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⁽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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2016/4**of 5 January 2016****amending Regulation (EC) No 216/2008 of the European Parliament and of the Council as regards essential requirements for environmental protection****(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 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ⁽¹⁾, and in particular Article 6(2) thereof,

Whereas:

- (1) Article 6(1) of Regulation (EC) No 216/2008 requires products, parts and appliances to comply with the environmental protection requirements contained in Volumes I and II of Annex 16 to the Convention on International Civil Aviation (hereinafter referred to as the 'Chicago Convention') as applicable on 17 November 2011, except for the Appendices to that Annex.
- (2) Volumes I and II of Annex 16 to the Chicago Convention have been amended in 2014 by introducing new noise standards.
- (3) Regulation (EC) No 216/2008 should therefore be amended accordingly.
- (4) The measures provided for in this Regulation are based on the opinion issued by the European Aviation Safety Agency in accordance with Articles 17(2)(b) and 19(1) of Regulation (EC) No 216/2008.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 6 of Regulation (EC) No 216/2008, paragraph 1 is replaced by the following:

'1. Products, parts and appliances shall comply with the environmental protection requirements contained in Amendment 11-B of Volume I and in Amendment 8 of Volume II of Annex 16 to the Chicago Convention as applicable on 1 January 2015, except for the Appendices to Annex 16.'

⁽¹⁾ OJ L 79, 13.3.2008, p. 1.

Article 2

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

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

Done at Brussels, 5 January 2016.

For the Commission

The President

Jean-Claude JUNKER

COMMISSION REGULATION (EU) 2016/5**of 5 January 2016****amending Regulation (EU) No 748/2012 as regards the implementation of essential requirements for environmental protection****(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 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ⁽¹⁾, and in particular Article 6(2) thereof,

Whereas:

- (1) Article 6(1) of Regulation (EC) No 216/2008 requires products, parts and appliances to comply with the environmental protection requirements contained in Volumes I and II of Annex 16 to the Convention on International Civil Aviation (hereinafter referred to as the 'Chicago Convention') as applicable on 17 November 2011, except for Appendices to that Annex. Those requirements were implemented in Union law by Commission Regulation (EU) No 748/2012 ⁽²⁾.
- (2) Volumes I and II of Annex 16 to the Chicago Convention have been amended in 2014 by introducing new noise standards.
- (3) Regulation (EU) No 748/2012 should therefore be amended accordingly.
- (4) The measures provided for in this Regulation are based on the opinion issued by the European Aviation Safety Agency in accordance with Articles 17(2)(b) and 19(1) of Regulation (EC) No 216/2008.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex I (Part-21) to Regulation (EU) No 748/2012, point 21.A.18(a) is replaced by the following:

- '(a) The applicable noise requirements for the issue of a type certificate for an aircraft are prescribed according to the provisions of Chapter 1 of Annex 16, Volume I, Part II to the Chicago Convention and:
1. for subsonic jet aeroplanes, in Volume I, Part II, Chapters 2, 3, 4 and 14, as applicable;
 2. for propeller-driven aeroplanes, in Volume I, Part II, Chapters 3, 4, 5, 6, 10 and 14, as applicable;
 3. for helicopters, in Volume I, Part II, Chapters 8 and 11, as applicable;

⁽¹⁾ OJ L 79, 13.3.2008, p. 1.

⁽²⁾ Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

4. for supersonic aeroplanes, in Volume I, Part II, Chapter 12, as applicable; and
5. for tilt-rotors, in Volume I, Part II, Chapter 13, as applicable.’

Article 2

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

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

Done at Brussels, 5 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2016/6**of 5 January 2016****imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 322/2014****(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾, and in particular Article 53(1)(b)(ii) thereof,

Whereas:

- (1) Article 53 of Regulation (EC) No 178/2002 provides for the possibility to adopt appropriate Union emergency measures for food and feed imported from a third country in order to protect public health, animal health or the environment, where the risk cannot be contained satisfactorily by means of measures taken by the Member States individually.
- (2) Following the accident at the Fukushima nuclear power station on 11 March 2011, the Commission was informed that radionuclide levels in certain food products originating in Japan exceeded the action levels in food applicable in Japan. Such contamination may constitute a threat to public and animal health in the Union and therefore Commission Implementing Regulation (EU) No 297/2011 ⁽²⁾ was adopted. That Regulation was replaced by Implementing Regulation (EU) No 961/2011 ⁽³⁾ which was later replaced by Implementing Regulation (EU) No 284/2012 ⁽⁴⁾. The latter was replaced by Implementing Regulation (EU) No 996/2012 ⁽⁵⁾ which was later replaced by Implementing Regulation (EU) No 322/2014 ⁽⁶⁾.
- (3) Since Implementing Regulation (EU) No 322/2014 provides that the measures provided therein are to be reviewed by 31 March 2015 and in order to take into account the further development of the situation and occurrence data for 2014 on radioactivity in feed and food, it is appropriate to repeal Implementing Regulation (EU) No 322/2014 and adopt a new Regulation.
- (4) The existing measures have been reviewed taking into account more than 81 000 occurrence data on radioactivity in feed and food other than beef and more than 237 000 occurrence data on radioactivity in beef, provided by the Japanese authorities concerning the fourth growing season after the accident.
- (5) Alcoholic beverages falling within the CN codes 2203 to 2208 are no longer explicitly excluded from the scope as the requirements as regards sampling and analysis and declaration apply to a defined list of feed and food.
- (6) The data submitted by the Japanese authorities provide evidence that it is no longer necessary to require the sampling and analysis of feed and food originating in the prefectures of Aomori and Saitama regarding the presence of radioactivity before export to the Union.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 297/2011 of 25 March 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station (OJ L 80, 26.3.2011, p. 5).

⁽³⁾ Commission Implementing Regulation (EU) No 961/2011 of 27 September 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Regulation (EU) No 297/2011 (OJ L 252, 28.9.2011, p. 10).

⁽⁴⁾ Commission Implementing Regulation (EU) No 284/2012 of 29 March 2012 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 961/2011 (OJ L 92, 30.3.2012, p. 16).

⁽⁵⁾ Commission Implementing Regulation (EU) No 996/2012 of 26 October 2012 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 284/2012 (OJ L 299, 27.10.2012, p. 31).

⁽⁶⁾ Commission Implementing Regulation (EU) No 322/2014 of 28 March 2014 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station (OJ L 95, 29.3.2014, p. 1).

- (7) For feed and food products originating in the prefecture of Fukushima, the criterion of no non-compliance found by the Japanese authorities for two consecutive years (2013 and 2014), has been used for the current review to lift the requirement of sampling and analysis before export to the Union for those feed and food products. For the other feed and food originating in that prefecture, it is appropriate to maintain the requirement of sampling and analysis before export to the Union.
- (8) It is appropriate to present the provisions of this Regulation in a manner that prefectures of which the same feed and food has to be sampled and analysed before export to the Union are grouped together, in order to facilitate the application of this Regulation.
- (9) As regards the prefectures of Gunma, Ibaraki, Tochigi, Miyagi, Iwate and Chiba, it is currently required to sample and analyse mushrooms, fishery products, rice, soybeans, buckwheat and certain edible wild plants and the processed and derived products thereof, before export to the Union. The same requirements apply to compound foodstuffs containing more than 50 % of those products. The occurrence data for the fourth growing season provide evidence that for several of those feed and food commodities, it is appropriate to no longer require sampling and analysis before export to the Union.
- (10) As regards the prefectures of Akita, Yamagata and Nagano, it is currently required to sample and analyse mushrooms and certain edible wild plants and the processed and derived products thereof before export to the Union. The occurrence data for the fourth growing season provide evidence that for one of the edible wild plants, it is appropriate to no longer require sampling and analysis before export to the Union. On the other hand, as a consequence of the finding of non-compliance in an edible wild plant, it is appropriate to require sampling and analysis of this edible wild plant originating from those prefectures.
- (11) The occurrence data from the fourth growing season provide evidence that it is appropriate to maintain the requirement for sampling and analysis before export to the Union for mushrooms originating from the prefectures of Shizuoka, Yamanashi and Niigata. As a consequence of the finding of non-compliance in an edible wild plant, it is appropriate to require sampling and analysis of this edible wild plant originating from those prefectures.
- (12) The controls performed at import show that the special conditions provided for by Union law are correctly implemented by the Japanese authorities and non-compliance has not been found at import controls for more than three years. Therefore, it is appropriate to keep the low frequency of controls at import and to no longer require that Member States inform the Commission every three months through the rapid alert system for food and feed (RASFF) of all analytical results.
- (13) The transitional measures provided for in Japanese legislation, set out in Annex III to Implementing Regulation (EU) No 322/2014, are no longer of relevance for the feed and food currently imported from Japan and should therefore no longer be referred to in this Regulation.
- (14) It is appropriate to foresee a review of the provisions of this Regulation when the results of sampling and analysis on the presence of radioactivity of feed and food of the fifth growing season (2015) after the accident are available, i.e. by 30 June 2016. The criteria for the review will be determined at the time of the review.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation applies to feed and food within the meaning of Article 1(2) of Council Regulation (Euratom) No 3954/87 ⁽¹⁾ ('the products') originating in or consigned from Japan, with the exclusion of:

- (a) products which have been harvested and/or processed before 11 March 2011;

⁽¹⁾ Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 371, 30.12.1987, p. 11).

- (b) personal consignments of feed and food of animal origin which are covered by Article 2 of Commission Regulation (EC) No 206/2009 ⁽¹⁾;
- (c) personal consignments of feed and food other than of animal origin which are non-commercial and destined to a natural person for personal consumption and use only. In case of doubt, the burden of proof lies with the recipient of the consignment.

Article 2

Definition

For the purposes of this Regulation, 'consignment' means:

- for products for which a sampling and analysis is required by Article 5, a quantity of any of the feed or food falling within the scope of this Regulation of the same class or description, covered by the same document(s), conveyed by the same means of transport and coming from the same prefecture of Japan,
- for the other products falling within the scope of this Regulation, a quantity of any of the feed or food falling within the scope of this Regulation, covered by the same document(s), conveyed by the same means of transport and coming from one or more prefectures of Japan, within the limits set in the declaration referred to in Article 5.

Article 3

Import into the Union

Products may only be imported into the Union if they comply with this Regulation.

Article 4

Maximum levels of caesium-134 and caesium-137

Products shall comply with the maximum level for the sum of caesium-134 and caesium-137 as set out in Annex I.

Article 5

Declaration for certain products

1. Each consignment of mushrooms, fish and fishery products, with the exception of scallops, rice, soybeans, (japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura or a derived product thereof or a compound feed or food containing more than 50 % of those products, originating in or consigned from Japan, shall be accompanied by a valid declaration drawn up and signed in accordance with Article 6.
2. The declaration referred to in paragraph 1 shall attest that the products comply with the legislation in force in Japan.
3. The declaration referred to in paragraph 1 shall furthermore certify that:
 - (a) the product has been harvested and/or processed before 11 March 2011; or
 - (b) the product does not originate in and is not consigned from one of the prefectures listed in Annex II ⁽²⁾, for which the sampling and analysis of this product is required; or

⁽¹⁾ Commission Regulation (EC) No 206/2009 of 5 March 2009 on the introduction into the Community of personal consignments of products of animal origin and amending Regulation (EC) No 136/2004 (OJ L 77, 24.3.2009, p. 1).

⁽²⁾ The list of products in Annex II is without prejudice to the requirements of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (c) the product is consigned from but does not originate in one of the prefectures listed in Annex II, for which the sampling and analysis of this product is required and has not been exposed to radioactivity during transiting; or
 - (d) the product originates in one of the prefectures listed in Annex II for which the sampling and analysis of this product is required and is accompanied by an analytical report containing the results of sampling and analysis; or
 - (e) where the origin of the product or of its ingredients present at more than 50 % is unknown, the product is accompanied by an analytical report containing the results of sampling and analysis.
4. Fish and fishery products caught or harvested in the coastal waters of the prefectures of Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Chiba or Iwate shall be accompanied by a declaration referred to paragraph 1 and by an analytical report containing the results of sampling and analysis, irrespective of where such products are landed.

Article 6

Drawing up and signing of the declaration

1. The declaration referred to in Article 5 shall be drawn up in accordance with the model set out in Annex III.
2. For the products referred to in points (a), (b) and (c) of Article 5(3), the declaration shall be signed by an authorised representative of the competent Japanese authority or by an authorised representative of an instance authorised by the competent Japanese authority under the authority and supervision of the competent Japanese authority.
3. For the products referred to in points (d) and (e) of Article 5(3) and in Article 5(4), the declaration shall be signed by an authorised representative of the competent Japanese authority and shall be accompanied by an analytical report containing the results of sampling and analysis.

Article 7

Identification

Each consignment of products referred to in Article 5(1) shall be identified by means of a code which shall be indicated on the declaration referred to in Article 5, on the analytical report referred to in Article 6(3), on the common entry document or common veterinary entry document, referred to in Article 9(2) and on the sanitary certificate accompanying the consignment.

Article 8

Border inspection posts and designated point of entry

1. Consignments of products referred to in Article 5(1) shall be introduced into the Union through a designated point of entry within the meaning of point (b) of Article 3 of Commission Regulation (EC) No 669/2009 ⁽¹⁾ ('the designated point of entry').
2. Paragraph 1 shall not apply to consignments of products referred to in Article 5(1) falling within the scope of Council Directive 97/78/EC ⁽²⁾. Those consignments shall be introduced into the Union via a border inspection post within the meaning of point (g) of Article 2(2) of that Directive.

⁽¹⁾ Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

⁽²⁾ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

*Article 9***Prior notification**

1. Feed and food business operators or their representatives shall give prior notification of the arrival of each consignment of products referred to in Article 5(1).
2. For the purpose of prior notification, feed and food business operators or their representatives shall complete:
 - (a) for products of non-animal origin: Part I of the common entry document (CED) referred to in point (a) of Article 3 of Regulation (EC) No 669/2009, taking into account the notes for guidance for the CED laid down in Annex II to that Regulation; for the purpose of this Regulation, Box I.13 of the CED can contain more than one commodity code;
 - (b) for fish and fishery products: the common veterinary entry document (CVED) set out in Annex III to Commission Regulation (EC) No 136/2004 ⁽¹⁾.

The respective document shall be transmitted to the competent authority at the designated point of entry or border inspection post, at least two working days prior to the physical arrival of the consignment.

*Article 10***Official controls**

1. The competent authorities of the border inspection post or designated point of entry shall carry out the following controls on the products referred to in Article 5(1):
 - (a) documentary checks on all consignments;
 - (b) random identity checks and random physical checks, including laboratory analysis on the presence of caesium-134 and caesium-137. The analytical results shall be available within a maximum of five working days.
2. In case the result of the laboratory analysis provides evidence that the guarantees provided in the declaration referred to in Article 5 are false, the declaration is considered not to be valid and the consignment of feed and food does not comply with this Regulation.

*Article 11***Costs**

All costs resulting from the official controls referred to in Article 10 and any measures taken following non-compliance shall be borne by the feed and food business operators.

*Article 12***Release for free circulation**

1. The release for free circulation of each consignment of products referred to in Article 5(1) shall be subject to the presentation (physically or electronically) by the feed or food business operator or their representative to the custom authorities of a CED duly completed by the competent authority once all official controls have been carried out. The custom authorities shall only release the consignment for free circulation if a favourable decision by the competent authority is indicated in box II.14 of the CED and signed in box II.21 of the CED.
2. Paragraph 1 shall not apply to consignments of products referred to in Article 5(1) falling within the scope of Directive 97/78/EC. The release for free circulation of those consignments shall be subject to Regulation (EC) No 136/2004.

⁽¹⁾ Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (OJ L 21, 28.1.2004, p. 11).

*Article 13***Non-compliant products**

Products which do not comply with this Regulation shall not be placed on the market. Such products shall be safely disposed of or returned to Japan.

*Article 14***Review**

This Regulation shall be reviewed before 30 June 2016.

*Article 15***Repeal**

Implementing Regulation (EU) No 322/2014 is repealed.

*Article 16***Transitional provision**

By way of derogation from Article 3, products may be imported into the Union under the following conditions:

- (a) they comply with Implementing Regulation (EU) No 322/2014; and
- (b) either they left Japan before the entry into force of this Regulation or they left Japan after the entry into force of this Regulation but before 1 February 2016 and they are accompanied by a declaration in accordance with Implementing Regulation (EU) No 322/2014 which was issued before the entry into force of this Regulation.

*Article 17***Entry into force**

This Regulation shall enter into force on the third 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 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

Maximum levels for food ⁽¹⁾ (Bq/kg) as provided for in the Japanese legislation

	Foods for infants and young children	Milk and milk-based drinks	Mineral water and similar drinks and tea brewed from unfermented leaves	Other food
Sum of caesium-134 and caesium-137	50 ⁽²⁾	50 ⁽²⁾	10 ⁽²⁾	100 ⁽²⁾

⁽¹⁾ For dried products that are intended to be consumed in a reconstituted state, the maximum level applies to the reconstituted product as ready for consumption.

For dried mushrooms a reconstitution factor of 5 is of application.

For tea, the maximum level applies to the infusion brewed from unfermented tea leaves. The processing factor for dried tea is 50, and therefore a maximum level of 500 Bq/kg on dried tea leaves ensures that the level in the brewed tea does not exceed the maximum level of 10 Bq/kg.

⁽²⁾ In order to ensure consistency with maximum levels currently applied in Japan, these values replace on a provisional basis the values laid down in Regulation (Euratom) No 3954/87.

Maximum levels for feed ⁽¹⁾ (Bq/kg) as provided for in the Japanese legislation

	Feed intended for cattle and horses	Feed intended for pigs	Feed intended for poultry	Feed for fish ⁽³⁾
Sum of caesium-134 and caesium-137	100 ⁽²⁾	80 ⁽²⁾	160 ⁽²⁾	40 ⁽²⁾

⁽¹⁾ Maximum level is relative to feed with a moisture content of 12 %.

⁽²⁾ In order to ensure consistency with maximum levels currently applied in Japan, these values replace on a provisional basis the values laid down in Commission Regulation (Euratom) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 83, 30.3.1990, p. 78).

⁽³⁾ With the exemption of feed for ornamental fish.

ANNEX II

Feed and food for which sampling and analysis regarding the presence of caesium-134 and caesium-137 are required before export to the Union

(a) Products originating in the prefecture of Fukushima:

- mushrooms and derived products thereof falling within CN codes 0709 51, 0709 59, 0710 80 61, 0710 80 69, 0711 51 00, 0711 59, 0712 31, 0712 32, 0712 33, 0712 39, 2003 10, 2003 90 and 2005 99 80,
- fish and fishery products falling within CN codes 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504 10, 1504 20, 1604 and 1605 with the exception of scallops falling within CN codes 0307 21, 0307 29 and 1605 52 00,
- rice and derived products thereof falling within CN codes 1006, 1102 90 50, 1103 19 50, 1103 20 50, 1104 19 91, 1104 19 99, 1104 29 17, 1104 29 30, 1104 29 59, 1104 29 89, 1104 30 90, 1901, 1904 10 30, 1904 20 95, 1904 90 10 and 1905 90,
- soybeans and derived products thereof falling within CN codes 1201 90, 1208 10 and 1507,
- giant butterbur or Japanese butterbur (*Petasites japonicus*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- *Aralia* spp. and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- bamboo shoot (*Phyllostacys pubescens*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90, 2004 90 and 2005 91,
- bracken (*Pteridium aquilinum*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- koshiabura (shoot of *Eleuterococcus sciadophylloides*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- Japanese royal fern (*Osmunda japonica*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- ostrich fern (*Matteuccia struthiopteris*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- (Japanese) persimmon (*Diospyros* sp.) and products derived thereof falling within CN codes 0810 70 00, 0810 90, 0811 90, 0812 90 and 0813 50.

(b) Products originating in the prefectures of Gunma, Ibaraki, Tochigi, Miyagi, Chiba or Iwate:

- mushrooms and derived products thereof falling within CN codes 0709 51, 0709 59, 0710 80 61, 0710 80 69, 0711 51 00, 0711 59, 0712 31, 0712 32, 0712 33, 0712 39, 2003 10, 2003 90 and 2005 99 80,
- fish and fishery products falling within CN codes 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504 10, 1504 20, 1604 and 1605 with the exception of scallops falling within CN codes 0307 21, 0307 29 and 1605 52 00,
- *Aralia* spp. and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- bamboo shoot (*Phyllostacys pubescens*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90, 2004 90 and 2005 91,
- bracken (*Pteridium aquilinum*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,

- Japanese royal fern (*Osmunda japonica*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- koshiabura (shoot of *Eleuterococcus sciadophylloides*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- ostrich fern (*Matteuccia struthiopteris*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90.

(c) Products originating in the prefectures of Akita, Yamagata or Nagano:

- mushrooms and derived products thereof falling within CN codes 0709 51, 0709 59, 0710 80 61, 0710 80 69, 0711 51 00, 0711 59, 0712 31, 0712 32, 0712 33, 0712 39, 2003 10, 2003 90 and 2005 99 80,
- *Aralia* spp. and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- bamboo shoot (*Phyllostachys pubescens*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90, 2004 90 and 2005 91,
- Japanese royal fern (*Osmunda japonica*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90,
- koshiabura (shoot of *Eleuterococcus sciadophylloides*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90.

(d) Products originating in the prefectures of Yamanashi, Shizuoka or Niigata:

- mushrooms and derived products thereof falling within CN codes 0709 51, 0709 59, 0710 80 61, 0710 80 69, 0711 51 00, 0711 59, 0712 31, 0712 32, 0712 33, 0712 39, 2003 10, 2003 90 and 2005 99 80,
- koshiabura (shoot of *Eleuterococcus sciadophylloides*) and derived products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90.

(e) Compound products containing more than 50 % of the products listed under points (a) to (d) of this Annex.

ANNEX III

Declaration for the import into the Union of

..... (Product and country of origin)

Batch identification Code **Declaration Number**

In accordance with Commission Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station the

.....

(authorised representative referred to in paragraphs 2 or 3 of Article 6 of Implementing Regulation (EU) 2016/6)

DECLARES that the
(products referred to in Article 5(1) of Implementing Regulation (EU) 2016/6) of this consignment
 composed of:
(description of consignment, product, number and type of packages, gross or net weight)
 embarked at (embarkation place)
 on (date of embarkation)
 by (identification of transporter)
 going to (place and country of destination)
 which comes from the establishment
(name and address of establishment)

is compliant with the legislation in force in Japan as regards the maximum levels for the sum of caesium-134 and caesium-137.

DECLARES that the consignment concerns:

- ☐ mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura or a derived product thereof or a compound feed or food containing more than 50 % of those products, which have been harvested and/or processed before 11 March 2011;
- ☐ mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura or a derived product thereof or a compound feed or food containing more than 50 % of those products, which do not originate in and are not consigned from one of the prefectures listed in Annex II to Implementing Regulation (EU) 2016/6, for which the sampling and analysis of this product is required;
- ☐ mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura or a derived product thereof or a compound feed or food containing more than 50 % of those products, which are consigned from but do not originate in one of the prefectures listed in Annex II to Implementing Regulation (EU) 2016/6, for which the sampling and analysis of this product is required and have not been exposed to radioactivity during transiting;
- ☐ mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura or a derived product thereof or a compound feed or food containing more than 50 % of those products, which originate in one of the prefectures listed in Annex II to Implementing Regulation (EU) 2016/6, for which the sampling and analysis of this product is required, and have been sampled on (date) and subjected to laboratory analysis on (date) in the (name of laboratory), to determine the level of the radionuclides, caesium-134 and caesium-137. The analytical report is attached;

- ☐ mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese or giant butterbur (fuki), *Aralia* spp., bamboo shoot, bracken, Japanese royal fern, ostrich fern and koshiabura of unknown origin or a derived product thereof or a compound feed or food containing more than 50 % of those products as (an) ingredient(s) of unknown origin, which have been sampled on (date) and subjected to laboratory analysis on (date) in the (name of laboratory), to determine the level of the radionuclides, caesium-134 and caesium-137. The analytical report is attached.

Done at on

Stamp and signature of the authorised representative
referred to in Article 6(2) or (3) of Implementing
Regulation (EU) 2016/6

COMMISSION IMPLEMENTING REGULATION (EU) 2016/7
of 5 January 2016
establishing the standard form for the European Single Procurement Document
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC ⁽¹⁾, and in particular Article 59(2) thereof, and to Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 80(3) thereof,

Whereas:

- (1) One of the major objectives of Directives 2014/24/EU and 2014/25/EU is the lessening the administrative burdens of contracting authorities, contracting entities and economic operators, not least small and medium-sized enterprises. A key element of that effort is the European single procurement document (ESPD). The standard form for the ESPD should consequently be drafted in such a manner that the need to produce a substantial number of certificates or other documents related to exclusion and selection criteria is obviated. With the same objective in mind, the standard form should also provide the relevant information in respect of entities on whose capacities an economic operator relies, so that the verification of that information can be carried out together with the verification in respect of the main economic operator and on the same conditions.
- (2) The ESPD should also be available for use by contracting entities which are subject to Directive 2014/25/EU and which, when applying the exclusion and selection criteria provided for under Directive 2014/24/EU, must do so in the same way and under the same conditions as contracting authorities.
- (3) To avoid administrative burdens for the contracting authorities and contracting entities and possible contradictory indications in the different procurement documents, the information which economic operators must provide in the ESPD should be clearly indicated by the contracting authorities and contracting entities in advance in the call for competition or through references therein to other parts of the procurement documents, which the economic operators must in any case examine carefully in view of their participation and possible submission of tenders.
- (4) The ESPD should also contribute to further simplification for both economic operators and contracting authorities and entities by replacing various and diverging national self-declarations with one standard form established at the European level. This should also help to reduce problems linked to the precise drafting of formal statements and declarations of consent as well as language issues, since the standard form will be available in the official languages. The ESPD should thereby facilitate an increased cross-border participation in public procurement procedures.
- (5) Any processing and exchange of data to be performed in connection with the ESPD should be performed in accordance with the national rules implementing Directive 95/46/EC of the European Parliament and of the Council ⁽³⁾, and in particular with national rules applicable to the processing of data relating to offences, criminal convictions or security measures under Article 8(5) of said Directive.
- (6) It should be recalled that the Commission shall review the practical application of the ESPD taking into account the technical development of databases in the Member States and report thereon to the European Parliament and the Council by 18 April 2017. In so doing, the Commission may also take into consideration possible suggestions to improve its functionality in view of enhancing the possibilities of cross-border participation in

⁽¹⁾ OJ L 94, 28.3.2014, p. 65.

⁽²⁾ OJ L 94, 28.3.2014, p. 243.

⁽³⁾ 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).

public procurement, not least for SMEs, or potential simplifications within the framework set out by Directive 2014/24/EU; it may as well consider possible issues relating to practices of systematic requests of certificates or other forms of documentary evidence of all participants in a given procurement procedure or practices consisting in identifying in a discriminatory manner the economic operators to be requested such documentation.

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Advisory Committee on Public Procurement,

HAS ADOPTED THIS REGULATION:

Article 1

From the moment the national measures implementing Directive 2014/24/EU enter into force, and at the latest from 18 April 2016, the standard form set out in Annex 2 to this Regulation shall be used for the purposes of drawing up the European single procurement document referred to in Article 59 of Directive 2014/24/EU. Instructions for its use are set out in Annex 1 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*.

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

Done at Brussels, 5 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX 1

Instructions

The ESPD is a self-declaration by economic operators providing preliminary evidence replacing the certificates issued by public authorities or third parties. As provided in Article 59 of Directive 2014/24/EU, it is a formal statement by the economic operator that it is not in one of the situations in which economic operators shall or may be excluded; that it meets the relevant selection criteria and that, where applicable, it fulfils the objective rules and criteria that have been set out for the purpose of limiting the number of otherwise qualified candidates to be invited to participate. Its objective is to reduce the administrative burden arising from the requirement to produce a substantial number of certificates or other documents related to exclusion and selection criteria.

To facilitate the task for economic operators when filling in an ESPD, Member States may issue guidance on the use of the ESPD, for instance to explain which provisions of national law are pertinent in relation to Part III, Section A ⁽¹⁾, that official lists of approved economic operators or equivalent certificates might not be established or issued in a given Member State, or to specify which references and information must be given to enable contracting authorities or contracting entities to retrieve a given certificate electronically.

When preparing the procurement documents for a given procurement procedure, contracting authorities and contracting entities must indicate in the call for competition, in procurement documents referred to in the call for competition or in the invitations to confirm interest which information they will require from the economic operators, including an explicit statement as to whether the information set out under Parts II and III ⁽²⁾ should or should not be provided in respect of subcontractors on whose capacities the economic operator does **not** rely ⁽³⁾. They may also make the task easier for economic operators by indicating this information directly in an electronic version of the ESPD, for instance by using the ESPD service <https://webgate.acceptance.ec.europa.eu/growth/tools-databases/ecertis2/resources/espd/index.html> ⁽⁴⁾ that Commission Services will make available, free of charge, for contracting authorities, contracting entities, economic operators, providers of electronic services and other interested parties.

Tenders in open procedures and requests for participation in restricted procedures, competitive procedures with negotiations, competitive dialogues or innovation partnerships, must be accompanied by the ESPD, which economic operators have completed in order to deliver the required information ⁽⁵⁾. Except in relation to certain contracts based on framework agreements, the tenderer to whom it is intended to award the contract will have to provide up to date certificates and supporting documents.

Member States may regulate or leave it to contracting authorities and contracting entities to decide whether to use the ESPD also as part of procurement procedures not or not fully subject to the detailed procedural rules of Directives 2014/24/EU or 2014/25/EU, for instance for procurement below the relevant thresholds or procurements subject to the particular rules applicable to social and other specific services (the 'light regime') ⁽⁶⁾. Similarly, Member States may regulate or leave it to contracting authorities and contracting entities to decide whether to use the ESPD also in connection with the award of concessions contracts, whether or not subject to the provisions of Directive 2014/23/EU ⁽⁷⁾.

⁽¹⁾ For instance that economic operators having been convicted under Articles x, y and z of the national penal code must state so when filling in the information concerning convictions for participation in a criminal organisation or money laundering ...

⁽²⁾ Information concerning exclusion grounds.

⁽³⁾ Cf. the third subparagraph of Article 71(5) of Directive 2014/24/EU and the third subparagraph of Article 88(5) of Directive 2014/25/EU

⁽⁴⁾ This is the link to the preliminary version under development. When available, the link to the full production version will be inserted or made available otherwise.

⁽⁵⁾ The situation is more complex in respect of **negotiated procedures without prior publication**, provided for under Article 32 of Directive 2014/24/EU and Article 50 of Directive 2014/25/EU as these provisions apply to very different realities.

Requesting an ESPD would constitute an unnecessary administrative burden or be otherwise inappropriate 1) where only one, predetermined participant is possible (for the two Directives, respectively Article 32, paragraph 2(b), paragraph 3(b), paragraph 3 (d) and paragraph 5 of Directive 2014/24/EU and Article 50, letters (c), (e), (f) and (i) of Directive 2014/25/EU and 2) because of the urgency involved (respectively Article 32(2)(c) of Directive 2014/24/EU and Article 50, letters (d) and (h) of Directive 2014/25/EU or because of the particular characteristics of the transaction for supplies quoted and purchased on a commodity market (Article 32(3)(c) of Directive 2014/24/EU and Article 50, letter (g) of Directive 2014/25/EU.

On the other hand, the ESPD would play its role in full and should be requested in the remaining cases, which are characterised by the possible participation of more than one participants and the absence of urgency or particular characteristics linked to the transaction; such is the case in respect of Article 32, paragraph 2(a), paragraph 3(a) and paragraph 4 of Directive 2014/24/EU and Article 50, letters (a), (b) and (j) of Directive 2014/25/EU.

⁽⁶⁾ Articles 74 to 77 and 91 to 94 of, respectively, Directives 2014/24/EU and 2014/25/EU.

⁽⁷⁾ Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts, OJ L 94, 28.3.2014, p. 1.

The contracting authority or contracting entity may ask any tenderer at any moment during the procedure to submit all or part of the required certificates and supporting documents where this is necessary to ensure the proper conduct of the procedure.

Economic operators may be excluded from the procurement procedure or be subject to prosecution under national law in cases of serious misrepresentation in filling in the ESPD or, generally, in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria, or where such information is withheld or the economic operators are unable to submit the supporting documents.

Economic operators may reuse the information that has been provided in an ESPD which has already been used in a previous procurement procedure as long as the information remains correct and continues to be pertinent. The easiest way to do so is by inserting the information in the new ESPD through use of the appropriate functionalities that are provided to that effect in the above-mentioned electronic ESPD-service. Of course, reuse of information through other forms of copy-paste of information, for instance information stored in the economic operator's IT-equipment (PCs, tablets, servers ...), will also be possible.

According to the second subparagraph of Article 59(2) of Directive 2014/24/EU, the ESPD shall be provided exclusively in electronic form; however, this may be postponed until 18 April 2018 at the latest ⁽⁸⁾. This means that both fully electronic and paper-based versions of the ESPD may co-exist until 18 April 2018 at the latest. The just-mentioned ESPD-service will allow economic operators to fill in their ESPD electronically in **all cases**, thus enabling them to draw the full advantages of the facilities offered (not least of reusing information). For use in procurement procedures in which use of electronic means of communication has been postponed (also possible until 18 April 2018 at the latest), the ESPD service allows economic operators to print their electronically filled-in ESPD as a paper document which can then be transmitted to the contracting authority or contracting entity by other means of communication than electronic ones ⁽⁹⁾.

As mentioned earlier, the ESPD consists of a formal statement by the economic operator that the relevant grounds for exclusion do not apply, that the relevant selection criteria are fulfilled and that it will provide the relevant information as required by the contracting authority or contracting entity.

Where procurements are divided into lots **and** selection criteria ⁽¹⁰⁾ vary from lot to lot, an ESPD should be filled in for each lot (or group of lots with the same selection criteria).

The ESPD further identifies the public authority or third party responsible for establishing the supporting documents ⁽¹¹⁾ and contains a formal statement to the effect that the economic operator will be able, upon request and without delay, to provide those supporting documents.

Contracting authorities or contracting entities may choose or may be required ⁽¹²⁾ by Member States to limit the information required on selection criteria to a single question whether, yes or no, economic operators meet all the required selection criteria. While this may be followed up by requests for further information and/or documentation, care should be taken to avoid imposing excessive administrative burdens on economic operators through systematic requests of certificates or other forms of documentary evidence of all participants in a given procurement procedure or practices consisting in identifying in a discriminatory manner the economic operators to be requested such documentation.

The obligations for the contracting authorities and contracting entities to obtain the documentation concerned directly by accessing a national database in any Member State that is available free of charge also applies where the information initially requested on selection criteria has been limited to a yes or no answer. If such electronic documentation is requested, economic operators will therefore provide the contracting authority or contracting entity with the information needed to obtain the documentation concerned when the selection criteria are being checked rather than directly in the ESPD.

⁽⁸⁾ Cf. Article 90(3) of Directive 2014/24/EU.

⁽⁹⁾ They will also be able to generate their ESPD as a pdf-file which can be electronically transmitted as an attachment. To be able subsequently to reuse the information, economic operators should save the filled-in ESPD in an appropriate electronic format (such as .xml).

⁽¹⁰⁾ This might be the case for the minimum required turnover, which in such cases must be determined in function of the maximum estimated value of the single lots.

⁽¹¹⁾ Unless the contracting authorities or contracting entities have indicated that general information ('yes'/'no') on meeting the requirements will be sufficient in the first instance. See below for more explanations on this option.

⁽¹²⁾ Such requirements may be general or limited to certain situations only, e.g. only in open procedures or, for two stage procedures, only when all candidates meeting the minimum requirements will be invited to participate.

Where an extract from the relevant register, for example judicial records, is available electronically to the contracting authority or contracting entity, the economic operator can state where the information can be found (i.e. the name of the repository, internet address, identification of the file or record etc.) so that the contracting authority or contracting entity may retrieve this information. **By indicating this information, the economic operator agrees that the contracting authority or contracting entity may retrieve the relevant documentation subject to the national rules implementing Directive 95/46/EC⁽¹³⁾ on the processing of personal data, and in particular of special categories of data such as on offences, criminal convictions or security measures.**

In accordance with Article 64 of Directive 2014/24/EU of the European Parliament and of the Council, economic operators which are registered on official lists of approved economic operators or possess a relevant certification by bodies established under public or private law may, in respect of the information required under Parts III to V, submit to the contracting authority or contracting entity the certificate of registration issued by the competent authority or the certificate issued by the competent certification body.

An economic operator participating **on its own** and which does **not rely** on the capacities of other entities in order to meet the selection criteria, must fill out **one** ESPD.

An economic operator participating on its own but relying on the capacities of one or more other entities must ensure that the contracting authority or contracting entity receives its own ESPD together with a **separate** ESPD setting out the relevant information⁽¹⁴⁾ for **each of the entities it relies on**.

Finally, where groups of economic operators, including temporary associations, participate together in the procurement procedure, **a separate ESPD** setting out the information required under Parts II to V must be given for **each** of the participating economic operators.

In all cases where more than one person is member of the administrative, management or supervisory body of an economic operator or has powers of representation, decision or control therein, each **may** have to sign the same ESPD, depending on national rules, including those governing data protection.

Concerning the signature(s) of the ESPD, please note that a signature on the ESPD might not be necessary where the ESPD is transmitted as part of a set of documents, whose authenticity and integrity is ensured through the required signature(s) of the means of transmission⁽¹⁵⁾.

For procurement procedures in which a call for competition has been published in the *Official Journal of the European Union*, the information required under Part I will be automatically retrieved, **provided that the above-mentioned electronic ESPD-service is used to generate and fill in the ESPD.**

If there is no call for competition in the OJEU, then the contracting authority or contracting entity must fill in the information allowing the procurement procedure to be unequivocally identified. All other information in all sections of the ESPD is to be filled in by the economic operator

The ESPD includes the following Parts and Sections:

- **Part I. Information concerning the procurement procedure and the contracting authority or contracting entity.**
- **Part II. Information concerning the economic operator.**

⁽¹³⁾ 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.

⁽¹⁴⁾ See Part II, Section C

⁽¹⁵⁾ For instance: if the tender and the accompanying ESPD in an open procedure are transmitted by an e-mail which is provided with an electronic signature of the required type, then additional signature(s) on the ESPD might not be necessary. The use of an e-Signature on the ESPD might also not be necessary, when the ESPD is integrated in an e-Procurement platform and e-authentication is required in order to use that platform.

— **Part III. Exclusion criteria:**

- **A: Grounds relating to criminal convictions** (their application is mandatory pursuant to Article 57(1) of Directive 2014/24/EU. Their application is also mandatory for contracting authorities pursuant to the second subparagraph of Article 80(1) of Directive 2014/25/EU, whereas contracting entities other than contracting authorities **may** decide to apply these exclusion criteria).
- **B: Grounds relating to the payment of taxes or social security contributions** (their application is mandatory pursuant to Article 57(2) of Directive 2014/24/EU in case of a final and binding decision. Under the same conditions, their application is also mandatory for contracting authorities pursuant to the second subparagraph of Article 80(1) of Directive 2014/25/EU, whereas contracting entities other than contracting authorities **may** decide to apply these exclusion grounds. Please note that national legislation of certain Member States may render exclusion obligatory also where the decision is not final and binding.).
- **C: Grounds relating to insolvency, conflicts of interests or professional misconduct (See Article 57(4) of Directive 2014/24/EU)** (cases in which economic operators may be excluded; application of these exclusion grounds may be rendered obligatory for contracting authorities by their Member States. Pursuant to Article 80(1) of Directive 2014/25/EU all contracting entities, whether or not they are contracting authorities, **may** decide to apply these exclusion grounds or be required by their Member State to do so).
- **D: Other exclusion grounds that may be foreseen in the national legislation of the contracting authority's or contracting entity's Member State.**

— **Part IV. Selection criteria** ⁽¹⁶⁾:

- **α: Global indication for all selection criteria**
- **A: Suitability.**
- **B: Economic and financial standing.**
- **C: Technical and professional ability.**
- **D: Quality assurance schemes and environmental management standards** ⁽¹⁷⁾ ⁽¹⁸⁾.

— **Part V. Reduction of the number of qualified candidates** ⁽¹⁹⁾.

— **Part VI. Concluding statements.**

⁽¹⁶⁾ Pursuant to Article 80(2) of Directive 2014/25/EU, contracting entities, whether or not they are contracting authorities, may decide to apply the selection criteria provided for in Article 58 of Directive 2014/24/EU (Part IV, Sections A, B and C).

⁽¹⁷⁾ Use of the ESPD by contracting entities in respect of requirements connected with quality assurance schemes and environmental management standards (Part IV, Section D) is not explicitly provided for under Directive 2014/25/EU, but should nevertheless be allowed for practical reasons, as Articles 62 and 81 of, respectively, Directives 2014/24/EU and 2014/25/EU are substantially the same.

⁽¹⁸⁾ Pursuant to Articles 77(2) and 78(1) of Directive 2014/25/EU, contracting entities shall select participants on the basis of objective rules and criteria. As described above, these criteria may in some case be those provided for in Directive 2014/24/EU or involve substantially identical provisions (see footnote 16). However, the objective rules and criteria may also be specific to a given contracting entity or a specific procurement procedure. Such cases can, however, not be covered in a standard form.

⁽¹⁹⁾ Use of the ESPD by contracting entities in respect of the reduction of the number of qualified candidates (Part V) is not explicitly provided for under Directive 2014/25/EU, but should nevertheless be allowed for practical reasons, as both Articles 65 and 78(2) of, respectively, Directives 2014/24/EU and 2014/25/EU require that any such reduction of numbers shall be carried out in accordance with objective and non-discriminatory criteria or rules.

ANNEX 2

STANDARD FORM FOR THE EUROPEAN SINGLE PROCUREMENT DOCUMENT (ESPD)

Part I: Information concerning the procurement procedure and the contracting authority or contracting entity

For procurement procedures in which a call for competition has been published in the *Official Journal of the European Union*, the information required under Part I will be automatically retrieved, provided that the electronic ESPD-service ⁽¹⁾ is used to generate and fill in the ESPD. Reference of the relevant notice ⁽²⁾ published in the *Official Journal of the European Union*:

OJEU S number [], date [], page [],

Notice number in the OJ S: []/[]/S []-[]-[]-[]-[]

If there is no call for competition in the OJEU, then the contracting authority or contracting entity must fill in the information allowing the procurement procedure to be unequivocally identified:

In case publication of a notice in the *Official Journal of the European Union* is not required, please give other information allowing the procurement procedure to be unequivocally identified (e. g. reference of a publication at national level): [...]

INFORMATION ABOUT THE PROCUREMENT PROCEDURE

The information required under Part I will be automatically retrieved, provided that the above-mentioned electronic ESPD-service is used to generate and fill in the ESPD. If not, this information must be filled in by the economic operator.

Identity of the procurer ⁽³⁾	Answer:
Name:	[]
Which procurement is concerned?	Answer:
Title or short description of the procurement ⁽⁴⁾ :	[]
File reference number attributed by the contracting authority or contracting entity (if applicable) ⁽⁵⁾ :	[]

All other information in all sections of the ESPD is to be filled in by the economic operator

⁽¹⁾ Commission Services will make the electronic ESPD-service available, free of charge, for contracting authorities, contracting entities, economic operators, providers of electronic services and other interested parties

⁽²⁾ For contracting authorities: either a Prior Information Notice used as a means of calling for competition or a Contract Notice.
For contracting entities: a Periodic Indicative Notice used as a means of calling for competition, a Contract Notice or a Notice on the Existence of a Qualification System.

⁽³⁾ Information to be copied from Section I, Point I.1, of the relevant notice, In case of joint procurement, please indicate the names of all involved procurers.

⁽⁴⁾ See points II.1.1 and II.1.3 of the relevant notice

⁽⁵⁾ See point II.1.1 of the relevant notice

Part II: Information concerning the economic operator

A: INFORMATION ABOUT THE ECONOMIC OPERATOR

Identification:	Answer:
Name:	[]
VAT-number, if applicable: If no VAT-number is applicable, please indicate another national identification number, if required and applicable	[] []
Postal address:	[.....]
Contact person or persons ⁽⁶⁾ : Telephone: E-mail: Internet address (web address) (if applicable):	[.....] [.....] [.....] [.....]
General information:	Answer:
Is the economic operator a Micro, a Small or a Medium-Sized Enterprise ⁽⁷⁾ ?	[] Yes [] No
Only in case the procurement is reserved ⁽⁸⁾: is the economic operator a sheltered workshop, a 'social business' ⁽⁹⁾ or will it provide for the performance of the contract in the context of sheltered employment programmes? If yes, what is the corresponding percentage of disabled or disadvantaged workers? If required, please specify which category or categories of disabled or disadvantaged workers the employees concerned belong to?	[] Yes [] No [.....] [.....]
If applicable, is the economic operator registered on an official list of approved economic operators or does it have an equivalent certificate (e.g. under a national (pre)qualification system)?	[] Yes [] No [] Not applicable
If yes: Please answer the remaining parts of this Section, Sections B and, where relevant, C of this Part, complete Part V, where applicable, and, in any case, fill in and sign Part VI. (a) Please provide the name of the list or certificate and the relevant registration or certification number, if applicable: (b) If the certificate of registration or certification is available electronically, please state:	(a) [.....] (b) (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....][.....]

⁽⁶⁾ Please repeat the information concerning contact persons as many times as needed.

⁽⁷⁾ Cf. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, (OJ L 124, 20.5.2003, p. 36). This information is required for statistical purposes only.

Micro enterprises: enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

Small enterprises: an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million;

Medium enterprises, enterprises which are neither micro nor small and which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million,

⁽⁸⁾ See contract notice point III.1.5

⁽⁹⁾ I.e. its main aim is the social and professional integration of disabled or disadvantaged persons.

(c) Please state the references on which the registration or certification is based, and, where applicable, the classification obtained in the official list ⁽¹⁰⁾: (d) Does the registration or certification cover all of the required selection criteria? If no: In addition, please complete the missing information in Part IV, Sections A, B, C or D as the case may be ONLY if this is required in the relevant notice or procurement documents: (e) Will the economic operator be able to provide a certificate with regard to the payment of social security contributions and taxes or provide information enabling the contracting authority or contracting entity to obtaining it directly by accessing a national database in any Member State that is available free of charge? If the relevant documentation is available electronically, please indicate:	(c) [.....] (d) ☐ Yes ☐ No (e) ☐ Yes ☐ No (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....] [.....]
Form of participation:	Answer:
Is the economic operator participating in the procurement procedure together with others ⁽¹¹⁾ ?	☐ Yes ☐ No
If yes, please ensure that the others concerned provide a separate ESPD form.	
If yes:	
(a) Please indicate the role of the economic operator in the group (leader, responsible for specific tasks ...):	(a): [.....]
(b) Please identify the other economic operators participating in the procurement procedure together:	(b): [.....]
(c) Where applicable, name of the participating group:	(c): [.....]
Lots	Answer:
Where applicable, indication of the lot(s) for which the economic operator wishes to tender:	[]

B: INFORMATION ABOUT REPRESENTATIVES OF THE ECONOMIC OPERATOR

Where applicable, please indicate the name(s) and address(es) of the person(s) empowered to represent the economic operator for the purposes of this procurement procedure:

Representation, if any:	Answer:
Full name;	[.....];
accompanied by the date and place of birth, if required:	[.....]
Position/Acting in the capacity of:	[.....]
Postal address:	[.....]
Telephone:	[.....]
E-mail:	[.....]
If needed, please provide detailed information on the representation (its forms, extent, purpose ...):	[.....]

⁽¹⁰⁾ The references and the classification, if any, are set out on the certification.

⁽¹¹⁾ Notably as part of a group, consortium, joint venture or similar.

C: INFORMATION ABOUT RELIANCE ON THE CAPACITIES OF OTHER ENTITIES

Reliance:	Answer:
Does the economic operator rely on the capacities of other entities in order to meet the selection criteria set out under Part IV and the criteria and rules (if any) set out under Part V below?	☐ Yes ☐ No

If yes, please provide a separate ESPD form setting out the information required under **Sections A and B of this Part and Part III for each** of the entities concerned, duly filled in and signed by the entities concerned.

Please note that this should also include any technicians or technical bodies, not belonging directly to the economic operator's undertaking, especially those responsible for quality control and, in the case of public works contracts, the technicians or technical bodies upon whom the economic operator can call in order to carry out the work.

Insofar as it is relevant for the specific capacity or capacities on which the economic operator relies, please include the information under Parts IV and V for each of the entities concerned ⁽¹²⁾.

D: INFORMATION CONCERNING SUBCONTRACTORS ON WHOSE CAPACITY THE ECONOMIC OPERATOR DOES NOT RELY

(Section to be filled-in only if this information is explicitly required by the contracting authority or contracting entity.)

Subcontracting:	Answer:
Does the economic operator intend to subcontract any share of the contract to third parties?	☐ Yes ☐ No If yes and in so far as known , please list the proposed subcontractors: [...]

If the contracting authority or contracting entity explicitly requests this information in addition to the information under this section, please provide the information required under Sections A and B of this Part and Part III for each of the (categories of) subcontractors concerned.

⁽¹²⁾ E.g. for technical bodies involved in quality control: Part IV, Section C, point 3.

Part III: Exclusion grounds

A: GROUNDS RELATING TO CRIMINAL CONVICTIONS

Article 57(1) of Directive 2014/24/EU sets out the following reasons for exclusion:

1. Participation in a criminal organisation ⁽¹³⁾;
2. Corruption ⁽¹⁴⁾;
3. Fraud ⁽¹⁵⁾;
4. Terrorist offences or offences linked to terrorist activities ⁽¹⁶⁾;
5. Money laundering or terrorist financing ⁽¹⁷⁾;
6. Child labour and other forms of trafficking in human beings ⁽¹⁸⁾.

Grounds relating to criminal convictions under national provisions implementing the grounds set out in Article 57(1) of the Directive:	Answer:
Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for one of the reasons listed above, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable?	☐ Yes ☐ No If the relevant documentation is available electronically, please indicate: (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....] ⁽¹⁹⁾
If yes, please indicate ⁽²⁰⁾: (a) Date of conviction, specify which of points 1 to 6 is concerned and the reason(s) for the conviction, (b) Identify who has been convicted []; (c) Insofar as established directly in the conviction:	(a) Date: [], point(s): [], reason(s): [] (b) [.....] (c) Length of the period of exclusion.[.....] and the point(s) concerned [] If the relevant documentation is available electronically, please indicate: (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....] ⁽²¹⁾
In case of convictions, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion ⁽²²⁾ ('Self-Cleaning')?	☐ Yes ☐ No
If yes, please describe the measures taken ⁽²³⁾:	[.....]

⁽¹³⁾ As defined in Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime (OJ L 300, 11.11.2008, p. 42).

⁽¹⁴⁾ As defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, OJ C 195, 25.6.1997, p. 1, and in Article 2(1) of Council Framework Decision 2003/568/JHA of 22 July 2003 on combating corruption in the private sector (OJ L 192, 31.7.2003, p. 54). This exclusion ground also includes corruption as defined in the national law of the contracting authority (contracting entity) or the economic operator.

⁽¹⁵⁾ Within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests (OJ C 316, 27.11.1995, p. 48).

⁽¹⁶⁾ As defined in Articles 1 and 3 of Council Framework Decision of 13 June 2002 on combating terrorism (OJ L 164, 22.6.2002, p. 3). This exclusion ground also includes inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of that Framework Decision.

⁽¹⁷⁾ As defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (OJ L 309, 25.11.2005, p. 15).

⁽¹⁸⁾ As defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA (OJ L 101, 15.4.2011, p. 1).

⁽¹⁹⁾ Please repeat as many times as needed.

⁽²⁰⁾ Please repeat as many times as needed.

⁽²¹⁾ Please repeat as many times as needed.

⁽²²⁾ In accordance with national provisions implementing Article 57(6) of Directive 2014/24/EU.

⁽²³⁾ Taking into account the character of the crimes committed (punctual, repeated, systematic ...), the explanation should show the adequacy of the measures to taken.

B: GROUNDS RELATING TO THE PAYMENT OF TAXES OR SOCIAL SECURITY CONTRIBUTIONS

Payment of taxes or social security contributions:	Answer:	
Has the economic operator met all its obligations relating to the payment of taxes or social security contributions , both in the country in which it is established and in Member State of the contracting authority or contracting entity if other than the country of establishment?	[] Yes [] No	
If not , please indicate:	Taxes	Social contributions
(a) Country or Member State concerned	(a) [.....]	(a) [.....]
(b) What is the amount concerned?	(b) [.....]	(b) [.....]
(c) How has this breach of obligations been established:		
(1) Through a judicial or administrative decision :	(c1) [] Yes [] No	(c1) [] Yes [] No
— Is this decision final and binding?	— [] Yes [] No	— [] Yes [] No
— Please indicate the date of conviction or decision.	— [.....]	— [.....]
— In case of a conviction, insofar as established directly therein , the length of the period of exclusion:	— [.....]	— [.....]
(2) By other means ? Please specify:	(c2) [.....]	(c2) [.....]
(d) Has the economic operator fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines?	(d) [] Yes [] No If yes , please provide details: [.....]	(d) [] Yes [] No If yes , please provide details: [.....]
If the relevant documentation concerning payment of taxes or social contributions is available electronically, please indicate:	(web address, issuing authority or body, precise reference of the documentation) ⁽²⁴⁾ : [.....][.....][.....]	

C: GROUNDS RELATING TO INSOLVENCY, CONFLICTS OF INTERESTS OR PROFESSIONAL MISCONDUCT ⁽²⁵⁾

Please note that, for the purpose of this procurement, some of the following exclusion grounds may have been defined more precisely, in national law, in the relevant notice or the procurement documents. Thus, national law may for instance provide that the notion of 'grave professional misconduct' may cover several different forms of conduct.

Information concerning possible insolvency, conflict of interest or professional misconduct	Answer:
Has the economic operator, to its knowledge , breached its obligations in the fields of environmental, social and labour law ⁽²⁶⁾ ?	[] Yes [] No If yes , has the economic operator taken measures to demonstrate its reliability despite the existence of this ground for exclusion ('Self-Cleaning')? [] Yes [] No If it has , please describe the measures taken: [.....]

⁽²⁴⁾ Please repeat as many times as needed.

⁽²⁵⁾ See Article 57(4) of Directive 2014/24/EU

⁽²⁶⁾ As referred to for the purposes of this procurement in national law, in the relevant notice or the procurement documents or in Article 18(2) of Directive 2014/24/EU

Has the economic operator experienced that a prior public contract, a prior contract with a contracting entity or a prior concession contract was terminated early, or that damages or other comparable sanctions were imposed in connection with that prior contract? If yes, please provide details:	☐ Yes ☐ No [.....] If yes, has the economic operator taken self-cleaning measures? ☐ Yes ☐ No If it has, please describe the measures taken: [.....]
Can the economic operator confirm that: (a) It has not been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria, (b) It has not withheld such information, (c) It has been able, without delay, to submit the supporting documents required by a contracting authority or contracting entity, and (d) It has not undertaken to unduly influence the decision making process of the contracting authority or contracting entity, to obtain confidential information that may confer upon it undue advantages in the procurement procedure or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award?	☐ Yes ☐ No

D: OTHER EXCLUSION GROUNDS THAT MAY BE FORESEEN IN THE NATIONAL LEGISLATION OF THE CONTRACTING AUTHORITY'S OR CONTRACTING ENTITY'S MEMBER STATE

Purely national exclusion grounds	Answer:
Do the purely national grounds of exclusion, which are specified in the relevant notice or in the procurement documents, apply? If the documentation required in the relevant notice or in the procurement documents is available electronically, please indicate:	☐ Yes ☐ No (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....] ⁽³¹⁾
In case any of the purely national exclusion grounds apply, has the economic operator taken self-cleaning measures? If it has, please describe the measures taken:	☐ Yes ☐ No [.....]

⁽³¹⁾ Please repeat as many times as needed.

Part IV: Selection criteria

Concerning the selection criteria (Section α or Sections A to D of this part), the economic operator declares that:

α: GLOBAL INDICATION FOR ALL SELECTION CRITERIA

The economic operator should only fill in this field in case the contracting authority or contracting entity has indicated in the relevant notice or in the procurement documents referred to in the notice that the economic operator can limit itself to filling in Section α of Part IV without having to fill in any other Section of Part IV:

Meeting all required selection criteria	Answer
It satisfies the required selection criteria:	☐ Yes ☐ No

A: SUITABILITY

The economic operator should only provide information where the selection criteria concerned have been required by the contracting authority or contracting entity in the relevant notice or in the procurement documents referred to in the notice.

Suitability	Answer
(1) It is enrolled in the relevant professional or trade registers kept in the Member State of its establishment ⁽³²⁾: If the relevant documentation is available electronically, please indicate:	[.....] (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]
(2) For service contracts: Is a particular authorisation or membership of a particular organisation needed in order to be able to perform the service in question in the country of establishment of the economic operator? If the relevant documentation is available electronically, please indicate:	☐ Yes ☐ No If yes, please specify which and indicate whether the economic operator has it: [...] ☐ Yes ☐ No (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]

B: ECONOMIC AND FINANCIAL STANDING

The economic operator should only provide information where the selection criteria concerned have been required by the contracting authority or contracting entity in the relevant notice or in the procurement documents referred to in the notice.

Economic and financial standing	Answer:
(1a) Its ('general') yearly turnover for the number of financial years required in the relevant notice or the procurement documents is as follows: And/or, (1b) Its average yearly turnover for the number of years required in the relevant notice or the procurement documents is as follows ⁽³³⁾: If the relevant documentation is available electronically, please indicate:	year: [.....] turnover: [.....][...]currency year: [.....] turnover: [.....][...]currency year: [.....] turnover: [.....][...]currency (number of years, average turnover): [.....], [.....][...]currency (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]

⁽³²⁾ As described in Annex XI of Directive 2014/24/EU; economic operators from certain Member States may have to comply with other requirements set out in that Annex

⁽³³⁾ Only if permitted in the relevant notice or the procurement documents.

(2a) Its yearly ('specific') turnover in the business area covered by the contract and specified in the relevant notice or the procurement documents for the number of financial years required is as follows: And/or, (2b) Its average yearly turnover in the area and for the number of years required in the relevant notice or the procurement documents is as follows ⁽³⁴⁾: If the relevant documentation is available electronically, please indicate:	year: [.....] turnover: [.....][...]currency year: [.....] turnover: [.....][...]currency year: [.....] turnover: [.....][...]currency (number of years, average turnover): [.....],[.....][...]currency (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]
(3) In case the information concerning turnover (general or specific) is not available for the entire period required, please state the date on which the economic operator was set up or started trading:	[.....]
(4) Concerning the financial ratios ⁽³⁵⁾ specified in the relevant notice or the procurement documents, the economic operator declares that the actual value(s) for the required ratio(s) is/are as follows: If the relevant documentation is available electronically, please indicate:	(identification of the required ratio – ratio between x and y ⁽³⁶⁾ — and the value): [.....], [.....] ⁽³⁷⁾ (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]
(5) The insured amount in its professional risk indemnity insurance is the following: If this information is available electronically, please indicate:	[.....][...]currency (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]
(6) Concerning the other economic or financial requirements, if any, that may have been specified in the relevant notice or the procurement documents, the economic operator declares that: If the relevant documentation that may have been specified in the relevant notice or the procurement documents, is available electronically, please indicate:	[.....] (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]

C: TECHNICAL AND PROFESSIONAL ABILITY

The economic operator should only provide information where the selection criteria concerned have been required by the contracting authority or contracting entity in the relevant notice or in the procurement documents referred to in the notice.

Technical and professional ability	Answer:
(1a) For public works contracts only: During the reference period ⁽³⁸⁾, the economic operator has performed the following works of the specified type: If the relevant documentation concerning satisfactory execution and outcome for the most important works is available electronically, please indicate:	Number of years (this period is specified in the relevant notice or the procurement documents): [.....] Works: [.....] (web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....]

⁽³⁴⁾ Only if permitted in the relevant notice or the procurement documents.

⁽³⁵⁾ E. g. the ratio between assets and liabilities.

⁽³⁶⁾ E. g. the ratio between assets and liabilities.

⁽³⁷⁾ Please repeat as many times as needed.

⁽³⁸⁾ Contracting authorities may require up to five years and allow experience dating from more than five years.

(1b) For public supply and public service contracts only: During the reference period ⁽³⁹⁾, the economic operator has delivered the following principal deliveries of the type specified or provided the following main services of the type specified: When drawing up the list, please indicate the amounts, dates and recipients, whether public or private ⁽⁴⁰⁾:	Number of years (this period is specified in the relevant notice or the procurement documents): [.....] <table border="1" data-bbox="809 309 1366 405"> <thead> <tr> <th>Description</th> <th>amounts</th> <th>dates</th> <th>recipients</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Description	amounts	dates	recipients				
Description	amounts	dates	recipients						
(2) It can call upon the following technicians or technical bodies ⁽⁴¹⁾, especially those responsible for quality control: In the case of public works contracts, the economic operator will be able to call on the following technicians or technical bodies to carry out the work:	[.....] [.....]								
(3) It uses the following technical facilities and measures for ensuring quality and its study and research facilities are as follows:	[.....]								
(4) It will be able to apply the following supply chain management and tracking systems when performing the contract:	[.....]								
(5) For complex products or services to be supplied or, exceptionally, for products or services which are required for a special purpose The economic operator will allow checks ⁽⁴²⁾ to be conducted on the production capacities or the technical capacity of the economic operator and, where necessary, on the means of study and research which are available to it and on the quality control measures?	[] Yes [] No								
(6) The following educational and professional qualifications are held by: (a) The service provider or the contractor itself, and/or (depending on the requirements set out in the relevant notice or the procurement documents) (b) Its managerial staff:	(a) [.....] (b) [.....]								
(7) The economic operator will be able to apply the following environmental management measures when performing the contract:	[.....]								
(8) The economic operator's average annual manpower and the number of managerial staff for the last three years were as follows:	Year, average annual manpower: [.....],[.....], [.....],[.....], [.....],[.....], Year, number of managerial staff: [.....],[.....], [.....],[.....], [.....],[.....]								
(9) The following tools, plant or technical equipment will be available to it for performing the contract:	[.....]								
(10) The economic operator intends possibly to subcontract ⁽⁴³⁾the following proportion (i.e. percentage) of the contract:	[.....]								

⁽³⁹⁾ Contracting authorities may **require** up to three years and **allow** experience dating from **more** than three years.

⁽⁴⁰⁾ In other words, **all** recipients should be listed and the list should include both public clients and private clients for the supplies or services concerned.

⁽⁴¹⁾ For technicians or technical bodies not belonging directly to the economic operator's undertaking but on whose capacities the economic operator relies as set out under Part II, Section C, separate ESPD forms must be filled in.

⁽⁴²⁾ The check is to be performed by the contracting authority or, in case the latter consents to this, on its behalf by a competent official body of the country in which the supplier or service provider is established;

⁽⁴³⁾ Please note that if the economic operator **has** decided to subcontract a part of the contract **and** relies on the subcontractor's capacities to perform that part, then please fill in a separate ESPD for such subcontractors, see Part II, Section C above.

(11) For public supply contracts: The economic operator will supply the required samples, descriptions or photographs of the products to be supplied, which do not need to be accompanied by certifications of authenticity; Where applicable, the economic operator furthermore declares that it will provide the required certificates of authenticity. If the relevant documentation is available electronically, please indicate:	☐ Yes ☐ No ☐ Yes ☐ No (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....]
(12) For public supply contracts: Can the economic operator provide the required certificates drawn up by official quality control institutes or agencies of recognised competence attesting the conformity of products clearly identified by references to the technical specifications or standards, which are set out in the relevant notice or the procurement documents? If not, please explain why and state which other means of proof can be provided: If the relevant documentation is available electronically, please indicate:	☐ Yes ☐ No [.....] (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....]

D: QUALITY ASSURANCE SCHEMES AND ENVIRONMENTAL MANAGEMENT STANDARDS

The economic operator should only provide information where quality assurance schemes and/or environmental management standards have been required by the contracting authority or contracting entity in the relevant notice or in the procurement documents referred to in the notice.

Quality Assurance Schemes and Environmental Management Standards	Answer:
Will the economic operator be able to produce certificates drawn up by independent bodies attesting that the economic operator complies with the required quality assurance standards, including accessibility for disabled persons? If not, please explain why and specify which other means of proof concerning the quality assurance scheme can be provided: If the relevant documentation is available electronically, please indicate:	☐ Yes ☐ No [.....] [.....] (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....]
Will the economic operator be able to produce certificates drawn up by independent bodies attesting that the economic operator complies with the required environmental management systems or standards? If not, please explain why and specify which other means of proof concerning the environmental management systems or standards can be provided: If the relevant documentation is available electronically, please indicate:	☐ Yes ☐ No [.....] [.....] (web address, issuing authority or body, precise reference of the documentation): [.....] [.....] [.....]

Part V: Reduction of the number of qualified candidates

The economic operator should only provide information where the contracting authority or contracting entity has specified the objective and non-discriminatory criteria or rules to be applied in order to limit the number of candidates that will be invited to tender or to conduct a dialogue. This information, which can be accompanied by requirements concerning the (types of) certificates or forms of documentary evidence, if any, to be produced, is set out in the relevant notice or in the procurement documents referred to in the notice.

For restricted procedures, competitive procedures with negotiation, competitive dialogue procedures and innovation partnerships only:

The economic operator declares that:

Reduction of numbers	Answer:
It meets the objective and non-discriminatory criteria or rules to be applied in order to limit the number of candidates in the following way:	[...]
In case certain certificates or other forms of documentary evidence are required, please indicate for each whether the economic operator has the required documents:	[] Yes [] No ⁽⁴⁵⁾
If some of these certificates or forms of documentary evidence are available electronically ⁽⁴⁴⁾ , please indicate for each :	(web address, issuing authority or body, precise reference of the documentation): [.....][.....][.....] ⁽⁴⁶⁾

Part VI: Concluding statements

The undersigned formally declare that the information stated under Parts II – V above is accurate and correct and that it has been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declare to be able, upon request and without delay, to provide the certificates and other forms of documentary evidence referred to, except where:

- (a) *The contracting authority or contracting entity has the possibility of obtaining the supporting documentation concerned directly by accessing a national database in any Member State that is available free of charge ⁽⁴⁷⁾, or*
- (b) *As of 18 October 2018 at the latest ⁽⁴⁸⁾, the contracting authority or contracting entity already possesses the documentation concerned.*

The undersigned formally consent to [identify the contracting authority or contracting entity as set out in Part I, Section A], gaining access to documents supporting the information, which has been provided in [identify the Part/Section/Point(s) concerned] of this European Single Procurement Document for the purposes of [identify the procurement procedure: (summary description, reference of publication in the Official Journal of the European Union, reference number)].

Date, place and, where required or necessary, signature(s): [.....]

⁽⁴⁴⁾ Please indicate clearly, which item the answer relates to.

⁽⁴⁵⁾ Please repeat as many times as needed.

⁽⁴⁶⁾ Please repeat as many times as needed.

⁽⁴⁷⁾ On condition that the economic operator has provided the necessary information (web address, issuing authority or body, precise reference of the documentation) allowing the contracting authority or contracting entity to do so. Where required, this must be accompanied by the relevant consent to such access.

⁽⁴⁸⁾ Depending on the national implementation of the second subparagraph of Article 59(5) of Directive 2014/24/EU.

COMMISSION IMPLEMENTING REGULATION (EU) 2016/8
of 5 January 2016
specifying the technical characteristics of the 2017 ad hoc module on self-employment
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community ⁽¹⁾, and in particular Article 7a(5) thereof,

Whereas:

- (1) For the purpose of monitoring progress towards the common objectives set out in the Europe 2020 strategy the Commission should receive from the Member States a comprehensive set of data on self-employment that allows comparisons to be made between Member States.
- (2) Commission Regulation (EU) No 318/2013 ⁽²⁾ establishes an ad hoc module on self-employment.
- (3) Commission Delegated Regulation (EU) No 1397/2014 ⁽³⁾ specifies and gives a description of the areas of specialised information ('ad hoc sub-modules') which should be included in the 2017 ad hoc module on self-employment.
- (4) The Commission should specify the technical characteristics, the filters, the codes and the deadline for the transmission of data under the ad hoc sub-module on self-employment.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The technical characteristics of the 2017 ad hoc module on self-employment, the filters, the codes to be used and the deadline by which the results shall be sent to the Commission are laid down in the Annex 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*.

⁽¹⁾ OJ L 77, 14.3.1998, p. 3.

⁽²⁾ Commission Regulation (EU) No 318/2013 of 8 April 2013 adopting the programme of ad hoc modules, covering the years 2016 to 2018, for the labour force sample survey provided for by Council Regulation (EC) No 577/98 (OJ L 99, 9.4.2013, p. 11).

⁽³⁾ Commission Delegated Regulation (EU) No 1397/2014 of 22 October 2014 amending Regulation (EU) No 318/2013 adopting the programme of ad hoc modules, covering the years 2016 to 2018, for the labour force sample survey provided for by Council Regulation (EC) No 577/98 (OJ L 370, 30.12.2014, p. 42).

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

Done at Brussels, 5 January 2016.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

This Annex sets out the technical characteristics, filters and codes to be used in the ad hoc module on self-employment scheduled to be carried out in 2017. It also sets the dates for submission of data to the Commission.

Deadline for transmission of the results to the Commission: 31 March 2018.

Filters and codes to be used for sending data: as set out in Annex III to Commission Regulation (EC) No 377/2008 ⁽¹⁾.

Columns reserved for optional weighting factors, to be used in cases of subsampling or non-response: columns 222-225 containing whole numbers and columns 226-227 containing decimal places.

(1) **Sub-module ‘Economically dependent self-employment’**

Name/Column	Code	Description	Filter
MAINCLNT		Economic dependency	STAPRO = 1,2
211		<i>Number and importance of clients in the last 12 months</i>	
	1	No client in the last 12 months	
	2	Only one client in the last 12 months	
	3	2-9 clients in the last 12 months, but one was dominant	
	4	2-9 clients in the last 12 months, and none was dominant	
	5	More than 9 clients in the last 12 months, but one was dominant	
	6	More than 9 clients in the last 12 months, and none was dominant	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
WORKORG		Organisational dependency	STAPRO = 1,2 AND MAINCLNT ≠ 1
212		<i>Influence over deciding working hours</i>	
	1	The respondent decides	
	2	The client/s of the respondent decide(s)	
	3	Any other party decides	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	

⁽¹⁾ Commission Regulation (EC) No 377/2008 of 25 April 2008 implementing Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community as regards the codification to be used for data transmission from 2009 onwards, the use of a subsample for the collection of data on structural variables and the definition of the reference quarters (OJ L 114, 26.4.2008, p. 57).

(2) Sub-module 'Working conditions for self-employed people'

Name/Column	Code	Description	Filter
REASSE		Main reason for becoming self-employed	STAPRO = 1,2
213		<i>Main reason for becoming self-employed when starting to work as self-employed in the current job</i>	
	1	Could not find a job as an employee	
	2	The respondent's former employer requested the respondent to become self-employed	
	3	It is the usual practice in the respondent's field	
	4	A suitable opportunity presented itself	
	5	Continued the family business	
	6	Did not want to or plan to become self-employed, but started working as self-employed for another reason than listed previously	
	7	Wanted to be self-employed because of flexible working hours	
	8	Wanted to be self-employed for other reason	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
SEDIFFIC		Main difficulty as self-employed	STAPRO = 1,2
214		<i>Self-perceived main difficulty in working as self-employed during the last 12 months</i>	
	0	Lack of influence on setting the price of own work	
	1	Lack of access to financing for the business	
	2	Delayed payments or non-payments	
	3	Inappropriate levels of administrative burden	
	4	Lack of income in case of sickness	
	5	Periods of financial hardship	
	6	Periods of having no customer, no assignments or project to work on	
	7	Other difficulty	
	8	Had no difficulties	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
REASNOEM		Main reason for not having employees	STAPRO = 2
215		<i>Self-perceived main reason for not having any employees</i>	
	0	Respondent primarily wants to employ him/herself	
	1	There is not enough work	

Name/Column	Code	Description	Filter
BPARTNER 216	2	Difficult to find suitable staff	STAPRO = 1,2
	3	Legal framework is too complicated	
	4	High social contributions	
	5	Not possible in the respondent's occupation	
	6	Respondent prefers to work with sub-contractors or associates	
	7	The respondent's client/s want(s) the respondent to do the work	
	8	Other reason	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
		Working with business partners	
		<i>Working with a co-owner and/or in a network of other self-employed</i>	
	1	Works together with a co-owner	
	2	Works together with other self-employed in a network	
	3	Both	
	4	Neither	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
PLANEMPL 217		Planned hiring of employees or subcontractors	STAPRO = 1,2
		<i>Plans to employ or sub-contract in the next 12 months</i>	
	1	Plans to employ only permanent employees	
	2	Plans to employ only temporary employees	
	3	Plans to employ both permanent and temporary employees	
	4	Plans to only hire subcontractors	
	5	Plans to hire subcontractors and employ employees	
	6	Does not plan to hire employees or subcontractors	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	

(3) Sub-module 'The self-employed and employees'

Name/Column	Code	Description	Filter
JBSATISF 218		Job satisfaction <i>The level of job satisfaction in the main job</i>	WSTATOR = 1,2
	1	Satisfied to a large extent	
	2	Satisfied to some extent	

Name/Column	Code	Description	Filter
AUTONOMY 219	3	Satisfied to a small extent	WSTATOR = 1,2
	4	Not satisfied at all	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	
		Job autonomy	
		<i>The level of influence over content and order of tasks in the main job</i>	
	1	Able to influence both contents and order of tasks	
	2	Able to influence contents but not order of tasks	
	3	Able to influence order but not contents of tasks	
	4	Not able to influence contents, nor order of tasks	
PREFSTAP 220	9	Not applicable (not included in the filter)	WSTATOR = 1,2
	Blank	No answer/Don't know	
		Preferred professional status for the main job	
		<i>Preference to work as an employee if currently self-employed, or preference to work as self-employed if currently working as an employee</i>	
	1	Does not want to change professional status	
	2	Is self-employed but wishes to work as an employee	
	3	Is working as an employee or family worker but wishes to be self-employed	
OBSTACSE 221	9	Not applicable (not included in the filter)	PREFSTAP = 3
	Blank	No answer/Don't know	
		Main reason for not becoming self-employed in the main job	
		<i>The main reason why current employees or family workers who wish they were self-employed have not switched to their preferred professional status</i>	
	1	Financial insecurity	
	2	Difficulties with getting financing for the business	
	3	Too much stress, responsibilities, or risk	
	4	Less coverage from social protection	
	5	Other reason	
	9	Not applicable (not included in the filter)	
	Blank	No answer/Don't know	

COMMISSION IMPLEMENTING REGULATION (EU) 2016/9**of 5 January 2016****on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)****(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 132 thereof,

Whereas:

- (1) For the purposes of registration of substances, Titles II and III of Regulation (EC) No 1907/2006 include provisions that require manufacturers and importers to share data and to jointly submit information to the Agency.
- (2) The experience acquired by authorities through the 2010 and 2013 registration deadlines set out in Article 23 of Regulation (EC) No 1907/2006 for phase-in substances, together with information received from stakeholders directly and via the REACH registration workshop that took place in Brussels on 10-11 December 2013, indicate that the provisions of Regulation (EC) No 1907/2006 on data-sharing and joint submission have not been used to their full potential, their implementation falling short of expectations. This has been especially prejudicial to small and medium size enterprises.
- (3) In order for the system of data-sharing, established by Regulation (EC) No 1907/2006, to operate effectively, it is necessary to promote good management practices and to ensure the efficient functioning of agreements pertaining to sharing such data. Rules should therefore be established for an efficient implementation of that Regulation as regards data sharing.
- (4) Costs relating to sharing and jointly submitting information, in accordance with Articles 11(1), 19(1), 27(3) and 30(1) of Regulation (EC) No 1907/2006, should be determined in a fair, transparent and non-discriminatory manner.
- (5) It is necessary to clarify that in accordance with Articles 27(3) and 30(1) of Regulation (EC) No 1907/2006, both administrative costs and costs related to information requirements should only be shared where those costs are relevant to the information that a party is obliged to submit for registration under that Regulation. Costs relating to information requirements include any cost that was required for performing an existing study or is required for performing a new study, whether relating to preparing the necessary specifications, contracting with a laboratory or monitoring its performance. Costs of fulfilling a REACH information requirement not involving testing studies should also be included.
- (6) To ensure that data is shared in a transparent and effective manner, all agreements to share data for the purposes of Regulation (EC) No 1907/2006 should be structured in a way that all relevant costs are clearly described and identifiable. However, where parties to data-sharing agreements that already exist on the date of entry into force of this Regulation are satisfied with the functioning of such agreements, it should be possible to waive the obligation to itemise costs when all parties consent.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

- (7) In order to ascertain that the costs of sharing data are justified and are adequately distributed between the parties to a data-sharing agreement, annual records of costs incurred and compensation received should be kept by those parties. In accordance with Articles 27(3) and 30(1) of Regulation (EC) No 1907/2006, parties to existing data-sharing agreements should make every effort to establish proof of costs incurred before the entry into force of this Regulation.
- (8) To ensure consistency with Article 25(3) of Regulation (EC) No 1907/2006 and to ensure that there is documentation of the cost of any study that may be subject to a data-sharing agreement, those annual records should be kept for a minimum of 12 years following the submission of a study in the framework of a registration under that Regulation
- (9) A data-sharing agreement should include a model for sharing all relevant costs. A reimbursement mechanism should be envisaged in each cost-sharing model to allow for potential adjustment of the share of costs that each registrant pays when other registrants join that agreement at a later stage.
- (10) In order to ensure that no unnecessary administrative burden is placed on parties to data-sharing agreements that already exist on the date of entry into force of this Regulation, those parties should be allowed to waive the obligation to include a reimbursement mechanism if all parties to the agreement consent. In the case of such agreements, potential registrants who intend to join the existing agreement should be allowed to request the inclusion of a reimbursement mechanism.
- (11) In the interest of providing legal certainty, it should be clarified that in accordance with Article 50(4) of Regulation (EC) No 1907/2006, the costs associated with a substance evaluation decision may also apply to registrants who have already ceased their activities pursuant to paragraph 2 or 3 of Article 50 of that Regulation.
- (12) The principle of 'one substance, one registration', which underpins the operation of Titles II and III of Regulation (EC) No 1907/2006, should be reinforced by emphasising the role of the Agency in ensuring that all submissions of information regarding the same substance are part of the same registration under that Regulation.
- (13) Where tests on vertebrate animals are not required for the purposes of a party's registration under Regulation (EC) No 1907/2006, it should be clarified that that party is not obliged to share data with other registrants of the same substance and may choose to submit separately the information referred to in Article 10(a) in accordance with Article 11(3) or 19(2) of that Regulation.
- (14) In order to ensure consistency with the principle of 'one substance, one registration', the Agency should ensure that a separate submission of the information referred to in Article 10(a), justified under Article 11(3) or 19(2) of Regulation (EC) No 1907/2006, is still part of the existing registration for that substance.
- (15) In order to promote the development and use of alternative methods for the assessment of hazards of substances and to minimise animal testing, this Regulation encourages the sharing of relevant (animal and non-animal) studies that are conducted on a substance which is structurally similar to the substance being registered (grouping or read-across).
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down specific duties and obligations for parties to agreements where the sharing of information and associated costs are required under Regulation (EC) No 1907/2006.

*Article 2***Transparency**

1. Where multiple registrants of the same substance or participants in a Substance Information Exchange Forum (SIEF) are obliged to share information in accordance with their duties under Regulation (EC) No 1907/2006, they shall make every effort to reach an agreement on the sharing of the information. This data-sharing agreement, which involves only persons or entities subject to that Regulation, shall be clear and comprehensible to all parties and shall include the following sections:

- (a) the itemisation of the data to be shared, including the cost of each data item, a description indicating the information requirements in Regulation (EC) No 1907/2006 to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement;
- (b) the itemisation and justification of any cost of creating and managing the data-sharing agreement and the joint submission of information between registrants of the same substance as required by Regulation (EC) No 1907/2006 (hereinafter referred to as 'administrative costs') applicable for that data-sharing agreement;
- (c) a cost-sharing model, which shall include a reimbursement mechanism.

2. Where a data-sharing agreement already exists on the date of entry into force of this Regulation, parties to that agreement may, by unanimous consent, waive their obligation to itemise the data as described in points (a) and (b) of paragraph 1.

A potential registrant of a substance for which a data-sharing agreement has already been reached by previous registrants, who requests a study or set of studies to be shared in accordance with Articles 27 and 30 of Regulation (EC) No 1907/2006 shall not be bound by an existing waiver, unless he provides his signed consent to it to the previous registrants, and shall have the right to request itemisation as described in points (a) and (b) of paragraph 1.

Where such a request is made, the previous registrants shall:

- (a) itemise all relevant costs incurred after the date of entry into force of this Regulation as described in points (a) and (b) of paragraph 1;
- (b) provide proof of the cost of any study, completed before the date of entry into force of this Regulation, that is requested in accordance with Article 30(1) of Regulation (EC) No 1907/2006;
- (c) make every effort to provide itemisation of all other relevant costs, including administrative costs and study costs not covered in point (b), incurred before the date of entry into force of this Regulation as described in points (a) and (b) of paragraph 1.

The itemisation of costs shall be provided to the potential registrant without undue delay.

3. Where registrants of the same substance have shared information and submitted it jointly in accordance with Regulation (EC) No 1907/2006, they shall document yearly any further costs incurred in relation to the operation of their data-sharing agreement.

The annual documentation shall contain the sections indicated in paragraph 1 and include, for the purposes of the reimbursement mechanism, a record of any compensation received from new registrants.

In the absence of detailed documentation of costs incurred or compensation received before the entry into force of this Regulation, parties to an agreement shall make every effort to collate proof, or to make the best approximation, of such costs and compensation for each year since the commencement of that agreement.

Such annual documentation shall be kept by the registrants for a minimum of 12 years following the latest submission of a study and shall be made available free of charge upon request from any party to the data-sharing agreement concerned within reasonable time and in full consideration of the requirements related to applicable registration deadlines.

*Article 3***One substance, one registration**

1. Without prejudice to Articles 11(3) and 19(2) of Regulation (EC) No 1907/2006, the Agency shall ensure that all registrants of the same substance are part of the same registration under that Regulation.
2. Where the Agency permits a potential registrant of a substance that has already been registered to refer to requested information in accordance with Articles 27(6) and 30(3) of Regulation (EC) No 1907/2006, the Agency shall ensure that any subsequent submission of information by that potential registrant is part of the existing joint submission for that substance.
3. Where a potential registrant has complied with his obligations under Articles 26 or 29 of Regulation (EC) No 1907/2006 and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration, he may decide to invoke Articles 11(3) or 19(2) in order to submit separately all or part of the relevant information in Article 10(a) of that Regulation.

In such cases, the potential registrant shall inform any previous registrants of that substance of his decision. He shall also inform the Agency which shall ensure that this separate submission, made in accordance with Article 11(3) or 19(2) of Regulation (EC) No 1907/2006, remains part of the existing registration for that substance in accordance with paragraph 1.

*Article 4***Fairness and non-discrimination**

1. Pursuant to Articles 27(3) and 30(1) of Regulation (EC) No 1907/2006, any registrant of a substance shall only be required to share the costs of information that such registrant is obliged to submit to the Agency to satisfy his registration requirements under that Regulation. This condition applies also to administrative costs.
2. The cost-sharing model referred to in Article 2(1)(c) shall apply to all registrants of that substance, including the possibility of future registrants joining the data-sharing agreement at a later stage.

The cost-sharing model shall include for all registrants of a particular substance provisions for sharing any costs resulting from a potential substance evaluation decision.

The following factors shall also be considered in agreeing on a particular cost-sharing model: the number of potential registrants estimated to register for that substance; and the possibility of future additional information requirements for that substance, other than those resulting from a potential substance evaluation decision.

In the event that a cost-sharing model includes the possibility to cover the costs of future additional information requirements for that substance, other than those resulting from a potential substance evaluation decision, this possibility shall be justified and indicated separately from other costs in the data-sharing agreement.

Compiling information for the purposes of establishing substance sameness should not be the subject of any cost sharing between previous registrants and potential registrants.

3. Pursuant to Articles 27 and 30 of Regulation (EC) No 1907/2006, if the participants to a data-sharing agreement cannot agree to such a cost-sharing model, each participant shall pay an equal share of the costs required for their participation. Reimbursement of part of such costs paid shall still occur as if a reimbursement mechanism has been agreed subject to the first subparagraph of paragraph 4.
4. The reimbursement mechanism referred to in Article 2(1)(c) shall be envisaged in every cost-sharing model and shall include a method of proportional redistribution to each participant of their share of costs paid where a potential registrant joins that agreement in the future.

The reimbursement mechanism shall also take account of the following factors: the possibility of future additional registration requirements for that substance, other than those resulting from a potential substance evaluation decision; and the economic viability of certain reimbursements where the costs of reimbursement are higher than the amount to be reimbursed.

5. Where a data-sharing agreement already exists on the date of entry into force of this Regulation, parties to that agreement may, by unanimous consent, waive their obligation to include a reimbursement mechanism in their cost-sharing model.

A potential registrant who intends to participate in an existing data-sharing agreement shall not be bound by an existing waiver unless he provides his signed consent to it to the previous registrants and shall have the right to obtain the inclusion of a reimbursement mechanism in the cost-sharing model in accordance with this Regulation.

6. Any registrant who has ceased his activities pursuant to paragraph 2 or 3 of Article 50 of Regulation (EC) No 1907/2006 may still be required to share costs resulting from a substance evaluation decision in accordance with Article 50(4) of that Regulation.

Article 5

Dispute Resolution

1. When settling a data-sharing dispute pursuant to Articles 27(5) and 30(3) of Regulation (EC) No 1907/2006, the Agency shall take account of the parties' compliance with the obligations set out in Articles 2, 3 and 4 of this Regulation.

2. This Regulation operates without prejudice to the full and complete application of the Union competition law.

Article 6

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 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2016/10**of 5 January 2016****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 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽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, 5 January 2016.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽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	IL	236,2
	MA	77,5
	TR	111,7
	ZZ	141,8
0707 00 05	MA	88,9
	TR	156,8
	ZZ	122,9
0709 93 10	MA	43,8
	TR	144,8
	ZZ	94,3
0805 10 20	EG	53,0
	MA	64,8
	TR	70,6
	ZA	74,1
	ZZ	65,6
0805 20 10	IL	171,2
	MA	67,7
	ZZ	119,5
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	118,6
	MA	86,7
	TR	66,6
	ZZ	90,6
0805 50 10	TR	96,5
	ZZ	96,5
0808 10 80	CL	83,4
	US	150,1
	ZZ	116,8
0808 30 90	TR	130,5
	ZZ	130,5

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION IMPLEMENTING DIRECTIVE (EU) 2016/11

of 5 January 2016

amending Annex II to Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants ⁽¹⁾, and in particular Article 24 thereof,

Whereas:

- (1) Point (2)(b) of Section I of Annex II to Directive 2002/57/EC lays down the minimum varietal purity of seed of hybrids of swede rape.
- (2) The current purity standard of 90 % which is applicable for hybrid varieties of both spring swede rape and winter swede rape does no longer reflect the special technical features nor the limitations in seed production of spring swede rape.
- (3) The conditions for seed production provided for in Directive 2002/57/EC are based on internationally accepted standards of the Seed Schemes established by the OECD (Organisation for Economic Cooperation and Development).
- (4) The varietal purity standard for the seed of spring swede rape should be adapted to the standard set by the OECD.
- (5) Annex II to Directive 2002/57/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Amendment to Annex II to Directive 2002/57/EC

In Section I of Annex II to Directive 2002/57/EC, point (2)(b) is replaced by the following:

‘(b) The minimum varietal purity of the seed shall be:

- basic seed, female component: 99,0 %,
- basic seed, male component: 99,9 %,

⁽¹⁾ OJ L 193, 20.7.2002, p. 74.

- certified seed of winter swede rape varieties: 90,0 %,
- certified seed of spring swede rape varieties: 85,0 %.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 December 2016 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2017.

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

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

Article 3

Entry into force

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

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 5 January 2016.

For the Commission
The President
Jean-Claude JUNCKER

