will be subject to verification.

Table A

Commodity groups for the validation of screening methods

Commodity groups	Commodity categories	Typical representative commodities included in the category
High water content	Fruit Juices	Apple juice, grape juice
	Alcoholic beverages	Wine, beer, cider
	Root and tuber vegetables	Fresh ginger
	Cereal or fruit based purees	Purees intended for infants and small children

Commodity groups	Commodity categories	Typical representative commodities included in the category
High oil content	Tree nuts	Walnut, hazelnut, chestnut
	Oil seeds and products thereof	Oilseed rape, sunflower, cotton-seed, soybeans, peanuts, sesame etc.
	Oily fruits and products thereof	Oils and pastes (e.g. peanut butter, tahina)
High starch and/or protein content and low water and fat content	Cereal grain and products thereof	Wheat, rye, barley, maize, rice, oats Wholemeal bread, white bread, crackers, breakfast cereals, pasta
	Dietary products	Dried powders for the preparation of food for infants and small children
High acid content and high water content (*)	Citrus products	
"Difficult or unique commodities" (**)		Cocoa beans and products thereof, copra and products thereof, coffee, tea Spices, liquorice
High sugar low water content	Dried fruits	Figs, raisins, currants, sultanas
Milk and milk products	Milk	Cow, goat and buffalo milk
	Cheese	Cow, goat cheese
	Dairy products (e.g. milk powder)	Yogurt, cream

(*) If a buffer is used to stabilise the pH changes in the extraction step, then this commodity group can be merged into one commodity group "High water content".
(**) "Difficult or unique commodities" should only be fully validated if they are frequently analysed. If they are only analysed occasionally, validation may be reduced to just checking the reporting levels using spiked blank extracts.

Table B

One tailed t-value for a false negative rate of 5 %

Degrees of Freedom	Number of replicates	t-value (5 %)
10	11	1,812
11	12	1,796
12	13	1,782
13	14	1,771
14	15	1,761
15	16	1,753
16	17	1,746
17	18	1,74
18	19	1,734

Degrees of Freedom	Number of replicates	t-value (5 %)
19	20	1,729
20	21	1,725
21	22	1,721
22	23	1,717
23	24	1,714
24	25	1,711
25	26	1,708
26	27	1,706
27	28	1,703
28	29	1,701
29	30	1,699
30	31	1,697
40	41	1,684
60	61	1,671
120	121	1,658
∞	∞	1,645

4.3.3. *Requirements for qualitative screening methods (methods that do not give numerical values)*

The development of validation guidelines for binary test methods is currently subject of various standardization bodies (e.g. AOAC, ISO). Very recently AOAC has drafted a guideline on this matter. This document can be regarded as the current state of the art in its field. Therefore methods that give binary results (e.g. visual inspection of dip-stick tests) should be validated according to this guideline

http://www.aoac.org/imis15_prod/AOAC_Docs/ISPAM/Qual_Chem_Guideline_Final_Approved_031412.pdf

4.4. **Estimation of measurement uncertainty, recovery calculation and reporting of results** ([1])

4.4.1. *Confirmatory methods*

The analytical result must be reported as follows:

(a) Corrected for recovery, the level of recovery being indicated. The correction for recovery is not necessary in case the recovery rate is between 90-110 %.

(b) As x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

For food of animal origin, the taking into account of the measurement uncertainty can also be done by establishing the decision limit (CCα) in accordance with Commission Decision 2002/657/EC ([2]) (point 3.1.2.5 of Annex I — the case of substances with established permitted limit).

However if the result of the analysis is significantly (> 50 %) lower than the maximum level or much higher than the maximum level (i.e. more than 5 times the maximum level), and on the condition that the appropriate quality procedures are applied and the analysis serves only the purpose of checking compliance with legal provisions, the analytical result might be reported without correction for recovery and the reporting of the recovery rate and measurement uncertainty might be omitted in these cases.

([1]) More details on procedures for the estimation of measurement uncertainty and on procedures for assessing recovery can be found in the report "Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation" — http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

([2]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8).

The present interpretation rules of the analytical result in view of acceptance or rejection of the lot apply to the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.

4.4.2. *Screening methods*

The result of the screening shall be expressed as compliant or suspected to be non-compliant.

"Suspected to be non-compliant" means the sample exceeds the cut-off level and may contain the mycotoxin at a level higher than the STC. Any suspect result triggers a confirmatory analysis for unambiguous identification and quantification of the mycotoxin.

"Compliant" means that the mycotoxin content in the sample is < STC with a certainty of 95 % (i.e. there is a 5 % chance that samples will be incorrectly reported as negative). The analytical result is reported as "< level of STC" with the level of STC specified.'

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2014

of 16 May 2014

adding to the 2014 fishing quotas certain quantities withheld in the year 2013 pursuant to Article 4(2) of Council Regulation (EC) No 847/96

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas ([1]), and in particular Article 4(2) thereof,

Whereas:

(1) According to Article 4(2) of Regulation (EC) No 847/96, Member States may ask the Commission, before 31 October of the year of application of a fishing quota allocated to them, to withhold a maximum of 10 % of that quota to be transferred to the following year. The Commission is to add to the relevant quota the quantity withheld.

(2) Council Regulations (EU) No 1262/2012 ([2]), (EU) No 1088/2012 ([3]), (EU) No 1261/2012 ([4]), (EU) No 39/2013 ([5]) and (EU) No 40/2013 ([6]) fix fishing quotas for certain stocks for 2013 and specify which stocks may be subject to the measures provided for in Regulation (EC) No 847/96.

(3) Council Regulations (EU) No 1262/2012, (EU) No 1180/2013 ([7]), (EU) No 24/2014 ([8]), and (EU) No 43/2014 ([9]) fix fishing quotas for certain stocks for 2014.

(4) Certain Member States have requested, before 31 October of 2013, pursuant to Article 4(2) of Regulation (EC) No 847/96, that part of their quotas for 2013 be withheld and transferred to the following year. Within the limits indicated in that Regulation, the quantities withheld should be added to the quotas for 2014.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

The fishing quotas fixed for 2014 in Regulations (EU) No 1262/2012, (EU) No 1180/2013, (EU) No 24/2014 and (EU) No 43/2014 are increased as set out in the Annex.

([1]) OJ L 115, 9.5.1996, p. 3.
([2]) Council Regulation (EU) No 1262/2012 of 20 December 2012 fixing for 2013 and 2014 the fishing opportunities for EU vessels for certain deep-sea fish stocks (OJ L 356, 22.12.2012, p. 22).
([3]) Council Regulation (EU) No 1088/2012 of 20 November 2012 fixing for 2013 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea (OJ L 323, 22.11.2012, p. 2).
([4]) Council Regulation (EU) No 1261/2012 of 20 December 2012 fixing for 2013 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Black Sea (OJ L 356, 22.12.2012, p. 19).
([5]) Council Regulation (EU) No 39/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available to EU vessels for certain fish stocks and groups of fish stocks which are not subject to international negotiations or agreements (OJ L 23, 25.1.2013, p. 1).
([6]) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non- EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements (OJ L 23, 25.1.2013, p. 54).
([7]) Council Regulation (EU) No 1180/2013 of 19 November 2013 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea (OJ L 313, 22.11.2013, p. 4).
([8]) Council Regulation (EU) No 24/2014 of 10 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks in the Black Sea (OJ L 9, 14.1.2014, p. 4).
([9]) Council Regulation (EU) No 43/2014 of 20 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, to Union vessels, in certain non-Union waters (OJ L 24, 28.1.2014, p. 1).

Article 2

This Regulation shall enter into force on the seventh 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, 16 May 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
BE	ANF/07.	Anglerfish	VII	1 702,800	1 127,900	134,600	74,14 %	170,280
BE	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	343,800	136,800	0	39,79 %	34,380
BE	ANF/8ABDE.	Anglerfish	VIIIa, VIIIb, VIIId and VIIIe	259,500	238,000	0	91,71 %	21,500
BE	COD/07A.	Cod	VIIa	20,800	12,900	0	62,02 %	2,080
BE	COD/07D.	Cod	VIId	67,100	52,200	0	77,79 %	6,710
BE	COD/7XAD34	Cod	VIIb, VIIc, VIIe-k, VIII, IX and X, Union waters of CECAF 34.1.1	513,700	202,000	0	39,32 %	51,370
BE	HAD/07A.	Haddock	VIIa	37,900	6,200	0	16,36 %	3,790
BE	HAD/2AC4.	Haddock	IV; Union waters of IIa	85,400	78,400	0	91,80 %	7,000
BE	HAD/5BC6A.	Haddock	Union and international waters of Vb and VIa	0,700	0	0	0 %	0,070
BE	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	2,800	0	0	0 %	0,280
BE	HKE/2AC4-C	Hake	Union waters of IIa and IV	38,200	31,200	0	81,68 %	3,820
BE	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	97,300	12,000	0	12,33 %	9,730
BE	HKE/8ABDE.	Hake	VIIIa, VIIIb, VIIId and VIIIe	13,000	7,600	0	58,46 %	1,300
BE	LEZ/07.	Megrims	VII	578,100	520,200	0	89,98 %	57,810
BE	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	6,900	0,400	0	5,80 %	0,690
BE	LEZ/8ABDE.	Megrims	VIIIa, VIIIb, VIIId and VIIIe	25,000	18,200	0	72,80 %	2,500
BE	LIN/04-C.	Ling	Union waters of IV	15,400	14,800	0	96,10 %	0,600

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
BE	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	77,400	52,100	0	67,31 %	7,740
BE	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	79,100	61,600	0	77,88 %	7,910
BE	NEP/07.	Norway lobster	VII	16,200	13,600	0	83,95 %	1,620
BE	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	1 034,800	286,800	0	27,72 %	103,480
BE	NEP/8ABDE.	Norway lobster	VIIIa, VIIIb, VIIId and VIIIe	5,600	0,400	0	7,14 %	0,560
BE	PLE/07A.	Plaice	VIIa	220,300	144,100	0	65,41 %	22,030
BE	PLE/7DE.	Plaice	VIId and VIIe	1 556,300	1 391,100	0	89,39 %	155,630
BE	PLE/7HJK.	Plaice	VIIh, VIIj and VIIk	1,200	0	0	0 %	0,120
BE	SOL/07D.	Common sole	VIId	1 771,900	953,000	0	53,78 %	177,190
BE	SOL/07E.	Common sole	VIIe	34,600	29,500	0	85,26 %	3,460
BE	SOL/24-C.	Common sole	Union waters of II and IV	1 339,800	697,300	0	52,05 %	133,980
BE	SOL/7FG.	Common sole	VIIf and VIIg	860,200	787,600	0	91,56 %	72,600
BE	SOL/7HJK.	Common sole	VIIh, VIIj and VIIk	36,900	4,500	0	12,20 %	3,690
BE	SOL/8AB.	Common sole	VIIIa and VIIIb	331,800	311,900	0	94,00 %	19,900
BE	WHG/07A.	Whiting	VIIa	4,500	2,300	0	51,11 %	0,450
BE	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	390,600	319,800	0	81,87 %	39,060
DE	ANF/07.	Anglerfish	VII	353,900	310,413	0	87,71 %	35,390
DE	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	369,600	248,831	0	67,32 %	36,960

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
DE	ARU/1/2.	Greater silver smelt	Union and international waters of I and II	27,300	0	0	0 %	2,730
DE	ARU/34-C	Greater silver smelt	Union waters of III and IV	11,200	0	0	0 %	1,120
DE	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	432,600	416,765	0	96,34 %	15,835
DE	BLI/5B67-	Blue ling	Union and international waters of Vb, VI, VII	5,000	0	0	0 %	0,500
DE	BSF/56712-	Black scabbardfish	EU and international waters of V, VI, VII and XII	57,500	0	0	0 %	5,750
DE	COD/03AS.	Cod	Kattegat	1,200	0,481	0	40,08 %	0,120
DE	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	4 711,350	0	540,701	11,48 %	471,135
DE	GFB/1234-	Greater forkbeard	EU and international waters of I, II, III and IV	9,900	0	0	0 %	0,990
DE	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	11,000	0	0	0 %	1,100
DE	GHL/2A-C46	Greenland halibut	Union waters of IIa and IV, Union and international waters of Vb and VI	8,000	0	0	0 %	0,800
DE	HAD/2AC4.	Haddock	IV; Union waters of IIa	700,990	233,909	436,130	95,58 %	30,951
DE	HAD/5BC6A.	Haddock	Union and international waters of Vb and VIa	1,800	0	0	0 %	0,180
DE	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	4,000	0	0	0 %	0,400
DE	HER/1/2-	Herring	Union, Norwegian and international waters of I and II	4 431,130	2 321,619	1 922,228	95,77 %	187,283
DE	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	1 416,000	0	1 415,315	99,95 %	0,685
DE	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	4 481,680	4 032,643	0	89,98 %	448,168
DE	HER/7G-K.	Herring	VIIg, VIIh, VIIj and VIIk	501,970	450,217	0	89,69 %	50,197
DE	HKE/2AC4-C	Hake	Union waters of IIa and IV	171,250	92,375	0	53,94 %	17,125

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
DE	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	27 659,260	24 834,294	49,803	89,97 %	2 765,926
DE	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	5,600	1,071	0	19,13 %	0,56
DE	LIN/04-C.	Ling	Union waters of IV	104,160	45,061	0	43,26 %	10,416
DE	LIN/1/2.	Ling	Union and international waters of I and II	8,900	0,663	0	7,45 %	0,890
DE	LIN/3A/BCD	Ling	IIIa; Union waters of IIIbcd	4,150	0,410	0	9,88 %	0,415
DE	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	93,070	2,589	0	2,78 %	9,307
DE	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	871,140	836,766	0	96,05 %	34,374
DE	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	531,650	419,588	0	78,92 %	53,165
DE	NEP/3A/BCD	Norway lobster	IIIa; Union waters of Subdivisions 22-32	12,500	3,139	0	25,11 %	1,250
DE	POK/56-14	Saithe	VI; Union and international waters of Vb, XII and XIV	85,270	0	0	0 %	8,527
DE	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	8,500	0	0	0 %	0,850
DE	RNG/8X14-	Roundnose grenadier	EU and international waters of VIII, IX, X, XII and XIV	41,000	0	0	0 %	4,100
DE	SOL/24-C.	Common sole	Union waters of II and IV	658,500	560,818	0	85,17 %	65,850
DE	SOL/3A/BCD	Common sole	IIIa; Union waters of Subdivisions 22-32	22,400	8,892	0	39,70 %	2,240
DE	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	10 322,000	0	10 315,365	99,94 %	6,635
DE	USK/04-C.	Tusk	Union waters of IV	20,800	1,817	0	8,74 %	2,080
DE	USK/1214EI	Tusk	Union and international waters of I, II and XIV	4,700	0,297	0	6,32 %	0,470

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
DE	USK/3A/BCD	Tusk	IIIa, Union waters of Subdivisions 22-32	7,700	0,018	0	0,23 %	0,770
DE	USK/567EI.	Tusk	Union and international waters of V, VI and VII	3,000	0	0	0 %	0,300
DE	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	12 618,360	11 341,048	37,671	90,18 %	1 239,641
DE	WHG/56-14	Whiting	VI, Union and international waters of Vb, international waters of XII and XIV	2,000	0	0	0 %	0,200
DK	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	756,580	196,140	0	25,92 %	75,658
DK	ARU/34-C	Greater silver smelt	Union waters of III and IV	1 017,300	317,760	0	31,24 %	101,730
DK	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	422,500	124,850	0	29,55 %	42,250
DK	COD/03AS.	Cod	Kattegat	71,700	56,730	0	79,12 %	7,170
DK	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	15 204,390	0	5 869,290	38,60 %	1 520,439
DK	GHL/2A-C46	Greenland halibut	Union waters of IIa and IV, Union and international waters of Vb and VI	13,200	0	0	0 %	1,320
DK	HAD/2AC4.	Haddock	IV; Union waters of IIa	1 470,160	1 282,900	0	87,26 %	147,016
DK	HER/1/2-	Herring	Union, Norwegian and international waters of I and II	17 184,200	16 880,370	0	98,23 %	303,830
DK	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	2 204,000	0	2 197,030	99,68 %	6,970
DK	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	247,500	208,370	0	84,19 %	24,750
DK	HKE/2AC4-C	Hake	Union waters of IIa and IV	1 351,570	870,060	0	64,37 %	135,157
DK	HKE/3A/BCD	Hake	IIIa; Union waters of Subdivisions 22-32	816,800	210,910	0	25,82 %	81,680
DK	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	7 868,710	6 681,950	43,700	85,47 %	786,871

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
DK	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	21,100	19,180	0	90,90 %	1,920
DK	LIN/04-C.	Ling	Union waters of IV	204,330	83,180	0	40,71 %	20,433
DK	LIN/1/2.	Ling	Union and international waters of I and II	8,900	0	0	0 %	0,890
DK	LIN/3A/BCD	Ling	IIIa; Union waters of IIIbcd	63,310	56,380	0	89,05 %	6,331
DK	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	5,600	0	0	0 %	0,560
DK	MAC/2A4A-N	Mackerel	Norwegian waters of IIa and IVa	11 413,440	0	11 413,080	100,00 %	0,360
DK	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	1 035,110	250,970	0	24,25 %	103,511
DK	NEP/3A/BCD	Norway lobster	IIIa; Union waters of Subdivisions 22-32	4 298,680	2 646,290	0	61,56 %	429,868
DK	PRA/2AC4-C	Northern prawn	Union waters of IIa and IV	2 530,600	163,460	0	6,46 %	253,060
DK	SOL/24-C.	Common sole	Union waters of II and IV	692,100	497,230	0	71,84 %	69,210
DK	SOL/3A/BCD	Common sole	IIIa; Union waters of Subdivisions 22-32	528,900	246,150	0	46,54 %	52,890
DK	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	27 569,000	0	27 113,080	98,35 %	455,920
DK	USK/04-C.	Tusk	Union waters of IV	69,900	4,830	0	6,91 %	6,990
DK	USK/3A/BCD	Tusk	IIIa; Union waters of Subdivisions 22-32	16,300	0,820	0	5,03 %	1,630
DK	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	3 417,510	2 165,250	14,710	63,79 %	341,751
EE	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	1 633,670	0	248,622	15,22 %	163,367
EE	HER/03D.RG	Herring	Subdivision 28.1	12 332,440	11 898,247	0	96,48 %	434,193
EE	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	10 142,000	0	10 042,332	99,02 %	99,668

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
EE	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	63,000	0	0	0 %	6,300
EE	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	29 810,000	0	29 805,065	99,98 %	4,935
ES	ANF/07.	Anglerfish	VII	2 971,400	2 868,090	0	96,52 %	103,310
ES	ANF/8ABDE.	Anglerfish	VIIIa, VIIIb, VIIId and VIIIe	1 070,400	1 019,850	0	95,28 %	50,550
ES	ANF/8C3411	Anglerfish	VIIIc, IX and X; Union waters of CECAF 34.1.1	2 121,690	1 816,280	0	85,61 %	212,169
ES	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	588,220	568,360	19,830	99,99 %	0,030
ES	GHL/2A-C46	Greenland halibut	Union waters of IIa and IV, Union and international waters of Vb and VI	13,200	0,110	0	0,83 %	1,320
ES	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	3,300	0	0	0 %	0,330
ES	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	12 446,040	11 941,040	0	95,94 %	505,000
ES	HKE/8ABDE.	Hake	VIIIa, VIIIb, VIIId and VIIIe	8 631,140	6 619,750	1 709,730	96,50 %	301,660
ES	HKE/8C3411	Hake	VIIIc, IX and X; Union waters of CECAF 34.1.1	9 882,200	7 099,500	0	71,84 %	988,220
ES	JAX/08C.	Horse mackerel and associated by-catches	VIIIc	23 628,510	18 787,770	0	79,51 %	2 362,851
ES	JAX/09.	Horse mackerel and associated by-catches	IX	10 840,780	10 127,150	0	93,42 %	713,630
ES	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	7 075,130	5 880,240	0	83,11 %	707,513
ES	LEZ/07.	Megrims	VII	5 437,900	4 539,310	0	83,48 %	543,790
ES	LEZ/56-14	Megrims	Union and international waters of Vb; VI; international waters of XII and XIV	427,400	212,710	0	49,77 %	42,740

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
ES	LEZ/8ABDE.	Megrims	VIIIa, VIIIb, VIIId and VIIIe	685,100	581,130	0	84,82 %	68,510
ES	LEZ/8C3411	Megrims	VIIIc, IX and X; Union waters of CECAF 34.1.1	1 158,770	735,070	0	63,44 %	115,877
ES	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	2 456,700	1 621,160	0	65,99 %	245,670
ES	MAC/8C3411	Mackerel	VIIIc, IX and X; Union waters of CECAF 34.1.1	20 223,800	15 444,990	620,400	79,44 %	2 022,380
ES	NEP/07.	Norway lobster	VII	1 498,480	76,510	132,180	13,93 %	149,848
ES	NEP/08C.	Norway lobster	VIIIc	68,700	21,950	0	31,95 %	6,870
ES	NEP/5BC6.	Norway lobster	VI; Union and international waters of Vb	37,200	0,060	0	0,16 %	3,720
ES	NEP/8ABDE.	Norway lobster	VIIIa, VIIIb, VIIId and VIIIe	131,200	0,570	0	0,43 %	13,120
ES	NEP/9/3411	Norway lobster	IX and X; Union waters of CECAF 34.1.1	36,850	31,340	0	85,05 %	3,685
ES	POK/56-14	Saithe	VI; Union and international waters of Vb, XII and XIV	23,000	21,190	0	92,13 %	1,810
ES	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	111,060	110,900	0	99,86 %	0,160
ES	RNG/8X14-	Roundnose grenadier	EU and international waters of VIII, IX, X, XII and XIV	3 650,020	2 417,700	202,060	71,77 %	365,002
ES	SBR/09-	Red Seabream	EU and international waters of IX	682,500	111,530	52,720	24,07 %	68,250
ES	SBR/10-	Red Seabream	EU and international waters of X	10,000	0,510	0	5,10 %	1,000
ES	SBR/678-	Red Seabream	EU and international waters of VI, VII and VIII	118,230	118,170	0	99,95 %	0,060
ES	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	1 587,170	74,530	0	4,70 %	158,717
ES	WHB/8C3411	Blue whiting	VIIIc, IX and X; Union waters of CECAF 34.1.1	21 487,890	14 538,070	0	67,66 %	2 148,789
ES	WHG/56-14	Whiting	VI, Union and international waters of Vb, international waters of XII and XIV	1,100	0	0	0 %	0,110

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
ES	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	11,200	4,190	0	37,41 %	1,120
FI	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	1 250,090	0	434,391	34,75 %	125,009
FI	HER/30/31.	Herring	Subdivisions 30-31	105 843,500	0	103 546,210	97,83 %	2 297,290
FI	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	19 556,000	0	18 052,464	92,31 %	1 503,536
FI	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	11 442,000	0	11 074,842	96,79 %	367,158
FR	ALF/3X14-	Alfonsinos	EU and international waters of III, IV, V, VI, VII, VIII, IX, X, XII and XIV	31,200	19,300	0	61,86 %	3,120
FR	ANF/07.	Anglerfish	VII	17 267,500	14 859,400	0	86,05 %	1 726,750
FR	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	70,200	17,600	0	25,07 %	7,020
FR	ANF/8ABDE.	Anglerfish	VIIIa, VIIIb, VIIId and VIIIe	7 397,600	6 154,300	0	83,19 %	739,760
FR	ANF/8C3411	Anglerfish	VIIIc, IX and X; Union waters of CECAF 34.1.1	49,500	38,400	0	77,58 %	4,950
FR	ARU/1/2.	Greater silver smelt	Union and international waters of I and II	8,900	0,200	0	2,25 %	0,890
FR	ARU/34-C	Greater silver smelt	Union waters of III and IV	7,800	1,800	0	23,08 %	0,780
FR	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	7,800	0	0	0 %	0,780
FR	BLI/5B67-	Blue ling	Union and international waters of Vb, VI, VII	2 239,640	1 694,000	0	75,64 %	223,964
FR	BSF/56712-	Black scabbardfish	EU and international waters of V, VI, VII and XII	2 887,090	2 167,100	0	75,06 %	288,709
FR	BSF/8910-	Black scabbardfish	EU and international waters of VIII, IX and X	31,900	7,400	0	23,20 %	3,190
FR	COD/07A.	Cod	VIIa	11,600	0,500	0	4,31 %	1,160
FR	COD/07D.	Cod	VIId	1 414,400	642,300	0	45,41 %	141,440

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
FR	COD/7XAD34	Cod	VIIb, VIIc, VIIe-k, VIII, IX and X, Union waters of CECAF 34.1.1	8 182,100	4 016,200	0	49,09 %	818,210
FR	GFB/1012-	Greater forkbeard	EU and international waters of X and XII	10,000	0	0	0 %	1,000
FR	GFB/1234-	Greater forkbeard	EU and international waters of I, II, III and IV	10,000	0,600	0	6,00 %	1,000
FR	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	727,000	438,100	17,300	62,64 %	72,700
FR	GFB/89-	Greater forkbeard	EU and international waters of VIII and IX	16,000	10,100	0	63,13 %	1,600
FR	GHL/2A-C46	Greenland halibut	Union waters of IIa and IV, Union and international waters of Vb and VI	598,400	305,600	0	51,07 %	59,840
FR	HAD/07A.	Haddock	VIIa	95,900	0,700	0	0,73 %	9,590
FR	HAD/2AC4.	Haddock	IV; Union waters of IIa	256,700	179,000	0	69,73 %	25,670
FR	HAD/5BC6A.	Haddock	Union and international waters of Vb and VIa	103,100	51,700	0	50,15 %	10,310
FR	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	149,800	0	0	0 %	14,980
FR	HAD/7X7A34	Haddock	VIIb-k, VIII, IX and X; Union waters of CECAF 34.1.1	8 878,000	8 778,600	0	98,88 %	99,400
FR	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	590,200	586,600	0	99,39 %	3,600
FR	HER/7G-K.	Herring	VIIg, VIIh, VIIj and VIIk	1 200,400	0,900	0	0,07 %	120,040
FR	HKE/2AC4-C	Hake	Union waters of IIa and IV	1 032,750	800,800	0	77,54 %	103,275
FR	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	17 925,400	16 129,600	0	89,98 %	1 792,540
FR	HKE/8ABDE.	Hake	VIIIa, VIIIb, VIIId and VIIIe	18 839,000	13 633,600	0	72,37 %	1 883,900
FR	HKE/8C3411	Hake	VIIIc, IX and X; Union waters of CECAF 34.1.1	951,700	368,700	0	38,74 %	95,170

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
FR	JAX/08C.	Horse mackerel and associated by-catches	VIIIc	411,100	9,800	0	2,38 %	41,110
FR	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	12 410,200	6 461,500	300	54,48 %	1 241,020
FR	LEZ/07.	Megrims	VII	6 633,800	3 679,500	0	55,47 %	663,380
FR	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	35,200	6,800	0	19,32 %	3,520
FR	LEZ/56-14	Megrims	Union and international waters of Vb; VI; international waters of XII and XIV	1 665,600	95,600	0	5,74 %	166,560
FR	LEZ/8ABDE.	Megrims	VIIIa, VIIIb, VIIId and VIIIe	1 194,700	849,700	0	71,12 %	119,470
FR	LEZ/8C3411	Megrims	VIIIc, IX and X; Union waters of CECAF 34.1.1	62,100	12,900	0	20,77 %	6,210
FR	LIN/04-C.	Ling	Union waters of IV	133,900	103,800	0	77,52 %	13,390
FR	LIN/1/2.	Ling	Union and international waters of I and II	8,900	7,400	0	83,15 %	0,890
FR	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	2 678,200	2 215,400	0	82,72 %	267,820
FR	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	1 725,200	1 341,900	0	77,78 %	172,520
FR	MAC/2CX14-	Mackerel	VI, VII, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of IIa, XII and XIV	16 821,900	13 367,400	1 322,300	87,32 %	1 682,190
FR	MAC/8C3411	Mackerel	VIIIc, IX and X; Union waters of CECAF 34.1.1	1 037,100	221,300	642,700	83,31 %	103,710
FR	NEP/07.	Norway lobster	VII	5 725,600	671,800	0	11,73 %	572,560
FR	NEP/08C.	Norway lobster	VIIIc	14,600	0,500	0	3,42 %	1,460

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
FR	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	30,800	0	0	0 %	3,080
FR	NEP/5BC6.	Norway lobster	VI; Union and international waters of Vb	147,700	0	0	0 %	14,770
FR	NEP/8ABDE.	Norway lobster	VIIIa, VIIIb, VIIId and VIIIe	4 195,500	2 430,900	0	57,94 %	419,550
FR	PLE/07A.	Plaice	VIIa	20,000	0,300	0	1,50 %	2,000
FR	PLE/7DE.	Plaice	VIId and VIIe	3 152,400	2 358,200	0	74,81 %	315,240
FR	PLE/7HJK.	Plaice	VIIh, VIIj and VIIk	50,300	48,600	0	96,62 %	1,700
FR	POK/56-14	Saithe	VI; Union and international waters of Vb, XII and XIV	4 794,000	3 805,600	0	79,38 %	479,400
FR	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	4 038,720	993,700	0	24,60 %	403,872
FR	RNG/8X14-	Roundnose grenadier	EU and international waters of VIII, IX, X, XII and XIV	133,900	0,200	0	0,15 %	13,390
FR	SBR/678-	Red Seabream	EU and international waters of VI, VII and VIII	78,500	51,200	0	65,22 %	7,850
FR	SOL/07D.	Common sole	VIId	3 505,600	2 864,500	0	81,71 %	350,560
FR	SOL/07E.	Common sole	VIIe	354,100	321,100	0	90,68 %	33,000
FR	SOL/24-C.	Common sole	Union waters of II and IV	947,100	680,100	0	71,81 %	94,710
FR	SOL/7FG.	Common sole	VIIf and VIIg	63,500	48,800	0	76,85 %	6,350
FR	SOL/7HJK.	Common sole	VIIh, VIIj and VIIk	106,800	76,000	0	71,16 %	10,680
FR	SOL/8AB.	Common sole	VIIIa and VIIIb	4 120,400	3 879,200	0	94,15 %	241,200
FR	USK/04-C.	Tusk	Union waters of IV	47,700	10,900	0	22,85 %	4,770
FR	USK/1214EI	Tusk	Union and international waters of I, II and XIV	7,700	6,900	0	89,61 %	0,770
FR	USK/567EI.	Tusk	Union and international waters of V, VI and VII	625,040	228,200	0	36,51 %	62,504

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
FR	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	8 319,000	7 181,600	0	86,33 %	831,900
FR	WHG/07A.	Whiting	VIIa	3,300	0,600	0	18,18 %	0,330
FR	WHG/56-14	Whiting	VI, Union and international waters of Vb, international waters of XII and XIV	39,000	1,400	0	3,59 %	3,900
FR	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	15 078,900	6 997,700	0	46,41 %	1 507,890
IE	ALF/3X14-	Alfonsinos	EU and international waters of III, IV, V, VI, VII, VIII, IX, X, XII and XIV	1,100	0	0	0 %	0,110
IE	ANF/07.	Anglerfish	VII	3 523,950	3 172,717	0	90,03 %	351,233
IE	ARU/34-C	Greater silver smelt	Union waters of III and IV	7,800	0	0	0 %	0,780
IE	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	338,800	0	0	0 %	33,880
IE	BLI/5B67-	Blue ling	Union and international waters of Vb, VI, VII	0,500	0,480	0	96,00 %	0,020
IE	BSF/56712-	Black scabbardfish	EU and international waters of V, VI, VII and XII	0,100	0	0	0 %	0,010
IE	COD/07A.	Cod	VIIa	175,100	159,692	0	91,20 %	15,408
IE	COD/7XAD34	Cod	VIIb, VIIc, VIIe-k, VIII, IX and X, Union waters of CECAF 34.1.1	1 612,010	1 452,085	0	90,08 %	159,925
IE	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	26,700	17,567	0	65,79 %	2,670
IE	HAD/07A.	Haddock	VIIa	541,640	491,903	0	90,82 %	49,737
IE	HAD/5BC6A.	Haddock	Union and international waters of Vb and VIa	777,260	746,274	0	96,01 %	30,986
IE	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	105,400	105,358	0	99,96 %	0,042
IE	HER/07A/MM	Herring	VIIa	2,500	0	0	0 %	0,250

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
IE	HER/1/2-	Herring	Union, Norwegian and international waters of I and II	3 755,230	0	3 593,584	95,70 %	161,646
IE	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	3 739,510	3 025,655	0	80,91 %	373,951
IE	HER/7G-K.	Herring	VIIg, VIIh, VIIj and VIIk	16 643,450	14 790,997	0	88,87 %	1 664,345
IE	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	1 972,160	1 772,351	0	89,87 %	197,216
IE	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	41 195,510	37 398,143	0	90,78 %	3 797,367
IE	LEZ/07.	Megrims	VII	3 386,900	3 053,295	0	90,15 %	333,605
IE	LEZ/56-14	Megrims	Union and international waters of Vb; VI; international waters of XII and XIV	487,300	384,113	0	78,82 %	48,730
IE	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	692,520	619,345	0	89,43 %	69,252
IE	MAC/2CX14-	Mackerel	VI, VII, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of IIa, XII and XIV	57 443,250	43 079,934	13 523,407	98,54 %	839,909
IE	NEP/*07U16	Norway lobster	VII (Porcupine Bank — Unit 16)	771,400	654,000	0	84,78 %	77,140
IE	NEP/07.	Norway lobster	VII	9 352,420	7 762,505	654,000	89,99 %	935,242
IE	NEP/5BC6.	Norway lobster	VI; Union and international waters of Vb	247,100	6,106	0	2,47 %	24,710
IE	PLE/07A.	Plaice	VIIa	1 047,800	102,697	0	9,80 %	104,780
IE	POK/56-14	Saithe	VI; Union and international waters of Vb, XII and XIV	465,000	312,944	0	67,30 %	46,500
IE	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	27,700	0	0	0 %	2,770

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
IE	RNG/8X14-	Roundnose grenadier	EU and international waters of VIII, IX, X, XII and XIV	5,700	0	0	0 %	0,570
IE	SOL/7HJK.	Common sole	VIIh, VIIj and VIIk	170,400	85,414	0	50,13 %	17,040
IE	USK/567EI.	Tusk	Union and international waters of V, VI and VII	14,300	1,865	0	13,04 %	1,430
IE	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	14 671,780	13 205,392	0	90,01 %	1 466,388
IE	WHG/07A.	Whiting	VIIa	47,910	44,360	0	92,59 %	3,550
IE	WHG/56-14	Whiting	VI, Union and international waters of Vb, international waters of XII and XIV	92,370	72,363	0	78,34 %	9,237
IE	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	7 668,960	6 902,221	0	90,00 %	766,739
LT	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	4 353,400	0	1 743,276	40,04 %	435,340
LT	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	2 663,000	0	2 478,427	93,07 %	184,573
LT	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	10 355,000	0	10 353,744	99,99 %	1,256
LV	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	6 283,000	0	2 441,400	38,86 %	628,300
LV	HER/03D.RG	Herring	Subdivision 28.1	18 463,000	18 462,300	0	100 %	0,700
NL	ANF/07.	Anglerfish	VII	15,200	0,501	0	3,30 %	1,520
NL	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	274,100	23,815	0	8,69 %	27,410
NL	ARU/1/2.	Greater silver smelt	Union and international waters of I and II	20,700	0	0	0 %	2,070
NL	ARU/34-C	Greater silver smelt	Union waters of III and IV	46,900	0	0	0 %	4,690
NL	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	3 147,100	1 430,210	0	45,45 %	314,710
NL	COD/07A.	Cod	VIIa	1,000	0	0	0 %	0,100

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
NL	COD/07D.	Cod	VIId	46,030	36,978	0	80,33 %	4,603
NL	COD/7XAD34	Cod	VIIb, VIIc, VIIe-k, VIII, IX and X, Union waters of CECAF 34.1.1	2,600	0,922	0	35,46 %	0,260
NL	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	149,000	0	0	0 %	14,900
NL	HAD/07A.	Haddock	VIIa	0,200	0	0	0 %	0,020
NL	HAD/2AC4.	Haddock	IV; Union waters of IIa	184,790	169,231	0	91,58 %	15,559
NL	HAD/7X7A34	Haddock	VIIb-k, VIII, IX and X; Union waters of CECAF 34.1.1	23,000	21,136	0	91,90 %	1,864
NL	HER/1/2-	Herring	Union, Norwegian and international waters of I and II	5 479,850	5 425,883	10,620	99,21 %	43,347
NL	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	2 370,260	2 130,949	0	89,90 %	237,026
NL	HER/7G-K.	Herring	VIIg, VIIh, VIIj and VIIk	865,370	314,834	0	36,38 %	86,537
NL	HKE/2AC4-C	Hake	Union waters of IIa and IV	81,020	42,102	0	51,96 %	8,102
NL	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	238,150	76,346	1,177	32,55 %	23,815
NL	HKE/8ABDE.	Hake	VIIIa, VIIIb, VIIId and VIIIe	24,800	0	6,700	27,02 %	2,480
NL	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	64 263,580	52 455,973	2450,424	85,44 %	6 426,358
NL	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	27,600	15,124	0	54,80 %	2,760
NL	LIN/04-C.	Ling	Union waters of IV	5,600	0	0	0 %	0,560
NL	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	0,300	0,100	0	33,33 %	0,030

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
NL	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	1 488,500	741,559	598,041	90,00 %	148,900
NL	MAC/2CX14-	Mackerel	VI, VII, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of IIa, XII and XIV	19 082,230	13 711,312	3 462,695	90,00 %	1 908,223
NL	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	1 219,270	862,899	0	70,77 %	121,927
NL	NEP/5BC6.	Norway lobster	VI; Union and international waters of Vb	18,000	0	0	0 %	1,800
NL	PLE/07A.	Plaice	VIIa	0,100	0	0	0 %	0,010
NL	PRA/2AC4-C	Northern prawn	Union waters of IIa and IV	41,900	0	0	0 %	4,190
NL	SOL/24-C.	Common sole	Union waters of II and IV	11 127,000	9 910,051	0	89,06 %	1 112,700
NL	SOL/3A/BCD	Common sole	IIIa; Union waters of Subdivisions 22-32	18,900	0	0	0 %	1,890
NL	SOL/7HJK.	Common sole	VIIh, VIIj and VIIk	59,040	0	0	0 %	5,904
NL	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	57 308,710	51 536,926	16,221	89,96 %	5 730,871
NL	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	972,250	736,710	0	75,77 %	97,225
PL	BSF/56712-	Black scabbardfish	EU and international waters of V, VI, VII and XII	38,500	0	0	0 %	3,850
PL	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	19 438,400	0	11 794,652	60,68 %	1 943,840
PT	BSF/8910-	Black scabbardfish	EU and international waters of VIII, IX and X	3 784,690	2 484,400	0	65,64 %	378,469
PT	GFB/1012-	Greater forkbeard	EU and international waters of X and XII	40,000	6,400	0	16,00 %	4,000
PT	HKE/8C3411	Hake	VIIIc, IX and X; Union waters of CECAF 34.1.1	4 624,560	3 191,100	0	69,00 %	462,456

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
PT	JAX/08C.	Horse mackerel and associated by-catches	VIIIc	2 281,270	1 778,700	0	77,97 %	228,127
PT	JAX/09.	Horse mackerel and associated by-catches	IX	22 413,800	20 088,700	0	89,63 %	2 241,380
PT	LEZ/8C3411	Megrims	VIIIc, IX and X; Union waters of CECAF 34.1.1	106,200	81,300	0	76,55 %	10,620
PT	NEP/9/3411	Norway lobster	IX and X; Union waters of CECAF 34.1.1	204,500	202,200	0	98,88 %	2,300
PT	SBR/09-	Red Seabream	EU and international waters of IX	184,200	109,800	0	59,61 %	18,420
PT	SBR/10-	Red Seabream	EU and international waters of X	1 128,000	571,700	0	50,68 %	112,800
SE	COD/3DX32.	Cod	EU waters of Subdivisions 25-32	16 032,100	0	5 287,710	32,98 %	1 603,210
SE	HAD/2AC4.	Haddock	IV; Union waters of IIa	28,500	17,570	0	61,65 %	2,850
SE	HER/1/2-	Herring	Union, Norwegian and international waters of I and II	57,340	50,550	0	88,16 %	5,734
SE	HER/30/31.	Herring	Subdivisions 30-31	11 892,500	0	10 937,740	91,97 %	954,760
SE	HER/3D-R30	Herring	Union waters of Subdivisions 25-27, 28.2, 29 and 32	29 272,000	0	28 830,000	98,49 %	442,000
SE	HKE/3A/BCD	Hake	IIIa; Union waters of Subdivisions 22-32	178,400	27,060	0	15,17 %	17,840
SE	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	677,300	0	0	0 %	67,730
SE	LIN/04-C.	Ling	Union waters of IV	11,100	0,240	0	2,16 %	1,110
SE	LIN/3A/BCD	Ling	IIIa; Union waters of IIIbcd	27,300	11,700	0	42,86 %	2,730
SE	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	2 941,540	2 101,050	829,280	99,62 %	11,210

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
SE	NEP/3A/BCD	Norway lobster	IIIa; Union waters of Subdivisions 22-32	1 538,400	1 124,740	0	73,11 %	153,840
SE	PRA/2AC4-C	Northern prawn	Union waters of IIa and IV	101,300	0	0	0 %	10,130
SE	SOL/3A/BCD	Common sole	IIIa; Union waters of Subdivisions 22-32	57,340	54,250	0	94,61 %	3,090
SE	SPR/3BCD-C	Sprat	Union waters of Subdivisions 22-32	50 490,000	0	50 489,430	100,00 %	0,570
SE	USK/04-C.	Tusk	Union waters of IV	6,600	0	0	0 %	0,660
SE	USK/3A/BCD	Tusk	IIIa; Union waters of Subdivisions 22-32	7,700	1,030	0	13,38 %	0,770
SE	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	29,710	26,710	0	89,90 %	2,971
UK	ALF/3X14-	Alfonsinos	EU and international waters of III, IV, V, VI, VII, VIII, IX, X, XII and XIV	11,100	1,400	0	12,61 %	1,110
UK	ANF/07.	Anglerfish	VII	6 533,860	6 152,200	197,500	97,18 %	184,160
UK	ANF/2AC4-C	Anglerfish	Union waters of IIa and IV	7 893,800	4 778,900	314,100	64,52 %	789,380
UK	ARU/1/2.	Greater silver smelt	Union and international waters of I and II	43,600	0	0	0 %	4,360
UK	ARU/34-C	Greater silver smelt	Union waters of III and IV	17,900	0	0	0 %	1,790
UK	ARU/567.	Greater silver smelt	Union and international waters of V, VI and VII	45,700	0	0	0 %	4,570
UK	BLI/5B67-	Blue ling	Union and international waters of Vb, VI, VII	253,560	203,600	0	80,30 %	25,356
UK	BSF/56712-	Black scabbardfish	EU and international waters of V, VI, VII and XII	76,860	56,900	0	74,03 %	7,686
UK	COD/07A.	Cod	VIIa	120,400	107,400	0	89,20 %	12,040
UK	COD/07D.	Cod	VIId	179,150	99,800	0	55,71 %	17,915

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
UK	COD/7XAD34	Cod	VIIb, VIIc, VIIe-k, VIII, IX and X, Union waters of CECAF 34.1.1	883,500	548,100	0	62,04 %	88,350
UK	GFB/1012-	Greater forkbeard	EU and international waters of X and XII	10,000	0	0	0 %	1,000
UK	GFB/1234-	Greater forkbeard	EU and international waters of I, II, III and IV	14,500	2,100	0	14,48 %	1,450
UK	GFB/567-	Greater forkbeard	EU and international waters of V, VI and VII	679,100	251,300	0	37,00 %	67,910
UK	GHL/2A-C46	Greenland halibut	Union waters of IIa and IV, Union and international waters of Vb and VI	535,000	344,500	0	64,39 %	53,500
UK	HAD/07A.	Haddock	VIIa	615,000	154,400	0	25,11 %	61,500
UK	HAD/2AC4.	Haddock	IV; Union waters of IIa	33 209,290	29 446,500	3 498,100	99,20 %	264,690
UK	HAD/5BC6A.	Haddock	Union and international waters of Vb and VIa	3 926,500	3 875,900	0	98,71 %	50,600
UK	HAD/6B1214	Haddock	Union and international waters of VIb, XII and XIV	1 097,800	595,400	0	54,24 %	109,780
UK	HER/07A/MM	Herring	VIIa	5 012,700	5 000,200	0	99,75 %	12,500
UK	HER/5B6ANB	Herring	Union and international waters of Vb, VIb and VIaN	16 314,850	15 734,300	0	96,44 %	580,550
UK	HER/7G-K.	Herring	VIIg, VIIh, VIIj and VIIk	23,800	1,200	0	5,04 %	2,380
UK	HKE/2AC4-C	Hake	Union waters of IIa and IV	1 838,900	1 658,000	0	90,16 %	180,900
UK	HKE/571214	Hake	VI and VII; Union and international waters of Vb; international waters of XII and XIV	6 527,800	5 224,300	86,300	81,35 %	652,780
UK	JAX/2A-14	Horse mackerel and associated by-catches	Union waters of IIa, IVa; VI, VIIa-c, VIIe-k, VIIIa, VIIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of XII and XIV	7 909,400	6 788,600	0	85,83 %	790,940
UK	LEZ/07.	Megrims	VII	3 212,050	3 055,400	0	95,12 %	156,650

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
UK	LEZ/2AC4-C	Megrims	Union waters of IIa and IV	2 043,600	1 686,900	0	82,55 %	204,360
UK	LEZ/56-14	Megrims	Union and international waters of Vb; VI; international waters of XII and XIV	1 179,300	527,400	0	44,72 %	117,930
UK	LIN/04-C.	Ling	Union waters of IV	2 172,400	2 069,100	0	95,24 %	103,300
UK	LIN/1/2.	Ling	Union and international waters of I and II	8,900	0,800	0	8,99 %	0,890
UK	LIN/6X14.	Ling	Union and international waters of VI, VII, VIII, IX, X, XII and XIV	2 872,800	2 365,700	0	82,35 %	287,280
UK	MAC/2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	1 364,600	795,400	546,700	98,35 %	22,500
UK	NEP/07.	Norway lobster	VII	7 740,000	6 872,000	118,200	90,31 %	749,800
UK	NEP/2AC4-C	Norway lobster	Union waters of IIa and IV	15 949,850	8 423,600	0	52,81 %	1 594,985
UK	NEP/5BC6.	Norway lobster	VI; Union and international waters of Vb	17 698,500	12 826,800	0	72,47 %	1 769,850
UK	PLE/07A.	Plaice	VIIa	519,600	90,000	0	17,32 %	51,960
UK	PLE/7DE.	Plaice	VIId and VIIe	1 822,400	1 680,400	0	92,21 %	142,000
UK	POK/56-14	Saithe	VI; Union and international waters of Vb, XII and XIV	4 485,830	3 647,500	0	81,31 %	448,583
UK	PRA/2AC4-C	Northern prawn	Union waters of IIa and IV	730,700	0,200	0	0,03 %	73,070
UK	RNG/5B67-	Roundnose grenadier	EU and international waters of Vb, VI, VII	192,900	6,000	0	3,11 %	19,290
UK	RNG/8X14-	Roundnose grenadier	EU and international waters of VIII, IX, X, XII and XIV	11,400	0	0	0 %	1,140
UK	SBR/10-	Red Seabream	EU and international waters of X	10,100	0	0	0 %	1,010

Country ID	Stock Id	Species	Zone name	Final Quota 2013 (1) (in tonnes)	Catches 2013 (in tonnes)	Special Condition catches 2013 (in tonnes)	Final quota	Transferred quantity (in tonnes)
UK	SBR/678-	Red Seabream	EU and international waters of VI, VII and VIII	5,400	0,400	0	7,41 %	0,540
UK	SOL/07D.	Common sole	VIId	1 233,200	604,900	0	49,05 %	123,320
UK	SOL/07E.	Common sole	VIIe	581,300	536,900	0	92,36 %	44,400
UK	SOL/24-C.	Common sole	Union waters of II and IV	976,200	857,800	0	87,87 %	97,620
UK	SOL/7HJK.	Common sole	VIIh, VIIj and VIIk	74,800	46,600	0	62,30 %	7,480
UK	USK/04-C.	Tusk	Union waters of IV	105,300	74,600	0	70,85 %	10,530
UK	USK/567EI.	Tusk	Union and international waters of V, VI and VII	264,760	77,800	0	29,39 %	26,476
UK	WHB/1X14	Blue whiting	Union and international waters of I, II, III, IV, V, VI, VII, VIIIa, VIIIb, VIIId, VIIIe, XII and XIV	14 939,800	13 498,600	0	90,35 %	1 441,200
UK	WHG/07A.	Whiting	VIIa	31,700	20,200	0	63,72 %	3,170
UK	WHG/56-14	Whiting	VI, Union and international waters of Vb, international waters of XII and XIV	164,100	118,500	0	72,21 %	16,410
UK	WHG/7X7A-C	Whiting	VIIb, VIIc, VIId, VIIe, VIIf, VIIg, VIIh, VIIj and VIIk	2 095,000	1 379,600	0	65,85 %	209,500

(1) Quotas available to a Member State pursuant to the relevant fishing opportunities Regulations after taking into account exchanges of fishing opportunities in accordance with Article 20(5) of Council Regulation (EC) No 2371/2002 (OJ L 358, 31.12.2002, p. 59), quota transfers in accordance with Article 4(2) of Regulation (EC) No 847/96 and/or reallocation and deduction of fishing opportunities in accordance with Articles 37 and 105 of Council Regulation (EC) No 1224/2009 (OJ L 343, 22.12.2009, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) No 521/2014

of 16 May 2014

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 16 May 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MA	41,3
	MK	84,5
	TR	65,9
	ZZ	63,9
0707 00 05	AL	41,5
	MK	41,5
	TR	125,0
	ZZ	69,3
0709 93 10	TR	113,0
	ZZ	113,0
0805 10 20	EG	44,1
	IL	74,1
	MA	40,7
	TN	68,6
	TR	53,3
	ZZ	56,2
0805 50 10	TR	85,1
	ZZ	85,1
0808 10 80	AR	100,1
	BR	88,0
	CL	102,6
	CN	127,0
	MK	32,3
	NZ	135,5
	US	190,9
	UY	78,1
	ZA	98,2
	ZZ	105,9

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION EUTM MALI/2/2014

of 13 May 2014

on the acceptance of third States' contributions to the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali)

(2014/285/CFSP)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Decision 2013/34/CFSP of 17 January 2013 on a European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) [1], and in particular Article 8(2) thereof,

Whereas:

(1) Pursuant to Article 8(2) of Decision 2013/34/CFSP, the Council authorised the Political and Security Committee (PSC) to take the relevant decisions on acceptance of the proposed contributions by third States.

(2) Following recommendation on contributions from Georgia, the Republic of Moldova, and Montenegro by the EU Mission Commander and the advice from the European Union Military Committee, the contributions from Georgia, the Republic of Moldova, and Montenegro should be accepted.

(3) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on the European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and implementation of decisions and actions of the Union which have defence implications,

HAS ADOPTED THIS DECISION:

Article 1

1. The contributions from Georgia, the Republic of Moldova, and Montenegro to the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) are accepted and are considered to be significant.

2. Georgia, the Republic of Moldova, and Montenegro are exempted from financial contributions to the budget of EUTM Mali.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 13 May 2014.

For the Political and Security Committee

The Chairperson

W. STEVENS

[1] OJ L 14, 18.1.2013, p. 19.

COMMISSION DELEGATED DECISION

of 10 March 2014

setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

(Text with EEA relevance)

(2014/286/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [1], and in particular point (a) of Article 12(4) thereof,

Whereas:

(1) Article 12 of Directive 2011/24/EU provides that the Commission is to support the Member States in the development of European Reference Networks ('Networks') between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases [2]. For the purposes of this, the Commission shall adopt a list of specific criteria and conditions that must be fulfilled by European Reference Networks and healthcare providers wishing to join and become a Member of a Network ('Member'). The Networks should improve access to diagnosis, treatment and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.

(2) According to Article 12(2) of Directive 2011/24/EU, each Network is to select at least three objectives from the list laid down in therein 12(2) of Directive 2011/24/EU and demonstrate that it has the necessary competences to pursue them effectively. In addition, Networks are required to fulfil the list of tasks or characteristics laid down in Article 12(4)(a)(i)-(vi) of Directive 2011/24/EU. This Decision sets out the specific list of criteria or conditions that will ensure the Networks fulfil these tasks. These criteria and conditions should provide the basis for the establishment and evaluation of the Networks.

(3) Among the set of criteria and conditions necessary to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU the Decision provides a list of criteria on the governance and coordination of the Networks that should ensure their transparent and effective functioning. Although Networks should be allowed to have different organisation models, it is appropriate to require that they all choose one of their Members as the coordinating Member. The coordinating Member shall appoint one person acting as the coordinator of the Network ('Coordinator'). They should be governed by a board of the Network ('Board') composed of representatives from each Member in the Network. The Board should be in charge of producing and adopting the rules of procedure, work plans and progress reports and any other documents related to the activities of the Network. The Coordinator, assisted by the Board, should support and facilitate the internal coordination within the Network and with other healthcare providers.

(4) The provision of highly specialised healthcare, one of the criteria to be fulfilled by the Networks, should be based on high quality, accessible and cost-effective healthcare services. It requires experienced, highly skilled and multidisciplinary healthcare teams and, most likely, advanced specialised medical equipment or infrastructures which commonly imply concentration of resources.

[1] OJ L 88, 4.4.2011, p. 45.
[2] COM(2008) 679 final.

(5) Healthcare providers who apply for membership of a Network should demonstrate that they fulfil the criteria and conditions laid down in this Decision. These criteria and conditions should guarantee that the services and healthcare are provided according to the highest possible quality criteria and available clinical evidence.

(6) The required criteria and conditions for a healthcare provider would vary depending on the diseases or conditions specifically addressed by the Network of which they want to become a Member. It therefore appears necessary to establish two sets of criteria and conditions: a first set of horizontal criteria and conditions that should be fulfilled by all healthcare providers wishing to join a Network, regardless of the field of expertise or the medical procedure or treatment they perform, and a second set of criteria and conditions that may vary depending on the scope of the concrete area of expertise, disease or condition addressed by the Network they wish to join.

(7) Among the first set of horizontal and structural criteria and conditions, those related to patients empowerment and patient-centred care; organisation, management and business continuity; research and training capacity appear to be essential in order to ensure that the objectives of the Networks are met.

(8) Further horizontal and structural criteria and conditions related to the exchange of expertise, information systems and eHealth tools should help developing, sharing and spreading information and knowledge and fostering improvements in the diagnosis and treatment of diseases within and outside the Networks and to collaborate closely with other centres of expertise and networks at national and international level. Interoperable and semantically compatible information and communication technology (ICT) systems would facilitate the exchange of health data and patients' information, and the establishment and maintenance of shared databases and registries.

(9) The ability to have an efficient and secure exchange of health data and other patient information as well personal data of the healthcare professionals in charge of the patient is a crucial aspect for the successful functioning of the Networks. The exchange of data should in particular take place in accordance with the specified purposes, necessity and legal grounds for the processing of data and be accompanied by appropriate safeguards and rights of the data subject. Personal data should be processed in compliance with Directive 95/46/EC of the European Parliament and of the Council ([1]).

(10) This Decision respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, as referred to in Article 6 of the Treaty on European Union and notably the right of human dignity, the right to the integrity of the person, the right to the protection of personal data and the right of access to healthcare. This Decision must be applied by the Member States in accordance with the rights and principles guaranteed in the Charter.

(11) In particular, the Charter requires that in the field of biology and medicine the free and informed consent of the person concerned must be respected. As Clinical Trials could likely be one of the areas of work of the Networks it is important to recall that an extensive set of rules for the protection of subjects in clinical trials is foreseen in Directive 2001/20/EC of the European Parliament and of the Council ([2]).

(12) In order to ensure the exchange of personal data in the context of the Networks, procedures concerning informed consent for processing this data could be simplified by using one single common consent model that needs to be subject to the requirements set out in Directive 95/46/EC with regard to the consent of the data subject.

(13) The criteria and conditions related to expertise, clinical practice, quality, patient safety and evaluation should help in developing and spreading the best practices for quality and safety benchmarks. They should also thus ensure the offer of a high level of expertise, produce good practice guidelines, implement outcome measures and quality control and follow a multi-disciplinary approach as required by Article 12(4) of Directive 2011/24/EU.

([1]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

([2]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

(14) Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given Network, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing in the provision of healthcare or as Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care. Member States may also wish to designate a national coordination hub with all types of Networks. That might help Member States to pursue Article 12(3)(a) of Directive 2011/24/EU particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU. The Coordinator should facilitate the cooperation with these healthcare providers linked to a Network. Those healthcare providers shall support the objectives and respect the rules of the Network and share the work related with the cooperation activities of the Network,

HAS ADOPTED THIS DECISION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Decision lays down:

(a) the criteria and conditions that the Networks referred to in Article 12 of Directive 2011/24/EU must fulfil; and

(b) the criteria and conditions required from healthcare providers wishing to join a Network referred to in Article 12 of Directive 2011/24/EU.

Article 2

Definitions

For the purpose of this Decision and in addition to the definitions laid down in Article 3 of Directive 2011/24/EU the following definitions shall apply:

(a) 'Member of a Network' means healthcare providers that are in compliance with the list of criteria and conditions laid down in Article 5 of this Decision and have been awarded with the membership of a given Network;

(b) 'Highly specialised healthcare' means healthcare that involves high complexity of a particular disease or condition in its diagnosis or treatment or management and high cost of the treatment and resources involved;

(c) Complex disease or condition' means a particular disease or disorder which combines a number of factors, symptoms, or signs that requires a multidisciplinary approach and well-planned organisation of services over time because it implies one or several of the following circumstances:

— a large number of possible diagnoses or management options and comorbidity,

— difficult interpretation of clinical and diagnostic tests data,

— a high risk of complications, morbidity, or mortality related to either the problem, the diagnostic procedure or the management;

(d) 'Multidisciplinary healthcare team' means a group of health professionals from several fields of healthcare, combining skills and resources, each providing specific services and collaborating on the same case and coordinating the healthcare to be provided to the patient;

(e) 'Informed consent under the framework of European Reference Networks' means any freely-given, specific, informed and explicit indication of a subject's wishes by which he or she, either by a statement or by a clear affirmative action, signifies agreement to the exchange of her or his personal and health data between healthcare providers and Members of a European Reference Network as provided in this Delegated Decision.

CHAPTER II

EUROPEAN REFERENCE NETWORKS

Article 3

Criteria and conditions for Networks

Networks shall fulfil the criteria and conditions necessary to enable them pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU set out in Annex I.

Article 4

Membership of the Networks

Networks shall be composed of healthcare providers identified as Members of the Network. For each network, one Member will act as Coordinator.

CHAPTER III

HEALTHCARE PROVIDERS

Article 5

Criteria and conditions for applicants of membership of a Network

All applicants wishing to join a given Network must have knowledge and expertise or offer a diagnosis or a treatment that focusses on a disease or condition falling within the field of specialisation of the Network and shall fulfil the criteria and conditions set out in Annex II.

CHAPTER IV

FINAL PROVISION

Article 6

This Decision shall enter into force on the 10th day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

CRITERIA AND CONDITIONS TO BE FULFILLED BY THE NETWORKS

(1) In order to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU, each Network shall:

(a) provide highly specialised healthcare for rare or low prevalence complex diseases or conditions;

(b) have a clear governance and coordination structure including at least the following:

(i) the Members' Representatives who will represent them within the Network Each Member shall choose its representative from among the health professionals belonging to its staff;

(ii) the Board of the Network that will be responsible for its governance. All Members of the Network must be represented on the Board;

(iii) the Coordinator of the Network, chosen from among the health professionals belonging to the staff of the coordinating Member, who will chair the meetings of the Board and represent the Network.

(2) To fulfil the requirement set out in point (i) of Article 12(4)(a) of Directive 2011/24/EU ('have knowledge and expertise to diagnose, follow up and manage patients with evidence of good outcomes'), the Networks must:

(a) promote good quality and safe care to patients suffering from certain diseases and conditions by fostering proper diagnosis, treatment, follow-up and management of patients across the Network;

(b) empower and involve patients in order to improve the safety and good quality of the care they receive.

(3) To fulfil the requirement set out in point (ii) of Article 12(4)(a) of Directive 2011/24/EU ('follow a multi-disciplinary approach'), the Networks must:

(a) identify areas and best practices for multi-disciplinary work;

(b) be made up of multi-disciplinary healthcare teams;

(c) offer and promote multi-disciplinary advice for complex cases.

(4) To fulfil the requirement set out in point (iii) of Article 12(4)(a) of Directive 2011/24/EU ('offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control'), the Networks must:

(a) exchange, gather and disseminate knowledge, evidence and expertise within and outside the Network, in particular on the different alternatives, therapeutic options and best practices with regard to the provision of services and the treatments available for each particular disease or condition;

(b) promote expertise and support healthcare providers in order to bring local, regional and national provision of healthcare closer to patients;

(c) develop and implement clinical guidelines and cross-border patient pathways;

(d) design and implement outcome and performance indicators;

(e) develop and maintain a quality, patient safety and evaluation framework.

(5) To fulfil the requirement set out in point (iv) of Article 12(4)(a) of Directive 2011/24/EU ('make a contribution to research'), the Networks must:

(a) identify and fill research gaps;

(b) promote collaborative research within the Network;

(c) reinforce research and epidemiological surveillance, through setting up of shared registries.

(6) To fulfil the requirement set out in point (v) of Article 12(4)(a) of Directive 2011/24/EU ('organise teaching and training activities'), the Networks must:

(a) identify and fill training gaps;

(b) encourage and facilitate the development of training and continuous education programmes and tools for health-care providers involved in the chain of care (within or outside the Network).

(7) To comply with the requirement set out in point (vi) of Article 12(4)(a) of Directive 2011/24/EU ('collaborate closely with other centres of expertise and networks at national and international level'), the Networks must:

(a) exchange and disseminate knowledge and best practices, in particular by supporting national centres and networks;

(b) set up networking elements, such as communication tools, and methodologies to develop clinical guidelines and protocols; exchange clinical information in accordance with EU data protection provisions and national implementing measures, in particular Directive 95/46/EC, and Article 3 of this Delegated Decision; develop training alternatives and models and operation and coordination practices, etc.;

(c) collaborate with Associated National Centres and Collaborative National Centres chosen by Member States with no Member of a given Network, particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU.

ANNEX II

CRITERIA AND CONDITIONS FOR APPLICANTS FOR MEMBERSHIP OF A NETWORK

1. **General criteria and conditions for all applicant healthcare providers**

All applicants wishing to join a Network shall comply with the following criteria and conditions:

(a) as regards patient empowerment and patient-centred care, applicant providers must:

(i) have put strategies in place to ensure that care is patient-centred, that patients' rights (such as the right to informed consent; the right to information concerning their own health; the right to access to their medical records; the right to privacy; the right to complain and the right to obtain compensation, the right to be empowered and to participate (for example, through customer relations management strategies, patient education strategies and active engagement strategies for patients and families throughout the healthcare institution)) are respected;

(ii) provide clear and transparent information about complaint procedures and the remedies and forms of redress available to both domestic and foreign patients;

(iii) ensure feedback on patient experience and the active evaluation of patient experience;

(iv) apply personal data protection rules and ensure access to medical records and clinical information in compliance with EU data protection provisions and national implementing measures and in particular with Directive 95/46/EC;

(v) ensure that the informed consent of the data subject complies with the requirements set out in Article 2(e) of this Delegated Decision, in particular informed consent given freely, unambiguously and explicitly by the subject or his/her legal representative after being informed of the purpose, nature, significance and implications of the use of his/her personal and health data, if personal health data is exchanged under this Delegated Decision, and being informed of his/her rights under the applicable data protection rules. The given consent should be duly documented;

(vi) ensure transparency, including providing information about clinical outcomes, treatment options and the quality and safety standards put in place;

(b) with regard to organisation, management and business continuity, applicant providers must:

(i) apply transparent and explicit organisation and management rules and procedures, including in particular the procedures for managing cross-border patients in their area of expertise;

(ii) ensure that tariffs are transparent;

(iii) have a business continuity plan over a given time frame, including ensuring:

— the provision of essential medical care in the case of unexpected resource failure, or access or referral to alternative resources if necessary,

— the maintenance of the stability and technical capacity and expertise of the provider, such as a plan for managing human resources and updating technology;

(iv) ensure coordination with and easy access of the provider to other resources or specific units or services necessary for managing patients;

(v) have good general facilities, such as surgery theatres, an intensive care unit, an isolation unit, an emergency ward and laboratories;

(vi) have the capacity to communicate with relevant post-discharge services, including the capacity for cross-border communication;

(c) with regard to research and training capacity, applicant providers must:

(i) have the capacity to provide academic, university or specialised level training;

(ii) have human, technical and structural capacity, skill mix and resources;

(iii) have research capacity, and demonstrated research experience or production in the area of expertise of the Network, at national and international level;

(iv) carry out teaching and education activities related to the area of expertise aimed at improving the knowledge and technical capacity of the healthcare providers involved in the same chain of care within and outside the provider facility, such as continuing medical education and distance learning;

(d) with regard to the exchange of expertise, information systems and e-health tools, applicant providers must:

(i) be able to exchange expertise with other healthcare providers and to support them;

(ii) have established procedures and a framework for ensuring the management, safeguarding and exchange of medical data, including established outcomes, process indicators and patient registers for the specific area of expertise in accordance with the EU data protection legislation, in particular with Directive 95/46/EC, and with Article 2(e) of this Delegated Decision;

(iii) be able to foster the use of telemedicine and other e-health tools within and outside their facilities, by fulfilling the minimum interoperability requirements and when possible, using agreed standards and recommendations;

(iv) use a standardised information and coding system in line with nationally or internationally recognised systems, for example International Classification of Diseases and complementary codes when appropriate;

(e) with regard to expertise, good practices, quality, patient safety and evaluation, applicant providers must:

(i) have a quality assurance or management system and plans including governance and evaluation of the system;

(ii) have a patient safety programme or plan consisting of specific goals, procedures, standards and process and outcome indicators focusing on key areas, such as information, a system for reporting on and learning from adverse events; training and education activities; hand hygiene; healthcare related infections; medication errors and the safe use of medication; safe procedures and surgery; safe patient identification;

(iii) commit itself to using the best knowledge- and evidence-based health technologies and treatments;

(iv) develop and use clinical guidelines and pathways in their area of expertise.

2. **Specific criteria and conditions for applicant providers with regard to the area of expertise, disease or conditions the Networks they wish to join focus on**

(a) with regard to competence, experience and outcomes of care, applicant providers must:

(i) document competence, experience and activity (e.g. the volume of activity, referrals and accumulated experience and when possible, the minimum/optimal number of patients/year, in accordance with professional/technical standards or recommendations);

(ii) provide evidence of good clinical care and outcomes according to available standards, indicators and knowledge, and evidence that the treatments offered are recognised by international medical science in terms of their safety, value and potential positive clinical outcome;

(b) with regard to the specific human, structural and equipment resources and the organisation of care, applicant providers must document:

(i) the characteristics of human resources such as type, number, qualifications and skills;

(ii) the characteristics, organisation and functioning of the specific multidisciplinary healthcare team;

(iii) specific equipment within the centre or easily accessible (such as radiotherapy laboratories or hemodynamic facilities), including the capacity, when appropriate and based on the area of expertise, to process, manage and exchange information and biomedical images (such as in the case of radiology x-ray machines, microscopy, video-endoscopy and other dynamic explorations) or clinical samples with external providers.

COMMISSION IMPLEMENTING DECISION

of 10 March 2014

setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

(Text with EEA relevance)

(2014/287/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [1], and in particular Article 12(4)(b) and (c) thereof,

Whereas:

(1) Commission Delegated Decision 2014/286/EU [2] sets out the criteria and conditions that European Reference Networks ('Networks') and healthcare providers wishing to join such Networks must fulfil.

(2) Pursuant to Article 12(4)(b) and (c) of Directive 2011/24/EU, the Commission is to decide the criteria for establishing and evaluating the Networks and the measures for facilitating the exchange of information and expertise on establishing and evaluating the Networks.

(3) Networks should be established and healthcare providers approved as Members of the Networks on the basis of an open and transparent procedure. The procedure should include: (1) the call for interest; (2) Member States' endorsement of applications of their healthcare providers; (3) the submission of applications to the Commission; (4) the verification of the completeness of applications; (5) the technical assessment by an independent body of applications to form the Networks and of applications from individual healthcare providers wishing to be Members of a Network, to determine whether the applicants fulfil the criteria; (6) the communication of the assessment outcomes; (7) the approval of the Networks and their membership by Member States; and (8) the publication of the list of established Networks and of their Members.

(4) In order to increase the coverage of the Networks, individual healthcare providers wishing to join a Network should be allowed to do so at any time. Their applications should be assessed according to the same procedure as that used to assess applications for the initial Network, including the endorsement of applications by the Member State in question.

(5) In order to guarantee that the Network has genuine European Union added value and is big enough to enable the sharing of expertise and to improve access to care for patients across the Union, only applications from the minimum required numbers of healthcare providers and Member States, submitted in line with the call of interest, should be approved. If an insufficient number of healthcare providers apply or applications cover an insufficient number of Member States, the Commission should ask Member States to encourage their healthcare providers to join the proposed Network.

(6) It might be difficult to reach the required minimum number of healthcare providers or Member States for some rare diseases or conditions due to a lack of expertise. It would therefore be a good idea to group healthcare providers that focus on related rare diseases or conditions in a thematic Network. Networks could also include providers of high technology services which usually require very high capital investment, such as laboratories, radiology services or nuclear medicine services.

[1] OJ L 88, 4.4.2011, p. 45.
[2] See page 71 of this Official Journal.

(7) Member States none of whose healthcare providers are Members of a Network should designate collaborative and associated national centres to encourage them to cooperate with the relevant Network.

(8) Each Network's and healthcare provider's application, once their completeness has been established, should be technically assessed according to the criteria set out in Delegated Decision 2014/286/EU. The assessment should, on the basis of a common assessment manual, include an exhaustive documentation review and on-site audits of a selected number of applicants. It should be carried out by an independent assessment body appointed by the Commission.

(9) Member States are invited to set up a Board of Member States which should decide on the approval of proposed Networks and on their membership. Member States' participation should be voluntary. Only a positive assessment issued by an assessment body should generally prompt Member States to approve the establishment of a Network and to grant membership of the Network.

(10) Networks' Members should be licensed to use the 'European Reference Network' logo. The logo, owned by the European Union, should constitute the visual identity of the Networks and their Members.

(11) Using a common evaluation manual, an independent evaluation body appointed by the Commission should periodically evaluate Networks and their Members. The evaluation should conclude with a technical evaluation report detailing the extent to which the objectives set out in Article 12(2) of Directive 2011/24/EU have been achieved and the criteria and conditions set out in Delegated Decision 2014/286/EU fulfilled. It should also describe the outcomes and performance of the Network and the contribution of its Members. A negative evaluation report should generally prompt Member States to approve the termination of a Network. Compliance with the requirement to have a minimum number of healthcare providers and Member States should be monitored after the evaluation so that the European Union added value of the Network can be maintained.

(12) The assessment and evaluation manuals should be based on internationally recognised practices and contain the core principles and methodologies for carrying out assessments and evaluations.

(13) The Commission should facilitate the exchange of information and expertise on establishing and evaluating the Networks. It should make general information on the Networks and their Members and the technical documentation and manuals on establishing and evaluating the Networks and their Members available to the public. It may offer to the Networks and their Members the use of specific communication media and tools. Conferences and experts meetings should be organised to provide a forum for technical and scientific debate among Networks.

(14) The personal data related to establishing and evaluating the Networks should be processed in compliance with Regulation (EC) No 45/2001 of the European Parliament and of the Council [1] as appropriate.

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 16 of Directive 2011/24/EU,

HAS ADOPTED THIS DECISION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Decision sets out:

(a) the criteria for establishing and evaluating the Networks referred to in Article 12 of Directive 2011/24/EU; and

(b) the measures to facilitate the exchange of information and expertise on establishing and evaluating the Networks referred to in Article 12 of Directive 2011/24/EU.

[1] OJ L 8, 12.1.2001, p. 1.

CHAPTER II

ESTABLISHMENT OF EUROPEAN REFERENCE NETWORKS

Article 2

Call for interest to establish a European Reference Network

1. The Commission shall publish a call for interest to establish Networks within two years following the entry into force of this Decision.

2. Any group of at least 10 healthcare providers established in at least 8 Member States may collectively respond by the deadline indicated in the call for interest with an application containing a proposal to establish a Network in a given field of expertise.

3. The content of the application shall be as set out in Annex I.

4. On receiving an application, the Commission shall verify whether the conditions on the minimum number of healthcare providers and Member States as set out in paragraph 2 are met.

5. If either of those conditions is not met, the application shall not be entitled to assessment and the Commission shall ask Member States to encourage their healthcare providers to join the proposed Network in order to help reach the required number(s).

6. After consulting the Member States, the Commission shall decide on the appropriate timing for the publication of subsequent calls for interest.

Article 3

Membership applications

1. The application containing a proposal to establish a Network shall be accompanied by a membership application for each healthcare provider concerned.

2. The content of the membership application shall be as set out in Annex II.

3. The membership application shall be accompanied by a written statement from the healthcare provider's Member State of establishment certifying that its participation in the proposal to establish a Network is in accordance with the Member State's national legislation.

Article 4

Technical assessment of applications

1. If the Commission concludes that the requirements set out in Article 2(2) and in Article 3(2) and (3) are fulfilled, it shall appoint an assessment body to assess applications.

2. The assessment body shall verify whether:

(a) the content of an application containing a proposal to establish a Network fulfils the requirements set out in Annex I to this Decision;

(b) the content of the membership applications fulfils the requirements of Annex II to this Decision;

(c) the proposed Network fulfils the requirement to provide highly specialised healthcare in point 1(a) of Annex I to Delegated Decision 2014/286/EU;

(d) the proposed Network fulfils the other criteria and conditions set out in Annex I to Delegated Decision 2014/286/EU;

(e) the applicant healthcare providers fulfil the criteria and conditions set out in Annex II to Delegated Decision 2014/286/EU.

3. The assessment pursuant to points (d) and (e) of paragraph 2 shall only take place if the assessment body concludes that the proposal fulfils the requirements referred to in points (a), (b) and (c) of paragraph 2.

4. The assessment body shall draw up an assessment report on the application containing a proposal to establish a Network and the membership applications and send all reports to the Commission.

5. The assessment body shall send to each applicant healthcare provider the assessment report on the proposed Network and on its own membership application. The healthcare provider may send comments to the assessment body within two months of receiving the reports. On receiving the comments, the assessment body shall amend its assessment reports explaining whether the comments justify a change in its assessment.

Article 5

Approval of Networks and Members

1. On receiving an assessment report on a proposal for a Network and the proposed list of Members, drawn up pursuant to Article 4, and after verifying that the minimum number of healthcare providers and Member States set out in Article 2(2) is reached, Member States shall, within a Board of Member States as provided in Article 6, decide on the approval of the proposed Network and its Members.

2. By virtue of the approval referred to in paragraph 1, the proposed Networks shall be established as European Reference Networks.

3. If the minimum number of healthcare providers or of Member States set out in Article 2(2) is not reached, the Network shall not be established and the Commission shall ask Member States to encourage their healthcare providers to join the proposed Networks.

4. If a healthcare provider is given a negative assessment, it will be for that healthcare provider to decide whether it wants to submit its membership application, with the assessment report on the application, to the Board of Member States for review.

Article 6

Board of Member States

1. Member States are invited to set up a Board of Member States which shall decide whether or not to approve the proposals for Networks, their membership and the termination of a Network. If their decision differs from the assessment of the assessment body, the Member States shall give the reasons for this.

2. Member States wishing to be on the Board of Member States shall notify the Commission the national authority that shall represent them.

3. The Board of Member States shall adopt by a simple majority of its members its own rules of procedures, on the proposal of the Commission services.

4. The rules of procedure shall cover the functioning and decision-making process of the Board of Member States and specify which of its members are entitled to vote on the approval of a specific Network, which majority will determine the outcome of a vote, and what procedure to follow if the Board's decision differs from the assessment report on a Network proposal or membership application.

5. The Commission shall provide the secretariat of the Board of Member States.

6. The personal data of representatives of Member States on the Board of Member States shall be collected, processed and published in accordance with Regulation (EC) No 45/2001.

Article 7

Logo

When a Network is approved, the Commission shall license the use of a unique graphic identifier ('logo'), which that Network and its Members shall use for the activities organised by the Network.

Article 8

Applications for membership of existing Networks

1. A healthcare provider wishing to join an existing Network shall submit a membership application to the Commission.

2. The content of the membership application shall be as set out in Annex II.

3. The membership application shall be accompanied by a written statement from the healthcare provider's Member State of establishment certifying that its participation in the Network is in accordance with the Member State's national legislation.

Article 9

Technical assessment of applications for membership of existing Networks

1. If the Commission concludes that the requirements set out in Article 8(2) and (3) are fulfilled, it shall appoint a body to assess the membership application.

2. The assessment body shall verify whether:

(a) the content of the membership application fulfils the requirements set out in Annex II to this Decision; and

(b) the healthcare provider concerned fulfils the criteria and conditions set out in Annex II to Delegated Decision 2014/286/EU.

3. The assessment pursuant to point (b) of paragraph 2 shall only take place if the assessment body concludes that the membership application fulfils the requirements referred to in point (a) of paragraph 2.

4. The assessment body shall draw up an assessment report and send it to the Commission and to the applicant healthcare provider. The healthcare provider may send comments to the assessment body within two months of receiving the report. On receiving of such comments, the assessment body shall amend its assessment report explaining whether the comments justify a change in its assessment.

Article 10

Approval of new Members

1. On receiving a positive assessment report drawn up pursuant to Article 9, the Board of Member States shall decide whether or not to approve the new Member.

2. If a healthcare provider is given a negative assessment, it will be for that healthcare provider to decide whether it wants to submit its membership application, with the assessment report on the application, to the Board of Member States for review.

Article 11

Termination of the Network

1. A Network shall be terminated in the following cases:

(a) one of the minimum numbers set out in Article 2(2) is no longer reached;

(b) a negative evaluation report of the Network has been drawn up pursuant to Article 14;

(c) by decision of the Board of the Network according to its rules and procedures;

(d) if the Coordinator fails to request an evaluation of the Network within the five- year period after it was set up or since its last evaluation.

2. The termination of a Network, on the grounds listed in paragraph 1(a) and (b), must be approved by the Board of Member States referred to in Article 6.

Article 12

Loss of membership

1. A Member of a Network may lose membership for any of the following reasons:

(a) voluntary withdrawal, according to the rules and procedures agreed by the Board of the Network;

(b) by decision of the Board of the Network, according to the rules and procedures agreed by the Board;

(c) if a Member State of establishment notifies to the Member of the Network that its participation in the Network no longer complies with national legislation;

(d) if the Member refuses to be evaluated pursuant to Article 14;

(e) if a negative evaluation report on the Member has been drawn up pursuant to Article 14;

(f) if the Network where the Member participates is terminated.

2. The relevant Member State shall inform the Commission of the reasons for the notification referred to in paragraph 1(c).

3. The Board of the Network shall inform the Commission in the cases referred to in point 1(a), (b) and (d).

4. The loss of membership on the grounds listed in paragraph 1(e) must be approved by the Board of Member States referred to in Article 6.

5. In any case of loss of membership, the Commission shall verify whether the minimum numbers of healthcare providers and of Member States set out in Article 2(2) are still reached. If not, it shall ask the Network to find new Members within the next two years or terminate the Network, inform the Board of Member States of the situation and ask Member States to encourage their healthcare providers to join the Network.

6. Loss of membership shall lead to the automatic loss of any of the rights and responsibilities associated with participation in the Network, including the right to use the logo.

Article 13

Assessment manual

1. In consultation with Member States and interested parties, the Commission shall draw up a detailed manual regarding the content of, documentation and procedure for the assessment referred to in Articles 4 and 9.

2. The assessment procedure shall include the verification of the documentation submitted by the applicants and on-site audits.

3. The body appointed by the Commission pursuant to Articles 4(1) and 9(1) to assess a proposal for a Network and applications for membership of the Network shall use the assessment manual.

CHAPTER III

EVALUATION OF EUROPEAN REFERENCE NETWORKS

Article 14

Evaluation

1. All Networks and their Members shall be periodically evaluated, at the latest every five years after their approval or last evaluation.

2. On receiving the request for evaluation from the Coordinator of a Network, the Commission shall appoint a body to evaluate the Network and its Members.

3. The evaluation body shall verify and assess:

(a) the fulfilment of the criteria and conditions set out in Delegated Decision 2014/286/EU;

(b) the accomplishment of the objectives set out in Article 12(2) of Directive 2011/24/EU; and

(c) the outcomes and performance of the Network and the contribution of each Member.

4. The evaluation body shall draw up an evaluation report on the Network and send it to the Commission, the Board of the Network and the Members of the Network.

5. The evaluation body shall draw up an evaluation report on each Member of the Network and send it to the Commission and the Member in question.

6. The Coordinator and Members of the Network may send comments to the evaluation body within two months of receiving the report. On receiving the comments, the evaluation body shall amend its evaluation report explaining whether the comments justify a change in its evaluation.

7. Any termination of a Network or loss of membership on account of a negative evaluation must be approved by the Board of Member States referred to in Article 6. The Board of Member States may offer the Network or the Member in question one year to remedy the shortcomings identified before carrying out a new evaluation. That period of time shall only be offered to a specific Network or Member of a Network if the Board of the Network presents an improvement plan.

Article 15

Evaluation manual

1. In consultation with Member States and interested parties, the Commission shall draw up a manual regarding the content of and documentation and procedure for the evaluation of the Networks and their Members referred to in Article 14.

2. The evaluation procedure shall include the evaluation of the documentation submitted, including the self-evaluation reports, and on-site audits.

3. The body appointed by the Commission pursuant to Article 14(2) to evaluate a Network and its Members shall use the evaluation manual.

CHAPTER IV

EXCHANGE OF INFORMATION AND EXPERTISE

Article 16

Exchange of information on establishing and evaluating the Networks

1. The Commission shall facilitate the exchange of information and expertise on establishing and evaluating the Networks by:

(a) making general information on establishing and evaluating the Networks, including information on the assessment and evaluation manuals referred to in Articles 13 and 15 publicly available;

(b) publishing a regularly updated list of the Networks and their Members, together with the positive assessment and evaluation reports of the Networks and the decisions of the Board of Member States, in accordance with its rules of procedure;

(c) organising conferences and experts meetings for technical and scientific debate among the Members of Networks, if appropriate;

(d) providing electronic media and communication tools to the Networks, if appropriate.

2. For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.

CHAPTER V

FINAL PROVISIONS

Article 17

Revision

The Commission shall evaluate the functioning of this Implementing Decision five years after its entry into force.

Article 18

Entry into force

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

Done at Brussels, 10 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

CONTENT OF THE APPLICATION TO ESTABLISH A NETWORK

The application to establish a Network must be submitted according to the call for interest published by the Commission and must include:

(a) the name of the proposed Network;

(b) the completed application form, with the self-assessment questionnaire and additional documentation required in the assessment manual;

(c) evidence that all applicant healthcare providers share the same area of expertise and focus on the same health condition or conditions;

(d) the name of the healthcare provider that will act as Coordinator of the Network and the name and contact details of the person who will represent the proposed Coordinator;

(e) the names of all applicant healthcare providers.

ANNEX II

CONTENT OF THE MEMBERSHIP APPLICATION

The application of healthcare providers must include:

(a) the title of the relevant proposed Network or existing Network;

(b) the completed application form, with the self-assessment questionnaire and additional documentation required in the assessment manual;

(c) the name and contact details of the healthcare provider's representative.

COMMISSION IMPLEMENTING DECISION

of 12 May 2014

as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC

(notified under document C(2014) 2976)

(2014/288/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field [1], and in particular Article 27(10) thereof,

Whereas:

(1) Decision 2009/470/EC lays down the procedures governing the financial contribution from the Union towards the programmes for the eradication, control and monitoring of animal diseases and zoonoses.

(2) Pursuant to Article 27(1) of Decision 2009/470/EC a Union financial measure is introduced to reimburse the expenditure incurred by the Member States for the financing of national programmes for the eradication, control and monitoring of the animal diseases and zoonoses listed in the Annex to that Decision.

(3) Article 27(7) of Decision 2009/470/EC provides that Member States are to submit, for each approved programme, intermediate technical and financial reports and, by 30 April each year at the latest, an annual detailed technical report, including the assessment of the results achieved and detailed account of expenditure incurred for the previous year.

(4) Commission Decision 2008/940/EC [2] defines the information that Member States having programmes for the eradication, monitoring and control of certain animal diseases approved for Union co-financing shall provide within the intermediate and final technical and financial reports.

(5) Since the adoption of Decision 2008/940/EC and in the framework of simplification and improvement of the requirements and procedures in relation to the programmes, changes have been introduced as regards the measures considered eligible for Union financial contribution and the method of calculation of the reimbursement as laid down in the financing decisions approving the programmes for each calendar year.

(6) In addition, in order to further improve the process of submission of reports, their processing and evaluation as well as the follow up of progress over the years, the intermediate and final reports for the implementation of the programmes should be submitted by the Member States on-line from 1 July 2015 onwards using electronic templates developed by the Commission for this purpose. The structure of the relevant reports should therefore be adapted for the electronic submission and processing of data.

(7) Therefore, the standard requirements for the submission by Member States of applications for Union financing for the national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses should be amended and made consistent with the amendments to relevant Union legislation and compatible with the on-line submission system.

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[1] OJ L 155, 18.6.2009, p. 30.

[2] Commission Decision 2008/940/EC of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community (OJ L 335, 13.12.2008, p. 61).

(8) In the second half of each year, the Commission requests from the Member States to provide updated information on the usage of funds for eligible measures under their programmes since the beginning of the year and estimations for the total needed budget for the whole year. On the basis of this information and in order to improve the usage of available funds the Commission prepares every year a Decision amending the financing decision for that year to reallocate funds between programmes that are expected not to use their initial allocation of funds and programmes reported to be in need of additional funds.

(9) In order to optimise the efficiency of the exercise of reallocating funds amongst programmes, it is appropriate that the Member States also submit quantitative information on the activities already performed and expected to be performed, as well as unit cost data. Furthermore, to reduce administrative burden the submission of information for the reallocation of funds should be integrated within the submission of intermediate reports.

(10) It is therefore appropriate that Decision 2008/940/EC is repealed and replaced by the current Decision.

(11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Member States shall, in accordance with this Decision, submit intermediate and final reports as regards programmes approved pursuant to Article 27 of Decision 2009/470/EC.

Article 2

For the purposes of this Decision, the following definitions shall apply:

(a) 'intermediate reports' means intermediate technical [1] and financial reports on the implementation of running programmes, to be submitted to the Commission as provided for in Article 27(7)(a) of Decision 2009/470/EC;

(b) 'final reports' means detailed technical and financial reports to be submitted to the Commission by 30 April each year at the latest for the entire of the preceding year of application of each approved programme, as provided for in Article 27(7)(b) of Decision 2009/470/EC;

(c) 'payment applications' means the payment applications relating to the expenditure incurred by a Member State to be submitted to the Commission, as provided for in Article 27(8) of Decision 2009/470/EC.

Article 3

1. With regard to running programmes approved for co-financing by the Union in accordance with Article 27(5) of Decision 2009/470/EC, an intermediate report shall be submitted to the Commission by 31 August each year at the latest.

2. Intermediate reports shall provide all the relevant information in accordance with Annex I.

[1] Only intermediate financial report is due by 2015.

Article 4

Final reports and payment applications shall provide all the relevant information in accordance with Annex II, as well as:

(a) technical information in accordance with:

(i) Annex III, in respect of bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis, bluetongue in endemic or high risk areas, anthrax, contagious bovine pleuropneumonia, echinococcosis, trichinellosis and verotoxigenic *E. coli*;

(ii) Annex IV, in respect of Salmonellosis (zoonotic *Salmonella*);

(iii) Annex V, in respect of African swine fever, swine vesicular disease, classical swine fever;

(iv) Annex VI, in respect of rabies;

(v) Annex VII, in respect of transmissible spongiform encephalopathies (TSE);

(vi) Annex VIII, in respect of avian influenza;

(vii) Annex IX, in respect of infectious hematopoietic necrosis (IHN), infectious salmon anaemia (ISA), viral haemorrhagic septicaemia (VHS), Koi herpes virus infection (KHV), infection with *Bonamia ostreae*, infection with *Marteilia refringens* and white spot disease in crustaceans;

(b) information on the activities and costs, in accordance with Part I of Annex X and a signed declaration for each programme, in accordance with Part II of Annex X.

Article 5

1. From 1 July 2015, the intermediate reports provided for in Article 3 and the final reports and payment applications provided for in Article 4 shall be submitted on-line by Member States using the corresponding standard electronic templates provided by the Commission, except for the programmes for the diseases referred to in Article 4(a)(vii).

2. In addition to the requirements of paragraph 1, a signed version of the part of the final reports and payment applications referred to in Article 4(b) shall be submitted to the Commission.

Article 6

Decision 2008/940/EC is repealed.

Article 7

Without prejudice to Article 5, this Decision shall apply to programmes for the eradication, control and monitoring of animal diseases to be implemented as from 1 January 2015.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 12 May 2014.

For the Commission

Tonio BORG

Member of the Commission

ANNEX I

Requirements for intermediate reports

Member State: .....

☐ Annual

☒ Multiannual — period of implementation:

Disease/zoonosis ([1]): .....

Animal species:

Content and structure of the report:

1. Description and evaluation of the evolution of the epidemiological situation and the technical implementation of the activities foreseen under the programme.
2. Confirmation that all legislation concerning the implementation of the programme was in force at the beginning of the programme.
3. Information on the activities carried out under the programme and the eligible expenditure during the first 6 months of the year of implementation and for those expected to be carried out during the last 6 months of the year of implementation in accordance with Part I of Annex X.

([1]) Disease or zoonosis and animal species if necessary.

ANNEX II

Requirements for final reports and payment applications

Member State: .....

☐ Annual: Year of implementation: .....

☒ Multiannual — period of implementation:

Disease/zoonosis ([1]): .....

Animal species:

Content and structure of the report:

1. Description and evaluation of the evolution of the epidemiological situation, the technical implementation of the activities foreseen under the programme and the cost-effectiveness of the programmes.
2. Details on the level of achievement of the targets set in the approved programme and technical difficulties.
3. Submission of technical and financial data and payment application in accordance with the corresponding Annexes as set out in Article 4.
4. Epidemiological maps for infection and other relevant data on the disease/activities.
5. Additional epidemiological information: information on epidemiological inquiries, serotypes involved, abortions, lesions found in abattoir or necropsy, human cases, etc.

([1]) Disease or zoonosis and animal species if necessary.

ANNEX III

Final technical report on ruminant diseases programmes

Table A ([a])

Data on herds

Member State: ..... Date: ..... Year:.....

Disease: .....

Region ([b])	Animal species	Total number of herds ([c])	Total number of herds under the programme	Number of herds to be checked under the programme	Number of herds checked ([d])	Number of positive herds ([e])	Number of new positive herds ([f])	Number of herds depopulated	% positive herds depopulated	INDICATORS		
										% herd coverage	% positive herds Period herd prevalence	% new positive herds Herd incidence
1	2	3	4	5	6	7	8	9	10 = (9/7) × 100	11 = (6/5) × 100	12 = (7/6) × 100	13 = (8/6) × 100
Total												
Total previous												

([a]) One table per disease/species. Not to be filled in for bluetongue programmes.

([b]) Region as defined in the programme of the Member State.

([c]) Total number of herds existing in the region including eligible herds and non-eligible herds for the programme.

([d]) Check means to perform a herd level test under the programme for the respective disease with the purpose of maintaining or upgrading, the health status of the herd. In this column a herd must not be counted twice even if has been checked more than once.

([e]) Herds with at least one positive animal during the period independent of the number of times the herd has been checked.

([f]) Herds which status in the previous period was *Unknown, Not free-negative, Free, Officially Free or Suspended* and have at least one animal tested positive in this period.

Table B

Data on animals

Region [a]	Animal species	Total number of animals [b]	Number of animals under the programme	Number of animals [c] to be tested under the programme	Number of animals [c] tested	Number of animals tested individually [d]	Number of positive animals	Slaughtering [f]		INDICATORS	
								Number of animals with positive result slaughtered or culled	Total number of animals slaughtered [e]	% coverage at animal level [f]	% positive animals Animal prevalence [f]
1	2	3	4	5	6	7	8	9	10	11=(6/5) × 100	12=(8/6) × 100
	Total										
	Total previous year										

[a] Region as defined in the programme of the Member State.
[b] Total number of animals existing in the region including eligible herds and non-eligible herds for the programme.
[c] Includes animals tested individually or under bulk level scheme.
[d] Include only animals tested individually, do not include animals tested by bulk level samples (for instance: milk bulk tank tests).
[e] Include all positive animal slaughtered and also the negative animals slaughtered under the programme.
[f] Columns not to be filled in for bluetongue programmes.

Table C

Data on vaccination programmes

Region ([a])	Animal species	Total number of herds ([b])	Total number of animals	Information on vaccination programme							
				Serotype ([d])	Number of herds in vaccination programme	Number of herds vaccinated	Number of animals vaccinated	Number of doses of vaccine administered	Number of adults vaccinated ([c])	Number of young animals vaccinated[(c)]	Number of animals with primary vaccination ([d]) (initial+booster)
	Total										

([a]) Region as defined in the programme of the Member State.
([b]) Herds or flocks or holdings as appropriate.
([c]) For bluetongue programmes distinction between adult and young animals not required.
([d]) To be filled in only for bluetongue programmes.

Table D ([a])

Data on status of herds at the end of the period

Region ([b])	Animal species	Status of herds and animals under the programme ([c])													
		Total number of herds and animals under the programme		Unknown ([d])		Not free or not officially free from disease				Free or officially free-disease status suspended/withdrawn ([g])		Free from disease ([h])		Officially free from disease ([i])	
						Last check positive ([e])		Last check negative ([f])							
		Herds	Animals ([l])	Herds	Animals ([l])	Herds	Animals ([l])	Herds	Animals ([l])	Herds	Animals ([l])	Herds	Animals ([l])	Herds	Animals ([l])
Total															

([a]) Not to be filled in for bluetongue programmes.
([b]) Region as defined in the programme of the Member State.
([c]) At the end of the year.
([d]) Unknown: No previous checking results available.
([e]) Not free and last check positive: Herd checked with at least one positive result in the latest check.
([f]) Not free and last check negative: Herd checked with negative results in the latest check but not being Free or Officially Free.
([g]) Suspended as defined in Union or national legislation for the respective disease at the end of the reporting period.
([h]) Free herd as defined in Union or national legislation for the respective disease.
([i]) Officially free herd as defined in Union or national legislation for the respective disease.
([l]) Include animals under the programme in the herds with the referred status (left column).

Table E ([a])

Suspension/withdrawal of the free or officially free status

Region ([b])	Species	Reason ([c])	Number of herds suspended

([a]) Not to be filled in for bluetongue programmes.
([b]) Region as defined in the programme of the Member State.
([c]) Indicate the motive:
— non-negative result in diagnostic test,
— does not fulfil the routine testing frequency,
— entering animals in the herd with insufficient status,
— the disease is suspected,
— other (specify).

Table F

Stratified data on surveillance and laboratory tests

Region ([a])	Animal species/category	Test type ([b])	Description of test	Number of samples tested	Number of positive samples
Total					

([a]) Region as defined in the programme of the Member State.
([b]) Indicate whether the test is serological, virological etc.

ANNEX IV

Technical report on zoonotic *salmonella* programmes

Table A

Data on national implementation of *Salmonella* control programmes (SCP) ([a])

Type of flock	Flocks under the SCP		Total No of flocks checked ([d]) ([e])	Total No of flocks officially sampled ([e])	Total No of visits for taking official samples	No of positive ([f]) flocks	Targeted serotypes found ([g])	No of positive flocks depopulated	Total No of animals in these flocks	No of eggs destroyed	No of eggs sent for heat treatment
	Total No of flocks concerned ([b])	Total No of smaller flocks ([c])									
Breeders											
Layers											
Breeding turkeys											
Total											

Type of flock	Holdings/flocks under the SCP				Total No of flocks checked ([d]) ([e])	Total No of holdings officially sampled ([e])	Total No of visits for taking official samples	No of positive ([f]) flocks	Targeted serotypes found ([g])	Total No of animals in these flocks
	Total No of holdings concerned ([b])	Total No of flocks produced	Total No of smaller holdings ([c])	Total No of flocks produced						
Broilers										
Fattening turkeys										
Total										

([a]) As defined in Union legislation.

([b]) Flocks/holdings with official sampling requirements detailed in the Regulations specific to each poultry population:
Breeders: flocks of at least 250 adult birds; Layers: flocks of at least 1 000 birds; Breeding turkeys: flocks with at least 250 adult breeding turkeys and all flocks with elite, great grandparents and grandparent breeding turkeys;
Broilers: number of holdings with more than 5 000 birds; Fattening turkeys: number of holdings with at least 500 fattening turkeys.

([c]) Flocks/holdings below the size of those already reported in the second column and also covered by the *Salmonella* national control programme.

([d]) A checked flock is a flock where samples (official or at the initiative of the food business operator) were taken under a *Salmonella* national control programme.

([e]) In this column a flock must not be counted twice even if it has been checked more than once.

([f]) Flocks where at least one targeted serovar was found (on official or FBO samples). If more than one positive sample was found in the flock, it shall be taken into account only once.

([g]) Indicate the targeted serotypes found in the positive flocks (for instance SE = *Salmonella Enteritidis*, ST = *S. Typhimurium*, SH = *S. Hadar*, SI = *S. Infantis*, SV = *S. Virchow*) and the number of occurrences for each.

Table B

Stratified data on laboratory tests on official samples

Test description	Test type ([a])	Number of tests performed	Number of positive results
Microbiological tests			
Serotyping test			
Bacteriological test performed to verify the efficacy of disinfection of poultry houses after depopulation of a *Salmonella*-positive flock			
Tests for the detection of antimicrobials/bacterial growth inhibitors			
Total			

([a]) If the reference method is not used.

Table C

Data on vaccination programmes

Type of flock	Number of flocks in vaccination programme	Number of flocks vaccinated	Number of animals vaccinated	Number of doses of vaccine administered
Breeders				
Layers				
Breeding turkeys				
Total				

ANNEX V

Final technical report on swine diseases programmes

Member State: ..... Date: ..... Year:.....
Disease: .....

Table A

Disease surveillance in domestic pigs

Region	Number of farms sampled	Type of farm	Number of animals sampled	Number of farms with serologically positive result	Number of farms with active infection detected
1	2	3	4	5	6
		Commercial ([1])			
		Backyard ([1])			
Total					

([1]) As defined in the approved programme of the Member State.

Table B

Disease surveillance in wild boar/feral pigs

Region	Species	Type of surveillance	Number of animals tested	Positive	% Positive
		active, passive			
Total					

Table C

Wild boar oral vaccination			
Region/Area	Month	Number of baits	Size of vaccinated area (km^2)
1	2	3	4
	Total		

Table D

Stratified data on diagnostic tests and results							
Region	Animal population	Laboratory test used	Type of sample	Number of animals tested	Number of tests carried out	Number of positive results	Comments
	1	2	3	4	5	6	7
	Domestic pigs, Wild boar, feral pigs	ELISA, VNT, PCR	Serum, Blood, tissues				
	Other	Other	Other				
Total							

ANNEX VI

Final technical report on rabies programmes

Member State: ..... Date: ..... Year:.....

Table A

Test for the monitoring of vaccination effectiveness

Region	Species and age ([a])	Type of test ([b])	Test description ([c])	Number of tests	Number positive	% Positive
1	2	3	4	5	6	7=(6/5) × 100
Total						

Surveillance tests

Region	Species	Category ([d])	Test description ([c])	Number of tests	Number of positive results
1	2		3	4	5
Total					

Further investigation of positive cases

Rabies virus isolates typed for differentiation from vaccine strain:	Typing results:

([a]) Provide separately results between juvenile and adults and by target species (if more than one).
([b]) Serological or presence of biomarker.
([c]) Name the diagnostic method (e.g. ELISA, PCR, FAT etc.).
([d]) Present surveillance tests on suspected and dead animals (passive surveillance) separately from results on hunted animals (active surveillance).

Table B

Wildlife oral vaccination

Aerial distribution data files:

— flight routes recorded during the distribution

— bait release data (time and position of each bait released) recorded during the distribution

Description of the analysis performed by the Competent Authority on the aerial distribution data and conclusions of the assessment for the quality of the distribution:

Region/Area	Start date	Completion date	Product used	Number of doses	Size of vaccinated area (km^2)	Distribution method
		Total				

Table C

Official control of oral vaccines before their distribution

Number of batches distributed	Number of batches controlled by the CA	Number of batches rejected

Batch Number	Manufacturer	Sampling date	Virus titration result
Total			

ANNEX VII

Final technical report on tse monitoring and eradication programmes

Member State: ..... Date: ..... Year:.....

Table A ([a])

Rapid tests in bovine animals

	Age limit applied ([b])	Number of animals tested	Number of rapid tests, including those used for confirmation
Animals referred to in Annex III, Chapter A, Part I, points 2.1, 3 and 4 of Regulation (EC) No 999/2001 of the European Parliament and of the Council ([1])			
Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001			
Others (specify)			

([1]) OJ L 147, 31.5.2001, p. 1.

([a]) Member States may opt not to fill in Table A and declare that the relevant data already reported to the Commission in accordance with Article 6(4) of Regulation (EC) No 999/2001 shall be considered for the purposes of this report, provided that this data indicates separately the number of tested animals aged below the age limit applied in the Member State from the animals tested above that limit.

([b]) Cases of application of a different age limit than the one applied in the Member State for the subcategory (voluntary, fulfilment of export requirements etc.) should be mentioned in separate rows.

Table B

Population of ewes and ewe lambs put to the ram in the Member State

Rapid tests in ovine animals

	Number of animals tested
Ovine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001 ([a])	
Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001 ([a])	
Ovine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001 ([a])	
Ovine animals referred to in Annex VII, Chapter B, point 3.1 of Regulation (EC) No 999/2001	
Ovine animals referred to in Annex VII, Chapter B, point 4.1 of Regulation (EC) No 999/2001	
Ovine animals referred to in Annex VII, Chapter B, point 2.2.3 of Regulation (EC) No 999/2001	
Others (specify)	

([a]) Member States may opt not to fill in this field and declare instead that the relevant data reported to the Commission in accordance with Article 6(4) of Regulation (EC) No 999/2001 shall be considered for the purposes of this report.

Table C

Population of goats which have already kidded and goats mated in the Member State	
Rapid tests in caprine animals	
	Number of animals tested
Caprine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001 ([a])	
Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001 ([a])	
Caprine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001 ([a])	
Caprine animals referred to in Annex VII, Chapter B, point 3.1 of Regulation (EC) No 999/2001	
Caprine animals referred to in Annex VII, Chapter B, point 4.1 of Regulation (EC) No 999/2001	
Caprine animals referred to in Annex VII, Chapter B, point 2.2.3 of Regulation (EC) No 999/2001	
Others (specify)	

([a]) Member States may opt not to fill in this field and instead declare that the relevant data reported to the Commission in accordance with Article 6(4) of Regulation (EC) No 999/2001 shall be considered for the purposes of this report.

Table D

Confirmatory and discriminatory tests	
	Number of tests
Confirmatory tests ([a]) other than rapid tests ([b]) in bovine animals	
Confirmatory tests ([a]) in ovine and caprine animals	
Discriminatory tests ([c]) in ovine and caprine animals	
Discriminatory tests in bovine animals	

([a]) As referred to in Chapter C of Annex X to Regulation (EC) No 999/2001.
([b]) Rapid tests used as confirmatory tests must be included in Table A of Annex VII Rapid tests in bovine animals.
([c]) Primary molecular testing referred to in Annex X, Chapter C, point 3.2(c)(i) of Regulation (EC) No 999/2001.

Table E

Genotyping	
	Number of animals
Positive animals genotyped ([a]) ([b])	
Randomly selected animals genotyped ([a]) ([c])	
Animals in scrapie infected flocks genotyped ([d])	
Ewes genotyped under the framework of a breeding programme ([e])	
Rams genotyped under the framework of a breeding programme ([e])	

([a]) Member States may opt not to fill in this field and instead declare that the relevant data reported to the Commission in accordance with Article 6(4) of Regulation (EC) No 999/2001 shall be considered for the purposes of this report.
([b]) As required by Annex III, Chapter A, Part II, point 8.1 of Regulation (EC) No 999/2001.
([c]) As required by Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) No 999/2001.
([d]) In accordance with Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001.
([e]) In accordance with Article 6a of Regulation (EC) No 999/2001.

Table F

Culling of animals	
	Number of animals
Bovine animals culled and destroyed ([a])	
Ovine and caprine animals culled and destroyed ([b])	
Compulsory slaughter in scrapie infected flocks ([c])	
	Number of animals
Ovine and caprine animals slaughtered	

([a]) In accordance with Annex VII, Chapter B, point 2.1 of Regulation (EC) No 999/2001.
([b]) In accordance with Annex VII, Chapter B, point 2.2.2(b) and (c) of Regulation (EC) No 999/2001.
([c]) In accordance with Annex VII, Chapter B, point 2.2 of Regulation (EC) No 999/2001.

ANNEX VIII

Final technical report on avian influenza surveillance programmes

Member State: ..... Date: ..... Year:.....

Table A

Poultry Holdings ([a]) sampled

Serological investigation according to Annex I to Commission Decision 2010/367/EU ([1])

Poultry category ([b])	NUTS 2 code ([c])	Total number of holdings ([d])	Total number of holdings sampled	Number of samples per holding	Methods of laboratory analysis	Total number of tests performed per method
	Total					

([1]) OJ L 166, 1.7.2010, p. 22.
([a]) Holdings or flocks or establishments as appropriate.
([b]) broilers/fattening turkeys/chicken breeders/turkey breeders/laying hens/free range laying hens/ratites/farmed feathered game (pheasants, partridges, quails…)/ducks geese or mallards/'backyard flocks'/others.
([c]) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) 2 cannot be used, coordinates (long/lat) or region, as defined in the programme of the Member State, are requested.
([d]) Total number of holdings of one category of poultry in concerned NUTS 2 or region.

Table B

WILD BIRDS — Investigation according to the surveillance programme for avian influenza in wild birds set out in Annex II to Decision 2010/367/EU

NUTS 2 code ([a])	Total number of birds sampled	Total number of samples tested for passive surveillance
Total		

([a]) Refers to the place of collection of birds/samples. In case NUTS 2 code cannot be used, coordinates (long/lat) or region, as defined in the programme of the Member State, are requested.

ANNEX IX

Report on fish disease programmes

1.	**Diseases** [a]	
1.1.	Fish	☐ VHS ☐ IHN ☐ ISA ☐ KHV
1.2.	Molluscs	☐ Marteilia refringens ☐ Bonamia ostreae
1.3.	Crustaceans	☐ White spot disease

2.	**General information on the programmes**	
2.1.	Competent Authority [b]	
2.2.	Organisation, supervision of all stakeholders involved in the programme [c]	
2.3.	Duration of the programme	

([a]) Disease and species if necessary.
([b]) A description shall be provided of the structure, competencies, duties and powers of the Competent Authority or Competent Authorities involved.
([c]) A description shall be provided of the authorities in charge of the supervision and coordination of the programme and the different operators involved.

3. **Data on testing animals**

Member State, Zone or Compartment [a]

Disease: ..... Year: .....

Farm or mollusc farming area	Number of samplings	Number of clinical inspections	Water temperature at sampling/Inspection	Species at sampling	Species sampled	Number of animals sampled (total and by species)	Number of tests	Positive results of laboratorial examination	Positive results of clinical inspections
					Total				**Total**

([a]) Member State, zone or compartment as defined in the approved programme.

4. **Data on testing farms or farming areas**

Disease: ..... Year: .....

Member State, Zone or Compartment [a]	Total number of farms or mollusc farming areas [b]	Total number farms or mollusc farming areas under the programme	Number of farms or mollusc farming areas checked [c]	Number of positive farms or mollusc farming areas [d]	Number of new positive farms or mollusc farming areas [e]	Number of farms or mollusc farming areas depopulated	% positive farms or mollusc farming areas depopulated	Animals removed and disposed of [f]	TARGET INDICATORS		
									% farms or mollusc farming areas coverage	% positive farms or mollusc farming areas period farms or mollusc farming areas prevalence	% new positive farms or mollusc farming areas farms or mollusc farming areas incidence
1	2	3	4	5	6	7	8 = (7/5) × 100	9	10 = (4/3) × 100	11 = (5/4) × 100	12 = (6/4) × 100
Total											

(a) Member State, zone or compartment as defined in the approved programme.

(b) Total number of farms or mollusc farming areas existing in the Member State, Zone or Compartment as defined in the approved programme.

(c) Check means to perform a farm/mollusc farming area level test under the programme for the respective disease with the purpose of upgrading the health status of the farm/mollusc farming area. In this column a farm/mollusc farming area must not be counted twice even if has been checked more than once.

(d) Farms or mollusc farming areas with at least one positive animal during the period independent of the number of times the farms or mollusc farming areas has been checked.

(e) Farms or mollusc farming areas the health status of which in the previous period was, in accordance with Part A of Annex III to Directive 2006/88/EC, category I, category II, category III or category IV and which have at least one positive animal in this period.
In the case of programmes submitted before 1 August 2008, Farms or mollusc farming areas which were not positive to the disease in question in the previous period and have at least one positive animal in this period.

(f) Animals × 1000 or total weight of animals removed and disposed of.

ANNEX X

PART I

Report on activities and costs

Table A [a]

Eligible measures	Number of units	1 [b]			2 [b]		Co-funding rate	Claimed amount
		Financing on the basis of costs actually incurred [c]			Financing on the basis of unit costs			
		Declared total cost actually incurred [d]	Ceiling per unit	Total cost after application of ceiling	Unit costs [b] (100 %)	Eligible cost declared on the basis of unit costs [d] [e]		
Sampling								
Total sampling							%	
Testing								
Total testing							%	
Vaccination								
Total vaccination							%	
Compensation								
Total compensation							%	
Other eligible measures								
Total other eligible measures							%	
Total				3		4	%	
Total amount claimed [e][f]								

[a] In case of intermediate report fill in two separate tables, one for the results of the first 6 months and one for the forecast of the last 6 months of the year.
[b] For each eligible measure fill in either column 1 or 2 in line with the method of co-funding specified in the financing decision.
[c] 'Incurred' in the sense of the present Decision means costs for measures implemented from 1 January to 31 December of the year of implementation of the programme, and paid at the latest on the date of submission of the claim for reimbursement
[d] 'Incurred' in the case of final report and payment application, 'expected to be incurred' in case of intermediate report.
[e] The defined unit cost at 100 % multiplied by the number of units.
[f] Sum of cells 3 and 4 after the application of the co-funding rate.

Table B ([a])

Region	Additional information on compensation ([b])										
	Species of animals	Culled and destroyed/Slaughtered	Number of compensated animals	Total cost of compensated animals	Cost of animals compensated by 90 calendar days	Cost of animals compensated between 90 & 120 calendar days	Cost of animals compensated between 121 & 150 calendar days	Cost of animals compensated between 151 & 180 calendar days	Cost of animals compensated between 181 & 210 calendar days	Cost of animals compensated after 210 calendar days	Amount received for salvage
Total											

([a]) To be filled in only for final reports and in case eligible costs include amounts for the compensation paid to owners for their animals or products slaughtered or culled/destroyed.
([b]) Data to be given in national currency, VAT excluded.

Table C ([a])

Additional information on compensation ([b]) for zoonotic *Salmonella* control programmes														
Poultry population	**Compensation**													
	Number of animals and eggs compensated				Total cost of animals and eggs compensated				Compensation made by 90 calendar days	Compensation made between 91 & 120 calendar days	Compensation made between 121 & 150 calendar days	Compensation made between 151 & 180 calendar days	Compensation made between 181 & 210 calendar days	Total compensation paid
	Culled animals		Destroyed eggs	Heat-treated non incubated hatching eggs ([c])	Culled animals		Destroyed eggs	Heat-treated non incubated hatching eggs ([c])						
	without salvage value	with salvage value ([c])			without salvage value	with salvage value ([c])								
Breeders														
Layers														
Broilers														
Breeding turkeys														
Fattening turkeys														
Total	0	0	0	0	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00

([a]) To be filled in only for final reports.
([b]) Compensation paid to owners for the value of their birds slaughtered or culled, destroyed eggs and heat treated non incubated hatching eggs. Data shall be given in national currency, VAT excluded.
([c]) The salvage value shall be deducted from the compensation.

PART II

Signed declaration to accompany the final report/payment application

Member State:

Programme:

Year of implementation:

We certify that:

— *the information provided in the final report and payment application is full, reliable and true that the declared activities were actually performed and that the cost declared are accurately accounted for and eligible under the provision of Decision …/Regulation (EC) No … (mention specific financing decision); ….*

— *all supporting documents relating to the activities and expenditure are available for inspection, notably to justify the level of compensation for animals;*

— *the programme was executed in accordance with the relevant Union legislation, in particular the rules on competition, the award of public contracts and state aid;*

— *no other Union contribution was requested for this programme and all revenue accruing from operations under the programme is declared to the Commission;*

— *control procedures apply, in particular to verify the accuracy of the amount of activities and expenditure declared, to prevent, detect and correct irregularities.*

Date

Name and signature of operational director

COMMISSION IMPLEMENTING DECISION

of 15 May 2014

allowing Member States to extend provisional authorisations granted for the active substances pinoxaden and meptyldinocap

(notified under document C(2014) 3059)

(Text with EEA relevance)

(2014/289/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), and in particular the fourth subparagraph of Article 8(1) thereof,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([2]), and in particular Article 80(1)(a) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Directive 91/414/EEC shall continue to apply to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011.

(2) In accordance with Article 6(2) of Directive 91/414/EEC, in March 2004 the United Kingdom received an application from Syngenta Crop Protection AG for the inclusion of the active substance pinoxaden in Annex I to Directive 91/414/EEC. Commission Decision 2005/459/EC ([3]) confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.

(3) In accordance with Article 6(2) of Directive 91/414/EEC, in August 2005 the United Kingdom received an application from Dow Agrosciences for the inclusion of the active substance meptyldinocap in Annex I to Directive 91/414/EEC. Commission Decision 2006/589/EC ([4]) confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.

(4) Confirmation of the completeness of the dossiers was necessary in order to allow them to be examined in detail and to allow Member States the possibility of granting provisional authorisations, for periods of up to three years, for plant protection products containing the active substances concerned, while complying with the conditions laid down in Article 8(1) of Directive 91/414/EEC and, in particular, the conditions relating to the detailed assessment of the active substances and the plant protection products in the light of the requirements laid down by that Directive.

(5) For these active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The rapporteur Member State submitted the respective draft assessment reports to the Commission on 30 November 2005 (pinoxaden) and 25 October 2006 (meptyldinocap).

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 309, 24.11.2009, p. 1.
([3]) Commission Decision 2005/459/EC of 22 June 2005 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pinoxaden in Annex I to Council Directive 91/414/EEC (OJ L 160, 23.6.2005, p. 32).
([4]) Commission Decision 2006/589/EC of 31 August 2006 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of aviglycine HCl, mandipropamid and meptyldinocap in Annex I to Council Directive 91/414/EEC (OJ L 240, 2.9.2006, p. 9).

(6) Following submission of the draft assessment reports by the rapporteur Member State, it has been found to be necessary to request further information from the applicants and to have the rapporteur Member States examine that information and submit their assessment. Therefore, the examination of the dossiers is still ongoing and it will not be possible to complete the evaluation within the timeframe provided for in Directive 91/414/EEC, read in conjunction with Commission Implementing Decision 2012/191/EU [1].

(7) As the evaluation so far has not identified any reason for immediate concern, Member States should be given the possibility of prolonging provisional authorisations granted for plant protection products containing the active substances concerned for a period of 24 months in accordance with the provisions of Article 8 of Directive 91/414/EEC so as to enable the examination of the dossiers to continue. It is expected that the evaluation and decision-making process with respect to a decision on a possible approval in accordance with Article 13(2) of Regulation (EC) No 1107/2009 for pinoxaden and meptyldinocap will have been completed within 24 months.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations for plant protection products containing pinoxaden and meptyldinocap for a period ending on 31 May 2016 at the latest.

Article 2

This Decision shall expire on 31 May 2016.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 15 May 2014.

For the Commission
Tonio BORG
Member of the Commission

[1] Commission Implementing Decision 2012/191/EU of 10 April 2012 allowing Member States to extend provisional authorisations granted for the new active substances amisulbrom, chlorantraniliprole, meptyldinocap, pinoxaden, silver thiosulphate and tembotrione (OJ L 102, 12.4.2012, p. 15).

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 14 April 2014

on the position to be taken on behalf of the European Union within the EU-Chile Association Committee regarding the modification of Annex XII to the Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part, setting out the lists of Chilean entities which procure in accordance with the provisions of Title IV of Part IV on government procurement

(2014/290/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first paragraph of Article 207(4) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement establishing an association between the European Community and its Members States, of the one part, and the Republic of Chile, of the other part [1] ('the Association Agreement'), was signed on 18 November 2002.

(2) Annex XII to the Association Agreement provides lists of entities in the Republic of Chile ('Chile') which procure in accordance with the provisions on government procurement of Title IV of Part IV of the Association Agreement.

(3) On 10 February 2012, Chile notified the Union of its intention to modify its coverage on government procurement set out in Annex XII to the Association Agreement, in accordance with Article 159(1) of that Agreement. On 18 October 2012, Chile provided additional information. The modification consists in the simplification of certain lists of entities in Annex XII to the Association Agreement, namely: in Appendix 1 A, the entities listed under each Ministry and regional government are replaced by a catch-all clause which covers all entities subordinated to the listed Ministries and regional governments and in Appendix 2 A, the details of the list of all entities at sub-central level are replaced by a catch-all phrase: 'all municipalities' ('the modification of Annex XII to the Association Agreement'). Appendix 1 B and Appendix 2 B, as well as Appendix 3 to Appendix 5 of Annex XII to the Association Agreement, remain unchanged.

(4) Following that notification, and in accordance with Article 159(2) and (3) of the Association Agreement, the Parties to the Association Agreement consider it is appropriate for the EU-Chile Association Committee ('the Association Committee') to take a decision to reflect the modification of Annex XII to the Association Agreement.

(5) The position of the Union within the Association Committee should be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf within the EU-Chile Association Committee ('the Association Committee') regarding the modification of Annex XII to the Association Agreement setting out the lists of Chilean entities which procure in accordance with the provisions of Title IV of Part IV on Government Procurement, shall be based on the draft Decision of the Association Committee attached to this Decision.

[1] OJ L 352, 30.12.2002, p. 3.

Article 2

After its adoption, the Decision of the Association Committee shall be published in the *Official Journal of the European Union*.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 14 April 2014.

For the Council
The President
C. ASHTON

DRAFT

DECISION No …/2014 OF THE EU-CHILE ASSOCIATION COMMITTEE

of …

relating to Annex XII to the Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part, concerning the lists of Chilean entities which procure in accordance with the provisions of Title IV of Part IV on government procurement

THE EU-CHILE ASSOCIATION COMMITTEE,

Having regard to the Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part [1] ('the Association Agreement'), signed on 18 November 2002, and in particular to Article 159 thereof,

Whereas:

(1) Annex XII to the Association Agreement provides lists of entities in the Republic of Chile ('Chile') which procure in accordance with the provisions on government procurement of Title IV of Part IV of the Association Agreement.

(2) On 10 February 2012, Chile notified the European Union of its intention to modify its coverage on government procurement set out in Annex XII to the Association Agreement. The modification consists in the simplification of certain lists of entities in Annex XII to the Association Agreement, namely: in Appendix 1 A, the entities listed under each Ministry and regional government are replaced with a catch-all clause which covers all entities subordinated to the listed Ministries and regional governments, and in Appendix 2 A, the details of the list of all entities at sub-central level is replaced by a catch-all phrase: 'all municipalities' ('the modification of Annex XII to the Association Agreement'). Appendix 1 B and Appendix 2 B, as well as Appendix 3 to Appendix 5 of Annex XII to the Association Agreement, remain unchanged.

(3) For the purposes of Annex XII to the Association Agreement, it is appropriate to proceed with the modification of Annex XII to the Association Agreement notified by Chile,

HAS ADOPTED THIS DECISION:

Article 1

Annex XII to the Association Agreement containing the lists of Chilean entities which procure in accordance with the provisions of the Title IV of Part IV on government procurement is replaced by the text appearing in the Annex to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at …,

For the EU-Chile Association Committee

The President

[1] OJ L 352, 30.12.2002, p. 3.

ANNEX

'ANNEX XII

(Referred to in Article 137 of the Association Agreement)

CHILE'S COVERAGE ON GOVERNMENT PROCUREMENT

Appendix 1

Entities at central level

Entities which procure in accordance with the provisions of this Title

SUPPLIES

Thresholds SDR 130 000

SERVICES

Specified in Appendix 4

Thresholds SDR 130 000

WORKS

Specified in Appendix 5

Thresholds SDR 5 000 000

A. LIST OF ENTITIES

Presidencia de la República

Ministerio de Interior y Seguridad Pública

Ministerio de Relaciones Exteriores

Ministerio de Defensa Nacional

Ministerio de Hacienda

Ministerio Secretaría General de la Presidencia de la República

Ministerio Secretaría General de Gobierno

Ministerio de Economía, Fomento y Turismo

Ministerio de Minería

Ministerio de Desarrollo Social

Ministerio de Educación

Ministerio de Justicia

Ministerio del Trabajo y Previsión Social

Ministerio de Obras Públicas

Ministerio de Transporte y Telecomunicaciones

Ministerio de Salud

Ministerio de Vivienda y Urbanismo

Ministerio de Bienes Nacionales

Ministerio de Agricultura

Ministerio de Energía

Ministerio del Medio Ambiente

Gobiernos Regionales

Todas las Intendencias

Todas las Gobernaciones

Note to Section A)

Unless otherwise specified in this Appendix, all entities subordinated to the Ministries and regional governments listed above, are covered by this Agreement.

B. ALL OTHER CENTRAL PUBLIC ENTITIES INCLUDING THEIR REGIONAL AND SUB-REGIONAL SUBDIVISIONS PROVIDED THAT THEY DO NOT HAVE AN INDUSTRIAL OR COMMERCIAL CHARACTER.

Appendix 2

Entities at subcentral level and bodies governed by public law

Entities which procure in accordance with the provisions of this Title

SUPPLIES

Thresholds SDR 200 000

SERVICES

Specified in Appendix 4

Thresholds SDR 200 000

WORKS

Specified in Appendix 5

Thresholds SDR 5 000 000

A. LIST OF ENTITIES

All Municipalities

B. ALL OTHER SUB-CENTRAL PUBLIC ENTITIES INCLUDING THEIR SUBDIVISIONS AND ALL OTHER ENTITIES OPERATING IN THE GENERAL INTEREST AND SUBJECT TO EFFECTIVE AND MANAGERIAL OR FINANCIAL CONTROL BY PUBLIC ENTITIES, PROVIDED THAT THEY DO NOT HAVE AN INDUSTRIAL OR COMMERCIAL CHARACTER.

Appendix 3

Entities operating in the utilities sector

SUPPLIES

Thresholds SDR 400 000

SERVICES

Specified in Appendix 4

Thresholds SDR 400 000

WORKS

Specified in Appendix 5

Thresholds SDR 5 000 000

A. LIST OF ENTITIES

Empresa Portuaria Arica

Empresa Portuaria Iquique

Empresa Portuaria Antofagasta

Empresa Portuaria Coquimbo

Empresa Portuaria Valparaíso

Empresa Portuaria San Antonio

Empresa Portuaria San Vicente-Talcahuano

Empresa Portuaria Puerto Montt

Empresa Portuaria Chacabuco

Empresa Portuaria Austral

Aeropuertos de propiedad del Estado, dependientes de la Dirección de Aeronáutica Civil.

B. ALL OTHER PUBLIC UNDERTAKINGS, AS DEFINED IN ARTICLE 138(C), WHICH HAVE AS ONE OF THEIR ACTIVITIES ANY OF THOSE REFERRED TO BELOW OR ANY COMBINATION THEREOF:

(a) the provision of airport or other terminal facilities to carriers by air; and

(b) the provision of maritime or inland port or other terminal facilities to carriers by sea or inland waterway.

Appendix 4

Services

For the purposes of this Title and without prejudice to Article 137(2), no services of the Universal list of Services are excluded.

Appendix 5

Construction services

For the purposes of this Title and without prejudice to the provisions of Article 137(2), no construction services under the division of the CPC concerning construction work are excluded.'.

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